
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, 2017

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, 2017: 2,724,436,835

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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 (Do not check if a smaller reporting company)

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,	
	2017	2016	2017	2016
Sales	\$ 10,325	\$ 10,536	\$ 29,689	\$ 29,692
Costs, Expenses and Other				
Materials and production	3,274	3,409	9,369	10,559
Marketing and administrative	2,401	2,393	7,251	7,169
Research and development	4,383	1,664	7,927	5,475
Restructuring costs	153	161	470	386
Other (income) expense, net	(86)	22	30	88
	10,125	7,649	25,047	23,677
Income Before Taxes	200	2,887	4,642	6,015
Taxes on Income	251	699	1,186	1,487
Net (Loss) Income	(51)	2,188	3,456	4,528
Less: Net Income Attributable to Noncontrolling Interests	5	4	16	13
Net (Loss) Income Attributable to Merck & Co., Inc.	\$ (56)	\$ 2,184	\$ 3,440	\$ 4,515
Basic (Loss) Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	\$ (0.02)	\$ 0.79	\$ 1.26	\$ 1.63
(Loss) Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	\$ (0.02)	\$ 0.78	\$ 1.25	\$ 1.62
Dividends Declared per Common Share	\$ 0.47	\$ 0.46	\$ 1.41	\$ 1.38

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Net (Loss) Income Attributable to Merck & Co., Inc.	\$ (56)	\$ 2,184	\$ 3,440	\$ 4,515
Other Comprehensive Income (Loss) Net of Taxes:				
Net unrealized loss on derivatives, net of reclassifications	(66)	(74)	(441)	(367)
Net unrealized gain (loss) on investments, net of reclassifications	135	(30)	213	96
Benefit plan net gain (loss) and prior service credit (cost), net of amortization	13	(144)	86	(280)
Cumulative translation adjustment	67	82	423	447
	149	(166)	281	(104)
Comprehensive Income Attributable to Merck & Co., Inc.	\$ 93	\$ 2,018	\$ 3,721	\$ 4,411

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, 2017	December 31, 2016
Assets		
Current Assets		
Cash and cash equivalents	\$ 7,901	\$ 6,515
Short-term investments	3,294	7,826
Accounts receivable (net of allowance for doubtful accounts of \$222 in 2017 and \$195 in 2016)	7,671	7,018
Inventories (excludes inventories of \$1,029 in 2017 and \$1,117 in 2016 classified in Other assets - see Note 5)	5,263	4,866
Other current assets	3,790	4,389
Total current assets	27,919	30,614
Investments	12,206	11,416
Property, Plant and Equipment, at cost, net of accumulated depreciation of \$16,661 in 2017 and \$15,749 in 2016	12,189	12,026
Goodwill	18,340	18,162
Other Intangibles, Net	15,138	17,305
Other Assets	5,884	5,854
	\$ 91,676	\$ 95,377
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	\$ 5,157	\$ 568
Trade accounts payable	2,620	2,807
Accrued and other current liabilities	9,992	10,274
Income taxes payable	396	2,239
Dividends payable	1,302	1,316
Total current liabilities	19,467	17,204
Long-Term Debt	21,838	24,274
Deferred Income Taxes	4,159	5,077
Other Noncurrent Liabilities	7,713	8,514
Merck & Co., Inc. Stockholders' Equity		
Common stock, \$0.50 par value Authorized - 6,500,000,000 shares Issued - 3,577,103,522 shares in 2017 and 2016	1,788	1,788
Other paid-in capital	39,823	39,939
Retained earnings	43,701	44,133
Accumulated other comprehensive loss	(4,945)	(5,226)
	80,367	80,634
Less treasury stock, at cost: 850,698,697 shares in 2017 and 828,372,200 shares in 2016	42,119	40,546
Total Merck & Co., Inc. stockholders' equity	38,248	40,088
Noncontrolling Interests	251	220
Total equity	38,499	40,308
	\$ 91,676	\$ 95,377

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,	
	2017	2016
Cash Flows from Operating Activities		
Net income	\$ 3,456	\$ 4,528
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	3,509	4,286
Intangible asset impairment charges	376	572
Charge for future payments related to AstraZeneca collaboration license options	750	—
Deferred income taxes	(601)	(65)
Share-based compensation	232	225
Other	(31)	200
Net changes in assets and liabilities	(5,259)	(3,002)
Net Cash Provided by Operating Activities	2,432	6,744
Cash Flows from Investing Activities		
Capital expenditures	(1,173)	(1,063)
Purchases of securities and other investments	(8,397)	(10,084)
Proceeds from sales of securities and other investments	12,533	11,300
Acquisitions of businesses, net of cash acquired	(347)	(778)
Other	121	(22)
Net Cash Provided by (Used in) Investing Activities	2,737	(647)
Cash Flows from Financing Activities		
Net change in short-term borrowings	1,962	909
Payments on debt	(301)	(2,386)
Purchases of treasury stock	(2,312)	(2,418)
Dividends paid to stockholders	(3,884)	(3,853)
Proceeds from exercise of stock options	481	790
Other	(167)	(109)
Net Cash Used in Financing Activities	(4,221)	(7,067)
Effect of Exchange Rate Changes on Cash and Cash Equivalents	438	353
Net Increase (Decrease) in Cash and Cash Equivalents	1,386	(617)
Cash and Cash Equivalents at Beginning of Year	6,515	8,524
Cash and Cash Equivalents at End of Period	\$ 7,901	\$ 7,907

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

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of Merck & Co., Inc. (Merck or the Company) have been prepared pursuant to the rules and regulations for reporting on Form 10-Q. Accordingly, certain information and disclosures required by accounting principles generally accepted in the United States for complete consolidated financial statements are not included herein. These interim statements should be read in conjunction with the audited financial statements and notes thereto included in Merck's Form 10-K filed on February 28, 2017.

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.

On December 31, 2016, Merck and Sanofi Pasteur S.A. (Sanofi) terminated their equally-owned joint venture, Sanofi Pasteur MSD (SPMSD), which developed and marketed vaccines in Europe. Beginning in 2017, Merck is recording vaccine sales and incurring costs as a result of operating its vaccines business in the European markets that were previously part of the SPMSD joint venture, which was accounted for as an equity method affiliate.

Recently Issued Accounting Standards

In May 2014, the Financial Accounting Standards Board (FASB) issued amended accounting guidance on revenue recognition that will be applied 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 Company will adopt the new standard on January 1, 2018 and currently plans to use the modified retrospective method. The majority of the Company's business is ship and bill and, on that primary revenue stream, Merck does not expect significant differences. Additionally, the Company has not identified significant changes related to the recognition of revenue for its multiple element arrangements or discount and trade promotion programs when applying the new guidance. However, the Company's analysis is preliminary and subject to change. The Company anticipates the adoption of the new guidance will result in some additional disclosures.

In January 2016, the FASB issued revised guidance for the accounting and reporting of financial instruments. 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 new guidance also simplifies the impairment testing of equity investments without readily determinable fair values and changes certain disclosure requirements. This guidance is effective for interim and annual periods beginning in 2018. The Company is currently assessing the impact of adoption on its consolidated financial statements. The impact of adoption will be recorded as a cumulative-effect adjustment to retained earnings.

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 guidance is effective for interim and annual periods beginning in 2018. Early adoption is permitted. The guidance is to be applied retrospectively to all periods presented but may be applied prospectively if retrospective application would be impracticable. The Company does not anticipate the adoption of the new guidance will have a material effect on its Consolidated Statement of Cash Flows.

In October 2016, the FASB issued guidance on the accounting for the income tax consequences of intra-entity transfers of assets other than inventory. Under existing guidance, the recognition of current and deferred income taxes for an intra-entity asset transfer is prohibited until the asset has been sold to a third party. The new guidance will require 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. The guidance is effective for interim and annual periods beginning in 2018. 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 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 guidance is effective for interim and annual periods beginning in 2018 and should be applied using a retrospective transition method to each period presented. Early adoption is permitted. The Company does not anticipate the adoption of the new guidance will have a material effect on its Consolidated Statement of Cash Flows.

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 new guidance is effective for interim and annual periods in 2018.

Entities must use a retrospective transition method to adopt the requirement for separate presentation in the income statement of service costs and other components and a prospective transition method to adopt the requirement to limit the capitalization of benefit costs to the service cost component. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

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 new guidance is effective prospectively for interim and annual periods beginning in 2018. Early adoption is permitted. The Company does not anticipate the adoption of the new guidance will have a material effect on its consolidated financial statements.

In February 2016, the FASB issued new accounting guidance for the accounting and reporting of leases. 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 new guidance will be effective for interim and annual periods beginning in 2019. Early adoption is permitted. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

In August 2017, the FASB issued new guidance on hedge accounting 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 new guidance is effective for interim and annual periods beginning in 2019. Early application is permitted in any interim period. The Company does not anticipate the adoption of the new guidance will have a material effect on its consolidated financial statements and may elect to early adopt this guidance.

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 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 the adoption of the new guidance will have a material effect on its consolidated financial statements.

2. 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 October 2017, Merck acquired Rigontec GmbH (Rigontec). Rigontec is a leader in accessing the retinoic acid-inducible gene I (RIG-I) pathway, part of the innate immune system, as a novel and distinct approach in cancer immunotherapy to induce both immediate and long-term anti-tumor immunity. Rigontec's lead candidate, RGT100, is currently in Phase I development evaluating treatment in patients with various tumors. Under the terms of the agreement, Merck made an upfront cash payment of €119 million (\$140 million) and may make additional contingent payments of up to €349 million based on the attainment of certain clinical, development, regulatory and commercial milestones. The transaction will be accounted for as an acquisition of an asset and the upfront payment will be reflected within *Research and development* expenses in the fourth quarter of 2017.

In July 2017, Merck and AstraZeneca entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza (olaparib) for multiple cancer types. Lynparza is an oral, poly (ADP-ribose) polymerase (PARP) inhibitor currently approved for certain types of ovarian cancer. The companies will jointly develop and commercialize Lynparza, both as monotherapy and in combination trials with other potential medicines. Independently, Merck

and AstraZeneca will develop and commercialize Lynparza in combinations with their respective PD-1 and PD-L1 medicines, *Keytruda* (pembrolizumab) and Imfinzi (durvalumab). 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 including thyroid cancer. 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 will be 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. As part of the agreement, Merck made an upfront payment to AstraZeneca of \$1.6 billion and will make payments of \$750 million over a multi-year period for certain license options (\$250 million in November 2017, \$400 million in November 2018 and \$100 million in November 2019). The Company recorded an aggregate charge of \$2.35 billion in *Research and development* expenses in the third quarter of 2017 related to the upfront payment and future license options payments. In addition, Merck will pay AstraZeneca up to an additional \$6.15 billion contingent upon successful achievement of future regulatory and sales milestones for total aggregate consideration of up to \$8.5 billion. Future milestone payments will be capitalized and amortized over the estimated useful life of the corresponding intangible asset. Additionally, Merck will record its share of product sales of Lynparza and selumetinib, net of 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. Merck may terminate the agreement in its entirety or with respect to a given compound (and all products comprising such compound) upon prior written notice to AstraZeneca of at least 180 days. If the agreement is terminated with respect to a given compound, the agreement shall remain in full force and effect with respect to the other compounds. The parties also have the right to terminate the agreement in its entirety or on a product-by-product or country-by-country basis upon mutual written agreement. The agreement may also be terminated at any time with respect to a given product, upon written notice by a party if the other party is in material breach of the agreement with respect to such product and has not cured such breach within the time periods provided for under the agreement.

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 \$291 million related to currently marketed products, net deferred tax liabilities of \$93 million, other net assets of \$15 million and noncontrolling interest of \$25 million. In addition, the Company recorded liabilities of \$37 million for contingencies identified at 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 \$170 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 then 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 July 2016, Merck acquired Afferent Pharmaceuticals (Afferent), a privately held pharmaceutical company focused on the development of therapeutic candidates targeting the P2X3 receptor for the treatment of common, poorly-managed, neurogenic conditions. Afferent's lead investigational candidate, MK-7264 (formerly AF-219), is a selective, non-narcotic, orally-administered P2X3 antagonist being evaluated in a Phase 2b clinical trial for the treatment of refractory, chronic cough as well as in a Phase 2 clinical trial in idiopathic pulmonary fibrosis with cough. Total consideration transferred of \$510 million included cash paid for outstanding Afferent shares of \$487 million, as well as share-based compensation payments to settle equity awards attributable to precombination service and cash paid for transaction costs on behalf of Afferent. In addition, former Afferent shareholders are eligible to receive a total of up to an additional \$750 million contingent upon the attainment of certain clinical development and commercial milestones for multiple indications and candidates, including MK-7264. This transaction was accounted for as an acquisition of a business. The Company determined the fair value of the contingent consideration was \$223 million at the acquisition date utilizing a probability-weighted estimated cash flow stream adjusted for the expected timing of each payment using an appropriate discount rate dependent on the nature and timing of the milestone payment. Merck recognized an intangible asset for in-process research and development (IPR&D) of \$832 million, net deferred tax liabilities of \$258 million, and other net assets of \$29 million (primarily consisting of cash acquired). The excess of the consideration transferred over the fair value of net assets acquired of \$130 million was recorded as goodwill that was allocated to the Pharmaceutical segment and is not deductible for tax purposes. The fair value of the identifiable intangible asset related to IPR&D was determined using an income approach. The asset's probability-adjusted future net cash flows were then discounted to present value using a discount rate of 11.5%. Actual cash flows are likely to be different than those assumed.

Also in July 2016, Merck, through its wholly owned subsidiary Healthcare Services & Solutions, LLC, acquired a majority ownership interest in The StayWell Company LLC (StayWell), a portfolio company of Vestar Capital Partners (Vestar).

StayWell is a health engagement company that helps its clients engage and educate people to improve health and business results. Under the terms of the transaction, Merck paid \$150 million for a majority ownership interest. Additionally, Merck provided StayWell with a \$150 million intercompany loan to pay down preexisting third-party debt. Merck has an option to buy, and Vestar has an option to require Merck to buy, some or all of Vestar's remaining ownership interest at fair value beginning three years from the acquisition date. This transaction was accounted for as an acquisition of a business. Merck recognized intangible assets of \$238 million, deferred tax liabilities of \$84 million, other net liabilities of \$5 million and noncontrolling interest of \$124 million. The excess of the consideration transferred over the fair value of net assets acquired of \$275 million was recorded as goodwill and is largely attributable to anticipated synergies expected to arise after the acquisition. The goodwill was allocated to the Healthcare Services segment and is not deductible for tax purposes. The intangible assets recognized primarily relate to customer relationships, which are being amortized over a 10-year useful life, and medical information and solutions content, which are being amortized over a five-year useful life.

In June 2016, Merck and Moderna Therapeutics (Moderna) entered into a strategic collaboration and license agreement to develop and commercialize novel messenger RNA (mRNA)-based personalized cancer vaccines. The development program will entail multiple studies in several types of cancer and include the evaluation of mRNA-based personalized cancer vaccines in combination with Merck's *Keytruda*. Pursuant to the terms of the agreement, Merck made an upfront cash payment to Moderna of \$200 million, which was recorded in *Research and development* expenses. Following human proof of concept studies, Merck has the right to elect to make an additional payment to Moderna. If Merck exercises this right, the two companies will then equally share costs and profits under a worldwide collaboration for the development of personalized cancer vaccines. Moderna will have the right to elect to co-promote the personalized cancer vaccines in the United States. The agreement entails exclusivity around combinations with *Keytruda*. Moderna and Merck each have the ability to combine mRNA-based personalized cancer vaccines with other (non-PD-1) agents.

In January 2016, Merck acquired Iomet Pharma Ltd (Iomet), a privately held UK-based drug discovery company focused on the development of innovative medicines for the treatment of cancer, with a particular emphasis on the fields of cancer immunotherapy and cancer metabolism. The acquisition provides Merck with Iomet's preclinical pipeline of IDO (indoleamine-2,3-dioxygenase 1), TDO (tryptophan-2,3-dioxygenase), and dual-acting IDO/TDO inhibitors. The transaction was accounted for as an acquisition of a business. Total purchase consideration in the transaction included a cash payment of \$150 million and future additional milestone payments of up to \$250 million contingent upon certain clinical and regulatory milestones being achieved. The Company determined the fair value of the contingent consideration was \$94 million at the acquisition date utilizing a probability-weighted estimated cash flow stream adjusted for the expected timing of each payment utilizing a discount rate of 10.5%. Merck recognized intangible assets for IPR&D of \$155 million and net deferred tax assets of \$32 million. The excess of the consideration transferred over the fair value of net assets acquired of \$57 million was recorded as goodwill that was allocated to the Pharmaceutical segment and is not deductible for tax purposes. The fair values of the identifiable intangible assets related to IPR&D were determined using an income approach. The assets' probability-adjusted future net cash flows were then discounted to present value also using a discount rate of 10.5%. Actual cash flows are likely to be different than those assumed. In July 2017, Merck made a \$100 million payment as a result of the achievement of a clinical milestone, which was accrued for at estimated fair value at the time of acquisition as noted above.

Additionally, in January 2016, Merck sold the U.S. marketing rights to Cortrophin and Corticotropin Zinc Hydroxide to ANI Pharmaceuticals, Inc. (ANI). Under the terms of the agreement, ANI made a payment of \$75 million, which was recorded in *Sales*, and may make additional payments to the Company based on future sales. Merck does not have any ongoing supply or other performance obligations after the closing date.

3. Restructuring

The Company incurs substantial costs for restructuring program activities related to Merck's productivity and cost reduction initiatives, as well as in connection with the integration of certain acquired businesses. 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 \$180 million and \$212 million in the third quarter of 2017 and 2016, respectively, and \$605 million and \$759 million for the first nine months of 2017 and 2016, respectively, related to restructuring program activities. Since inception of the programs through September 30, 2017, Merck has recorded total pretax accumulated costs of approximately \$13.2 billion and eliminated approximately 42,120 positions comprised of employee separations, as well as the elimination of contractors and vacant positions. The Company expects to substantially complete the remaining actions under these programs by the end of 2017 and incur approximately \$250 million of additional pretax costs. 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.

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, 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

(\$ in millions)	Three Months Ended September 30, 2016				Nine Months Ended September 30, 2016			
	Separation Costs	Accelerated Depreciation	Other	Total	Separation Costs	Accelerated Depreciation	Other	Total
Materials and production	\$ —	\$ 18	\$ 18	\$ 36	\$ —	\$ 69	\$ 80	\$ 149
Marketing and administrative	—	1	—	1	—	8	83	91
Research and development	—	14	—	14	—	133	—	133
Restructuring costs	61	—	100	161	172	—	214	386
	\$ 61	\$ 33	\$ 118	\$ 212	\$ 172	\$ 210	\$ 377	\$ 759

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 2017 and 2016, approximately 205 positions and 300 positions, respectively, and for the first nine months of 2017 and 2016, approximately 1,225 positions and 1,355 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 2017 and 2016 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 10) and share-based compensation.

The following table summarizes the charges and spending relating to restructuring program activities for the nine months ended September 30, 2017:

(\$ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
Restructuring reserves January 1, 2017	\$ 395	\$ —	\$ 146	\$ 541
Expense	302	61	242	605
(Payments) receipts, net	(224)	—	(339)	(563)
Non-cash activity	—	(61)	74	13
Restructuring reserves September 30, 2017 ⁽¹⁾	\$ 473	\$ —	\$ 123	\$ 596

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

4. 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 effective portion of 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. The hedge relationship is highly effective and hedge ineffectiveness has been *de minimis*. For those derivatives which are not designated as cash flow hedges, but serve as economic hedges of forecasted sales, unrealized gains or losses are recorded in *Sales* each period. The cash flows from both designated and non-designated contracts are reported as operating activities in the Condensed Consolidated Statement of Cash Flows. The Company does not enter into derivatives for trading or speculative purposes.

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

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

The Company may also use 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 and measures ineffectiveness based upon changes in spot foreign exchange rates that are recorded in *Other (income) expense, net*. The effective portion of the unrealized gains or losses on these contracts is recorded in foreign currency translation adjustment within *OCI*, and remains in *AOCI* until either the sale or complete or substantially complete liquidation of the subsidiary. 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*. Included in the cumulative translation adjustment are pretax losses of \$467 million and \$60 million for the first nine months of 2017 and 2016, respectively, from the euro-denominated notes.

Interest Rate Risk Management

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

At September 30, 2017, the Company was a party to 26 pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes as detailed in the table below.

(\$ in millions)		September 30, 2017		
Debt Instrument	Par Value of Debt	Number of Interest Rate Swaps Held	Total Swap Notional Amount	
1.30% notes due 2018	\$ 1,000	4	\$ 1,000	
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 and offset by the 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.

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:

(\$ in millions)		September 30, 2017			December 31, 2016		
		Fair Value of Derivative		U.S. Dollar Notional	Fair Value of Derivative		U.S. Dollar Notional
	Balance Sheet Caption	Asset	Liability		Asset	Liability	
<i>Derivatives Designated as Hedging Instruments</i>							
Interest rate swap contracts	Other assets	\$ 15	\$ —	\$ 2,700	\$ 20	\$ —	\$ 2,700
Interest rate swap contracts	Accrued and other current liabilities	—	3	1,000	—	—	—
Interest rate swap contracts	Other noncurrent liabilities	—	23	2,500	—	29	3,500
Foreign exchange contracts	Other current assets	83	—	4,385	616	—	6,063
Foreign exchange contracts	Other assets	46	—	1,979	129	—	2,075
Foreign exchange contracts	Accrued and other current liabilities	—	88	1,574	—	1	48
Foreign exchange contracts	Other noncurrent liabilities	—	1	25	—	1	12
		\$ 144	\$ 115	\$ 14,163	\$ 765	\$ 31	\$ 14,398
<i>Derivatives Not Designated as Hedging Instruments</i>							
Foreign exchange contracts	Other current assets	\$ 77	\$ —	\$ 3,927	\$ 230	\$ —	\$ 8,210
Foreign exchange contracts	Accrued and other current liabilities	—	112	6,383	—	103	2,931
		\$ 77	\$ 112	\$ 10,310	\$ 230	\$ 103	\$ 11,141
		\$ 221	\$ 227	\$ 24,473	\$ 995	\$ 134	\$ 25,539

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)

(\$ in millions)	September 30, 2017		December 31, 2016	
	Asset	Liability	Asset	Liability
Gross amounts recognized in the consolidated balance sheet	\$ 221	\$ 227	\$ 995	\$ 134
Gross amount subject to offset in master netting arrangements not offset in the consolidated balance sheet	(137)	(137)	(131)	(131)
Cash collateral received	(8)	—	(529)	—
Net amounts	\$ 76	\$ 90	\$ 335	\$ 3

The table below provides information on the location and pretax gain or loss amounts for derivatives that are: (i) designated in a fair value hedging relationship, (ii) designated in a foreign currency cash flow hedging relationship and (iii) not designated in a hedging relationship:

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
<i>Derivatives designated in a fair value hedging relationship</i>				
Interest rate swap contracts				
Amount of loss (gain) recognized in <i>Other (income) expense, net</i> on derivatives ⁽¹⁾	\$ 8	\$ 59	\$ 2	\$ (139)
Amount of (gain) loss recognized in <i>Other (income) expense, net</i> on hedged item ⁽¹⁾	(9)	(60)	(5)	135
<i>Derivatives designated in foreign currency cash flow hedging relationships</i>				
Foreign exchange contracts				
Amount of gain reclassified from <i>AOCl</i> to <i>Sales</i>	(13)	(44)	(157)	(251)
Amount of loss recognized in <i>OCI</i> on derivatives	88	69	520	311
<i>Derivatives not designated in a hedging relationship</i>				
Foreign exchange contracts				
Amount of loss (gain) recognized in <i>Other (income) expense, net</i> on derivatives ⁽²⁾	119	29	70	(87)

⁽¹⁾ There was \$1 million of ineffectiveness on the hedge during both the third quarter of 2017 and 2016, and \$3 million and \$4 million, respectively, of ineffectiveness on the hedge during the first nine months of 2017 and 2016, respectively.

⁽²⁾ 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.

At September 30, 2017, the Company estimates \$164 million of pretax net unrealized losses on derivatives maturing within the next 12 months that hedge foreign currency denominated sales over that same period will be reclassified from *AOCl* to *Sales*. The amount ultimately reclassified to *Sales* may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity.

Investments in Debt and Equity Securities

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

(\$ in millions)	September 30, 2017				December 31, 2016			
	Fair Value	Amortized Cost	Gross Unrealized		Fair Value	Amortized Cost	Gross Unrealized	
			Gains	Losses			Gains	Losses
Corporate notes and bonds	\$ 10,259	\$ 10,242	\$ 31	\$ (14)	\$ 10,577	\$ 10,601	\$ 15	\$ (39)
U.S. government and agency securities	1,924	1,934	—	(10)	2,232	2,244	1	(13)
Asset-backed securities	1,473	1,473	2	(2)	1,376	1,380	1	(5)
Mortgage-backed securities	704	708	1	(5)	796	801	1	(6)
Commercial paper	695	695	—	—	4,330	4,330	—	—
Foreign government bonds	640	642	—	(2)	519	521	—	(2)
Equity securities	539	309	233	(3)	349	281	71	(3)
	\$ 16,234	\$ 16,003	\$ 267	\$ (36)	\$ 20,179	\$ 20,158	\$ 89	\$ (68)

Available-for-sale debt securities included in *Short-term investments* totaled \$3.0 billion at September 30, 2017. Of the remaining debt securities, \$11.2 billion mature within five years. At September 30, 2017 and December 31, 2016, there were no debt securities pledged as collateral.

Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The Company uses a fair value hierarchy which maximizes the use of observable inputs and minimizes the use of unobservable inputs when measuring fair value. There are three levels of inputs used to measure fair value with Level 1

having the highest priority and Level 3 having the lowest: *Level 1* - Quoted prices (unadjusted) in active markets for identical assets or liabilities, *Level 2* - Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities, *Level 3* - Unobservable inputs that are supported by little or no market activity. Level 3 assets or liabilities are those whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques with significant unobservable inputs, as well as assets or liabilities for which the determination of fair value requires significant judgment or estimation. If the inputs used to measure the financial assets and liabilities fall within more than one level described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

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

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

	Fair Value Measurements Using				Fair Value Measurements Using			
	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
(\$ in millions)	September 30, 2017				December 31, 2016			
Assets								
<i>Investments</i>								
Corporate notes and bonds	\$ —	\$ 10,110	\$ —	\$ 10,110	\$ —	\$ 10,389	\$ —	\$ 10,389
U.S. government and agency securities	68	1,622	—	1,690	29	1,890	—	1,919
Asset-backed securities ⁽¹⁾	—	1,395	—	1,395	—	1,257	—	1,257
Commercial paper	—	695	—	695	—	4,330	—	4,330
Foreign government bonds	—	639	—	639	—	518	—	518
Mortgage-backed securities ⁽¹⁾	—	603	—	603	—	628	—	628
Equity securities	368	—	—	368	201	—	—	201
	436	15,064	—	15,500	230	19,012	—	19,242
<i>Other assets</i> ⁽²⁾								
U.S. government and agency securities	—	234	—	234	—	313	—	313
Corporate notes and bonds	—	149	—	149	—	188	—	188
Mortgage-backed securities ⁽¹⁾	—	101	—	101	—	168	—	168
Asset-backed securities ⁽¹⁾	—	78	—	78	—	119	—	119
Foreign government bonds	—	1	—	1	—	1	—	1
Equity securities	171	—	—	171	148	—	—	148
	171	563	—	734	148	789	—	937
<i>Derivative assets</i> ⁽³⁾								
Purchased currency options	—	119	—	119	—	644	—	644
Forward exchange contracts	—	87	—	87	—	331	—	331
Interest rate swaps	—	15	—	15	—	20	—	20
	—	221	—	221	—	995	—	995
Total assets	\$ 607	\$ 15,848	\$ —	\$ 16,455	\$ 378	\$ 20,796	\$ —	\$ 21,174
Liabilities								
<i>Other liabilities</i>								
Contingent consideration	\$ —	\$ —	\$ 945	\$ 945	\$ —	\$ —	\$ 891	\$ 891
<i>Derivative liabilities</i> ⁽³⁾								
Forward exchange contracts	—	201	—	201	—	93	—	93
Interest rate swaps	—	26	—	26	—	29	—	29
Written currency options	—	—	—	—	—	12	—	12
	—	227	—	227	—	134	—	134
Total liabilities	\$ —	\$ 227	\$ 945	\$ 1,172	\$ —	\$ 134	\$ 891	\$ 1,025

⁽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. Mortgage-backed securities represent AAA-rated securities issued or unconditionally guaranteed as to payment of principal and interest by U.S. government agencies.

⁽²⁾ Investments included in other assets are restricted 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 2017. As of September 30, 2017, *Cash and cash equivalents* of \$7.9 billion included \$7.1 billion of cash equivalents (which would be considered Level 2 in the fair value hierarchy).

Contingent Consideration

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

(\$ in millions)	Nine Months Ended September 30,	
	2017	2016
Fair value January 1	\$ 891	\$ 590
Changes in fair value ⁽¹⁾	151	29
Additions	3	300
Payments	(100)	(25)
Fair value September 30 ⁽²⁾	\$ 945	\$ 894

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

⁽²⁾ Includes \$234 million recorded as a current liability for amounts expected to be paid within the next 12 months.

The additions to contingent consideration reflected in the table above in the first nine months of 2016 relate to the acquisitions of Afferent and IOmet (see Note 2). The payments of contingent consideration in 2017 relate to the achievement of a clinical milestone in connection with the acquisition of IOmet (see Note 2) and in 2016 relate to the first commercial sale of Zerbaxa in the European Union.

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, 2017, was \$28.3 billion compared with a carrying value of \$27.0 billion and at December 31, 2016, was \$25.7 billion compared with a carrying value of \$24.8 billion. Fair value was estimated using recent observable market prices and would be considered Level 2 in the fair value hierarchy.

Concentrations of Credit Risk

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

The majority of the Company's accounts receivable arise from product sales in the United States 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 economic conditions, including the volatility associated with international sovereign economies, and associated impacts on the financial markets and its business, taking into consideration global economic conditions and the ongoing sovereign debt issues in certain European countries. At September 30, 2017, the Company's total net accounts receivable outstanding for more than one year were approximately \$190 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, 2017 and December 31, 2016, the Company had received cash collateral of \$8 million and \$529 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, 2017 or December 31, 2016.

5. Inventories

Inventories consisted of:

(\$ in millions)	September 30, 2017	December 31, 2016
Finished goods	\$ 1,364	\$ 1,304
Raw materials and work in process	4,588	4,222
Supplies	198	155
Total (approximates current cost)	6,150	5,681
Increase to LIFO costs	142	302
	\$ 6,292	\$ 5,983
Recognized as:		
Inventories	\$ 5,263	\$ 4,866
Other assets	1,029	1,117

Amounts recognized as *Other assets* are comprised almost entirely of raw materials and work in process inventories. At September 30, 2017 and December 31, 2016, these amounts included \$957 million and \$1.0 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included \$72 million and \$80 million at September 30, 2017 and December 31, 2016, respectively, of inventories produced in preparation for product launches.

6. Other Intangibles

In connection with acquisitions, the Company measures the fair value of marketed products and research and development pipeline programs and capitalizes these amounts. See Note 2 for information on intangible assets acquired as a result of business acquisitions in the first nine months of 2017 and 2016.

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* are being adversely affected by the availability of new therapeutic options. During the second quarter, 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. The remaining intangible asset value for *Intron A* at September 30, 2017 was \$19 million.

During the first nine months of 2016, the Company recorded intangible asset impairment charges related to marketed products of \$347 million. Of this amount, \$252 million relates to *Zontivity*, a product for the reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction or with peripheral arterial disease. In March 2016, following several business decisions that reduced sales expectations for *Zontivity* in the United States and Europe, the Company lowered its cash flow projections for *Zontivity*. The Company utilized market participant assumptions and considered several different scenarios to determine the fair value of the intangible asset related to *Zontivity* that, when compared with its related carrying value, resulted in the impairment charge noted above. In addition, the Company wrote-off \$95 million that had been capitalized in connection with in-licensed products that, for business reasons, the Company returned to the licensor.

Also, 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* (elbasvir and grazoprevir), which is currently marketed by the Company for the treatment of 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 intangible asset related to uprifosbuvir.

During the first nine months of 2016, the Company recorded \$225 million of IPR&D impairment charges. Of this amount, \$112 million relates to an in-licensed program that, for business reasons, was returned to the licensor. The remaining IPR&D impairment charges in 2016 primarily relate to deprioritized pipeline programs that were deemed to have no alternative use during the period.

The Company may recognize additional non-cash impairment charges in the future related to other marketed products or pipeline programs and such charges could be material.

7. Contingencies

The Company is involved in various claims and legal proceedings of a nature considered normal to its business, including product liability, intellectual property, and commercial litigation, as well as certain additional matters including governmental and environmental matters. In the opinion of the Company, it is unlikely that the resolution of these matters will be material to the Company's financial 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, 2017, approximately 4,125 cases are filed and pending against Merck in either federal or state court. In approximately 15 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 4,110 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 December 2013, Merck reached an agreement in principle with the Plaintiffs' Steering Committee (PSC) in the *Fosamax* ONJ MDL to resolve pending ONJ cases not on appeal in the *Fosamax* ONJ MDL and in the state courts for an aggregate amount of \$27.7 million. Merck and the PSC subsequently formalized the terms of this agreement in a Master Settlement Agreement (ONJ Master Settlement Agreement) that was executed in April 2014 and included over 1,200 plaintiffs. In July 2014, Merck elected to proceed with the ONJ Master Settlement Agreement at a reduced funding level of \$27.3 million since the participation level was approximately 95%. Merck has fully funded the ONJ Master Settlement Agreement and 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.

Discovery is currently ongoing in some of the approximately 15 remaining ONJ cases that are pending in various federal and state courts and the Company intends to defend against these lawsuits.

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. The Motion to Transfer was granted in May 2011, and 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. The *Glynn* decision was not appealed by plaintiff.

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). The Femur Fracture MDL court has also dismissed without prejudice another approximately 510 cases pending plaintiffs' appeal of the preemption ruling to the Third Circuit. On March 22, 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. On April 5, 2017, Merck filed a petition seeking a rehearing on the Third Circuit's March 22, 2017 decision, which was denied on April 24, 2017. Merck filed a petition for a writ of certiorari to the U.S. Supreme Court on August 22, 2017, seeking review of the Third Circuit's decision.

In addition, in June 2014, the Femur Fracture MDL court granted Merck summary judgment in the *Gaynor v. Merck* case and found that Merck's updates in January 2011 to the *Fosamax* label regarding atypical femur fractures were adequate as a matter of law and that Merck adequately communicated those changes. The plaintiffs in *Gaynor* did not appeal the Femur Fracture MDL court's findings with respect to the adequacy of the 2011 label change but did appeal the dismissal of their case based on preemption grounds, and the Third Circuit subsequently reversed that dismissal in its March 22, 2017 decision. In August 2014, Merck filed a motion requesting that the Femur Fracture MDL court enter a further order requiring all plaintiffs in the Femur Fracture MDL who claim that the 2011 *Fosamax* label is inadequate and the proximate cause of their alleged injuries to show cause why their cases should not be dismissed based on the court's preemption decision and its ruling in the *Gaynor* case. In November 2014, the court granted Merck's motion and entered the requested show cause order. No plaintiffs responded to or appealed the November 2014 show cause order.

As of September 30, 2017, approximately 520 cases were pending in the Femur Fracture MDL following the reinstatement of the cases that had been on appeal to the Third Circuit. The 510 cases dismissed without prejudice that were also pending the final resolution of the aforementioned appeal have not yet been reinstated.

As of September 30, 2017, approximately 2,795 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 during 2016 and 2017.

As of September 30, 2017, approximately 280 cases alleging Femur Fractures have been filed and are pending in California state court. A petition was filed seeking to coordinate all Femur Fracture cases filed in California state court before a single judge in Orange County, California. The petition was granted and Judge Thierry Colaw is currently presiding over the coordinated proceedings. 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. Oral argument on plaintiff's appeal in *Galper* was held in November 2016 and, on April 24, 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 five 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, 2017, Merck is aware of approximately 1,225 product user claims alleging generally that use of *Januvia* and/or *Janumet* caused the development of pancreatic cancer and other injuries. These complaints were filed in several different state and federal courts.

Most of the claims were filed in a consolidated multidistrict litigation proceeding in the U.S. District Court for the Southern District of California called "In re Incretin-Based Therapies Products Liability Litigation" (MDL). The MDL includes federal lawsuits alleging pancreatic cancer due to use of the following medicines: *Januvia*, *Janumet*, Byetta and Victoza, the latter two of which are products manufactured by other pharmaceutical companies. The majority of claims not filed in the MDL were filed in 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 preemption. Of the approximately 1,225 product user claims, these rulings resulted in the dismissal of approximately 1,175 product user claims.

Plaintiffs are appealing the MDL and California State Court preemption rulings.

As of September 30, 2017, seven product users have claims pending against Merck in state courts other than the California State Court, including four active product user claims pending in Illinois state court. On June 30, 2017, the Illinois court denied Merck's motion for summary judgment on grounds of preemption. Merck has sought permission to appeal that order on an interlocutory basis and was granted a stay of proceedings in the trial court. As a result, trials for certain of the product users in Illinois have been delayed.

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*. As of September 30, 2017, approximately 915 lawsuits have been filed by plaintiffs who allege that they have experienced persistent sexual side effects following cessation of treatment with *Propecia* and/or *Proscar*. Approximately 20 of the plaintiffs also allege that *Propecia* or *Proscar* has caused or can cause prostate cancer, testicular cancer or male breast cancer. The lawsuits have been filed in various federal courts and in state court in New Jersey. The federal lawsuits have been 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 have been consolidated before Judge Hyland in Middlesex County. In addition, there is one matter pending in state court in California, one matter pending in state court in Ohio, and one matter on appeal in the Massachusetts Supreme Judicial Court. The Company intends to defend against these lawsuits.

Governmental Proceedings

In July 2017, the Company learned that the Prosecution Office of Milan, Italy is investigating interactions between the Company's Italian subsidiary, certain employees of the subsidiary and certain Italian healthcare providers. The Company understands that this is part of a larger investigation involving engagements between various healthcare companies and those healthcare providers. The Company is cooperating with the investigation.

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

Commercial and Other Litigation

K-DUR Antitrust Litigation

In June 1997 and January 1998, Schering-Plough Corporation (Schering-Plough) settled patent litigation with Upsher-Smith, Inc. (Upsher-Smith) and ESI Lederle, Inc. (Lederle), respectively, relating to generic versions of Schering-Plough's long-acting potassium chloride product supplement used by cardiac patients, for which Lederle and Upsher-Smith had filed Abbreviated New Drug Applications (ANDAs). Putative class and non-class action suits were then filed on behalf of direct and indirect purchasers of K-DUR against Schering-Plough, Upsher-Smith and Lederle and were consolidated in a multidistrict litigation in the U.S. District Court for the District of New Jersey. In February 2016, the court denied the Company's motion for summary judgment relating to all of the direct purchasers' claims concerning the settlement with Upsher-Smith and granted the Company's motion for summary judgment relating to all of the direct purchasers' claims concerning the settlement with Lederle.

As previously disclosed, in February 2017, Merck and Upsher-Smith reached a settlement in principle with the class of direct purchasers and the opt-outs to the class. Merck will contribute approximately \$80 million in the aggregate towards the overall settlement. On April 5, 2017, the claims of the opt-outs were dismissed with prejudice pursuant to a written settlement agreement with those parties. On May 15, 2017, Merck and the class executed a settlement agreement, which received preliminary approval from the court on May 23, 2017. On October 5, 2017, the court entered a Final Judgment and Order of Dismissal approving the settlement agreement with the direct purchaser class and dismissing the claims of the class with prejudice.

Patent Litigation

From time to time, generic manufacturers of pharmaceutical products file ANDAs 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. Certain products of the Company (or products marketed via agreements with other companies) currently involved in such patent infringement litigation in the United States include: *Invanz*, *Noxafil*, and *NuvaRing*. 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.

Invanz — In July 2014, a patent infringement lawsuit was filed in the United States against Hospira, Inc. (Hospira) in respect of Hospira's application to the FDA seeking pre-patent expiry approval to market a generic version of *Invanz*. The trial in this matter was held in April 2016 and, in October 2016, the district court ruled that the patent is valid and infringed. In August 2015, a patent infringement lawsuit was filed in the United States against Savior Lifetec Corporation (Savior) in respect of Savior's application to the FDA seeking pre-patent expiry approval to market a generic version of *Invanz*. The Company will lose the right to market exclusivity in the United States for *Invanz* on November 15, 2017.

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 can appeal this decision. 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 October 2017, the parties reached a settlement whereby Roxane can launch its generic version upon expiry of the patent, or earlier 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*. In October 2016, the parties reached a settlement whereby Par can launch its generic version in January 2023, or earlier under certain conditions.

NuvaRing — In December 2013, the Company filed a lawsuit against a subsidiary of Allergan plc 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 *NuvaRing*. The trial in this matter was held in January 2016. In August 2016, the district court ruled that the patent was invalid and the Company appealed this decision. In October 2017, the appellate court reversed the district court decision and found the patent to be valid. Allergan may seek further review of this decision. In September 2015, the Company filed a lawsuit against Teva Pharma 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 *NuvaRing*. Based on its ruling in the Allergan plc matter, the district court dismissed the Company's lawsuit in December 2016. The Company has appealed this decision and the matter is currently stayed.

Anti-PD-1 Antibody Patent Oppositions and Litigation

As previously disclosed, Ono Pharmaceutical Co. (Ono) has a European patent (EP 1 537 878) ('878) that broadly claims the use of an anti-PD-1 antibody, such as the Company's immunotherapy, *Keytruda*, for the treatment of cancer. Ono has previously licensed its commercial rights to an anti-PD-1 antibody to Bristol-Myers Squibb (BMS) in certain markets. BMS and Ono also own European Patent EP 2 161 336 ('336) that, as granted, broadly claimed anti-PD-1 antibodies that could include *Keytruda*.

As previously disclosed, the Company and BMS and Ono were engaged in worldwide litigation, including in the United States, over the validity and infringement of the '878 patent, the '336 patent and their equivalents.

In January 2017, the Company announced that it had entered into a settlement and license agreement with BMS and Ono resolving the worldwide patent infringement litigation related to the use of an anti-PD-1 antibody for the treatment of cancer, such as *Keytruda*. Under the settlement and license agreement, the Company made a one-time payment of \$625 million (which was recorded as an expense in the Company's 2016 financial results) to BMS and will pay royalties on the worldwide sales of *Keytruda* for a non-exclusive license to market *Keytruda* in any market in which it is approved. For global net sales of *Keytruda*, the Company will pay royalties of 6.5% of net sales occurring from January 1, 2017 through and including December 31, 2023; and 2.5% of net sales occurring from January 1, 2024 through and including December 31, 2026. The parties also agreed to dismiss all claims worldwide in the relevant legal proceedings.

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 has appealed the court's decision. Gilead has 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. The Company will pay 20%, net of legal fees, of damages or royalties, if any, that it receives to Ionis Pharmaceuticals, Inc.

The Company, through its Idenix Pharmaceuticals, Inc. subsidiary, has pending litigation against Gilead in the United States, the UK, Norway, Canada, Germany, France, and Australia based on different patent estates that would also be infringed by Gilead's sales of these two products. Gilead has 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 enhanced damages, granted its motion on prejudgment interest and deferred its motion on future royalties. The Company is currently awaiting the court's decision on Gilead's post-trial motions for judgment as a matter of law. In Australia, the Company was initially unsuccessful and that case is currently under appeal. In Canada, the Company was initially unsuccessful and the Federal Court of Appeals has affirmed the lower court decision. The Company has sought leave to the Supreme Court of Canada for further review. In the UK and Norway, the patent was held invalid and no further appeal was filed. The EPO opposition division revoked the European patent, and the Company has 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, 2017 and December 31, 2016 of approximately \$170 million and \$185 million, respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

8. Equity

(\$ and shares in millions)	Common Stock		Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock		Non-Controlling Interests	Total
	Shares	Par Value				Shares	Cost		
Balance at January 1, 2016	3,577	\$ 1,788	\$ 40,222	\$ 45,348	\$ (4,148)	796	\$ (38,534)	\$ 91	\$ 44,767
Net income attributable to Merck & Co., Inc.	—	—	—	4,515	—	—	—	—	4,515
Other comprehensive loss, net of taxes	—	—	—	—	(104)	—	—	—	(104)
Cash dividends declared on common stock	—	—	—	(3,835)	—	—	—	—	(3,835)
Treasury stock shares purchased	—	—	—	—	—	44	(2,418)	—	(2,418)
Share-based compensation plans and other	—	—	(325)	—	—	(25)	1,235	—	910
Changes in noncontrolling ownership interests	—	—	—	—	—	—	—	124	124
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	13	13
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(15)	(15)
Balance at September 30, 2016	3,577	\$ 1,788	\$ 39,897	\$ 46,028	\$ (4,252)	815	\$ (39,717)	\$ 213	\$ 43,957
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	—	—	—	(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

9. Share-Based Compensation Plans

The Company has share-based compensation plans under which the Company grants restricted stock units (RSUs) and performance share units (PSUs) to certain management level employees. In addition, employees and non-employee directors may be granted options to purchase shares of Company common stock at the fair market value at the time of grant.

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

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Pretax share-based compensation expense	\$ 76	\$ 77	\$ 232	\$ 225
Income tax benefit	(23)	(24)	(70)	(69)
Total share-based compensation expense, net of taxes	\$ 53	\$ 53	\$ 162	\$ 156

During the first nine months of 2017 and 2016, the Company granted 5 million RSUs with a weighted-average grant date fair value of \$63.96 per RSU and 6 million RSUs with a weighted-average grant date fair value of \$54.61 per RSU, respectively. During the first nine months of 2017 and 2016, the Company granted 4 million stock options with a weighted-average exercise price of \$63.96 per option and 6 million stock options with a weighted-average exercise price of \$54.62 per option, respectively. The weighted-average fair value of options granted for the first nine months of 2017 and 2016 was \$7.04 and \$5.89 per option, respectively, and was determined using the following assumptions:

	Nine Months Ended September 30,	
	2017	2016
Expected dividend yield	3.6%	3.8%
Risk-free interest rate	2.0%	1.4%
Expected volatility	17.8%	19.6%
Expected life (years)	6.1	6.2

At September 30, 2017, there was \$549 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.

10. Pension and Other Postretirement Benefit Plans

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

(\$ in millions)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2017		2016		2017		2016	
	U.S.	International	U.S.	International	U.S.	International	U.S.	International
Service cost	\$ 80	\$ 66	\$ 66	\$ 59	\$ 234	\$ 189	\$ 212	\$ 179
Interest cost	114	44	116	51	341	127	342	155
Expected return on plan assets	(210)	(101)	(203)	(95)	(646)	(292)	(623)	(288)
Amortization of unrecognized prior service credit	(13)	(3)	(14)	(3)	(40)	(8)	(41)	(9)
Net loss amortization	46	25	32	21	135	72	89	64
Termination benefits	3	1	6	1	11	2	11	2
Curtailments	4	(1)	3	(2)	8	(1)	3	(1)
	\$ 24	\$ 31	\$ 6	\$ 32	\$ 43	\$ 89	\$ (7)	\$ 102

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 cost (credit) of such plans consisted of the following components:

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	Service cost	\$ 15	\$ 14	\$ 43
Interest cost	20	19	61	62
Expected return on plan assets	(20)	(19)	(59)	(88)
Amortization of unrecognized prior service credit	(24)	(26)	(74)	(79)
Net loss amortization	—	1	1	1
Termination benefits	—	1	1	1
Curtailments	(1)	(5)	(6)	(7)
	\$ (10)	\$ (15)	\$ (33)	\$ (69)

In connection with restructuring actions (see Note 3), 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 were recorded on pension and other postretirement benefit plans as reflected in the tables above.

11. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	Interest income	\$ (90)	\$ (87)	\$ (284)
Interest expense	189	170	564	513
Exchange (gains) losses	(6)	3	5	79
Equity (income) loss from affiliates	(18)	(21)	(11)	(59)
Other, net	(161)	(43)	(244)	(201)
	\$ (86)	\$ 22	\$ 30	\$ 88

Interest paid for the nine months ended September 30, 2017 and 2016 was \$505 million and \$470 million, respectively.

12. Taxes on Income

The effective income tax rates of 125.5% and 24.2% for the third quarter of 2017 and 2016, respectively, and 25.5% and 24.7% for the first nine months of 2017 and 2016, 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 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 includes a benefit of \$88 million related to the settlement of a state income tax issue. The effective income tax rate for the first nine months of 2016 also reflects the beneficial impact of orphan drug federal income tax credits, primarily for *Keytruda*.

In the third quarter of 2017, the Internal Revenue Service 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 provision 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.

13. Earnings Per Share

The calculations of earnings per share are as follows:

(\$ and shares in millions except per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Net (loss) income attributable to Merck & Co., Inc.	\$ (56)	\$ 2,184	\$ 3,440	\$ 4,515
Average common shares outstanding	2,727	2,765	2,735	2,769
Common shares issuable ⁽¹⁾	—	21	19	22
Average common shares outstanding assuming dilution	2,727	2,786	2,754	2,791
Basic (loss) earnings per common share attributable to Merck & Co., Inc. common shareholders	\$ (0.02)	\$ 0.79	\$ 1.26	\$ 1.63
(Loss) earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	\$ (0.02)	\$ 0.78	\$ 1.25	\$ 1.62

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

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. For the three months ended September 30, 2016, 4 million, and for the first nine months of 2017 and 2016, 4 million and 13 million, respectively, of common shares issuable under share-based compensation plans were excluded from the computation of earnings per common share assuming dilution because the effect would have been antidilutive.

14. Other Comprehensive Income (Loss)Changes in *AOCI* by component are as follows:

(\$ in millions)	Three Months Ended September 30,				
	Derivatives	Investments	Employee Benefit Plans	Cumulative Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
Balance July 1, 2016, net of taxes	\$ 111	\$ 167	\$ (2,543)	\$ (1,821)	\$ (4,086)
Other comprehensive income (loss) before reclassification adjustments, pretax	(69)	(22)	(177)	70	(198)
Tax	24	(3)	21	12	54
Other comprehensive income (loss) before reclassification adjustments, net of taxes	(45)	(25)	(156)	82	(144)
Reclassification adjustments, pretax	(45) ⁽¹⁾	(5) ⁽²⁾	11 ⁽³⁾	—	(39)
Tax	16	—	1	—	17
Reclassification adjustments, net of taxes	(29)	(5)	12	—	(22)
Other comprehensive income (loss), net of taxes	(74)	(30)	(144)	82	(166)
Balance September 30, 2016, net of taxes	\$ 37	\$ 137	\$ (2,687)	\$ (1,739)	\$ (4,252)
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)

(\$ in millions)	Nine Months Ended September 30,				
	Derivatives	Investments	Employee Benefit Plans	Cumulative Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
Balance January 1, 2016, net of taxes	\$ 404	\$ 41	\$ (2,407)	\$ (2,186)	\$ (4,148)
Other comprehensive income (loss) before reclassification adjustments, pretax	(311)	108	(395)	424	(174)
Tax	109	8	88	23	228
Other comprehensive income (loss) before reclassification adjustments, net of taxes	(202)	116	(307)	447	54
Reclassification adjustments, pretax	(254) ⁽¹⁾	(26) ⁽²⁾	25 ⁽³⁾	—	(255)
Tax	89	6	2	—	97
Reclassification adjustments, net of taxes	(165)	(20)	27	—	(158)
Other comprehensive income (loss), net of taxes	(367)	96	(280)	447	(104)
Balance September 30, 2016, net of taxes	\$ 37	\$ 137	\$ (2,687)	\$ (1,739)	\$ (4,252)
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)

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

15. Segment Reporting

The Company's operations are principally managed on a products basis and include the Pharmaceutical, Animal Health, Healthcare Services and Alliances operating segments. The Animal Health, Healthcare Services and Alliances segments are not material for separate reporting.

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. Sales of vaccines in most major European markets were marketed through the Company's SPMSD joint venture until its termination on December 31, 2016.

The Company also has an Animal Health segment that discovers, develops, manufactures and markets animal health products, including vaccines, which the Company sells to veterinarians, distributors and animal producers. The Company's 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.

Sales of the Company's products were as follows:

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Primary Care and Women's Health				
Cardiovascular				
<i>Zetia</i>	\$ 320	\$ 671	\$ 1,021	\$ 1,985
<i>Ytorin</i>	142	273	565	843
<i>Atozet</i>	59	39	171	96
<i>Adepas</i>	70	48	221	120
Diabetes				
<i>Januvia</i>	1,012	1,006	2,799	2,976
<i>Janumet</i>	513	548	1,572	1,624
General Medicine and Women's Health				
<i>NuvaRing</i>	214	195	573	571
<i>Implanon/Nexplanon</i>	155	148	503	446
<i>Follistim AQ</i>	72	101	232	268
Hospital and Specialty				
Hepatitis				
<i>Zepatier</i>	468	164	1,363	326
HIV				
<i>Isentress/Isentress HD</i>	310	372	896	1,050
Hospital Acute Care				
<i>Bridion</i>	185	139	495	343
<i>Noxafil</i>	162	147	458	434
<i>Invanz</i>	159	152	445	409
<i>Cancidas</i>	94	142	327	406
<i>Cubicin</i>	91	320	290	969
<i>Primaxin</i>	73	77	206	231
Immunology				
<i>Remicade</i>	214	311	651	999
<i>Simponi</i>	219	193	602	581
Oncology				
<i>Keytruda</i>	1,047	356	2,512	919
<i>Emend</i>	137	137	413	405
<i>Temodar</i>	68	78	198	216
Diversified Brands				
Respiratory				
<i>Singulair</i>	161	239	550	705
<i>Nasonex</i>	42	94	266	425
<i>Dulera</i>	59	97	210	331
Other				
<i>Cozaar/Hyzaar</i>	128	131	360	389
<i>Arcoxia</i>	80	114	272	342
<i>Fosamax</i>	53	68	180	217
Vaccines ⁽¹⁾				
<i>Gardasil/Gardasil 9</i>	675	860	1,675	1,631
<i>ProQuad/M-M-R II/Varivax</i>	519	496	1,273	1,236
<i>Pneumovax 23</i>	229	175	558	403
<i>Zostavax</i>	234	190	547	464
<i>RotaTeq</i>	179	171	525	489
Other pharmaceutical ⁽²⁾	1,013	1,191	3,172	3,398
Total Pharmaceutical segment sales	9,156	9,443	26,101	26,247
Other segment sales ⁽³⁾	1,100	977	3,188	2,862
Total segment sales	10,256	10,420	29,289	29,109
Other ⁽⁴⁾	69	116	400	583
	\$ 10,325	\$ 10,536	\$ 29,689	\$ 29,692

⁽¹⁾ On December 31, 2016, Merck and Sanofi terminated their equally-owned joint venture, SPMSD, which marketed vaccines in most major European markets. Accordingly, vaccine sales in 2017 include sales in the European markets that were previously part of SPMSD. Amounts for 2016 do not include sales of vaccines sold through SPMSD, the results of which are reflected in equity income from affiliates which is included in Other (income) expense, net. Amounts for 2016 do, however, include supply sales to SPMSD.

⁽²⁾ Other pharmaceutical primarily reflects sales of other human health pharmaceutical products, including products within the franchises not listed separately.

⁽³⁾ Represents the non-reportable segments of Animal Health, Healthcare Services and Alliances.

⁽⁴⁾ 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 2017 and 2016 also includes \$60 million and \$75 million, respectively, related to the sale of the marketing rights to certain products.

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

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Segment profits:				
Pharmaceutical segment	\$ 5,929	\$ 6,162	\$ 16,722	\$ 16,698
Other segments	482	389	1,442	1,129
Total segment profits	6,411	6,551	18,164	17,827
Other profits	(78)	21	107	341
Unallocated:				
Interest income	90	87	284	244
Interest expense	(189)	(170)	(564)	(513)
Equity income from affiliates	23	(27)	16	(13)
Depreciation and amortization	(334)	(365)	(1,036)	(1,228)
Research and development	(1,829)	(1,444)	(4,955)	(4,651)
Aggregate charge related to the formation of an oncology collaboration with AstraZeneca	(2,350)	—	(2,350)	—
Amortization of purchase accounting adjustments	(765)	(772)	(2,322)	(2,933)
Restructuring costs	(153)	(161)	(470)	(386)
Gain on sale of certain migraine clinical development programs	—	40	—	40
Other unallocated, net	(626)	(873)	(2,232)	(2,713)
	\$ 200	\$ 2,887	\$ 4,642	\$ 6,015

Segment profits are comprised of segment sales less standard costs and certain operating expenses directly incurred by the segments. For internal management reporting presented to the chief operating decision maker, Merck does not allocate materials and production costs, other than standard costs, the majority of research and development expenses 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 intangible asset impairment charges, gains or losses on sales of businesses, expense or income related to changes in the estimated fair value of contingent consideration, and other miscellaneous income or expense items.

Recent Developments

Business Developments

In July 2017, Merck and AstraZeneca entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza (olaparib) for multiple cancer types. Lynparza is an oral, poly (ADP-ribose) polymerase (PARP) inhibitor currently approved for certain types of ovarian cancer. The companies will jointly develop and commercialize Lynparza, both as monotherapy and in combination trials with other potential medicines. Independently, Merck and AstraZeneca will develop and commercialize Lynparza in combinations with their respective PD-1 and PD-L1 medicines, *Keytruda* (pembrolizumab) and *Imfinzi* (durvalumab). 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 including thyroid cancer. As part of the agreement, Merck made an upfront payment to AstraZeneca of \$1.6 billion and will make payments of \$750 million over a multi-year period for certain license options (\$250 million in November 2017, \$400 million in November 2018 and \$100 million in November 2019). The Company recorded an aggregate charge of \$2.35 billion in *Research and development* expenses in the third quarter of 2017 related to the upfront payment and future license options payments. In addition, Merck will pay AstraZeneca up to an additional \$6.15 billion contingent upon successful achievement of future regulatory and sales milestones for total aggregate consideration of up to \$8.5 billion (see Note 2 to the condensed consolidated financial statements).

In October 2017, Merck acquired Rigontec GmbH (Rigontec). Rigontec is a leader in accessing the retinoic acid-inducible gene I (RIG-I) pathway, part of the innate immune system, as a novel and distinct approach in cancer immunotherapy to induce both immediate and long-term anti-tumor immunity. Rigontec's lead candidate, RGT100, is currently in Phase I development evaluating treatment in patients with various tumors. Under the terms of the agreement, Merck made an upfront cash payment of €119 million (\$140 million) and may make additional contingent payments of up to €349 million based on the attainment of certain clinical, development, regulatory and commercial milestones. The transaction will be accounted for as an acquisition of an asset and the upfront payment will be reflected within *Research and development* expenses in the fourth quarter of 2017.

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. Most of the Company's manufacturing sites are now largely operational, manufacturing active pharmaceutical ingredient (API), formulating, packaging and shipping product. The Company's external manufacturing was not impacted. Throughout this time, Merck has continued to fulfill orders and ship product.

The Company is confident in the continuous supply of key products such as *Keytruda*, *Januvia* (sitagliptin) and *Zepatier* (elbasvir and grazoprevir). However, as anticipated, the Company was unable to fulfill orders for certain other products in certain markets, which had an unfavorable effect on sales for the third quarter and first nine months of 2017 of approximately \$135 million. 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 \$175 million for the third quarter and first nine months of 2017. The Company anticipates a similar impact to revenue and expenses in the fourth quarter of 2017 and for the full year of 2018 from the cyber-attack. Additionally, the temporary production shut-down from the cyber-attack contributed to the Company's inability to meet higher than expected demand for *Gardasil 9* (Human Papillomavirus 9-valent Vaccine, Recombinant), which resulted in Merck's decision to borrow doses of *Gardasil 9* from the U.S. Centers for Disease Control and Prevention (CDC) Pediatric Vaccine Stockpile, reducing sales as discussed below. Merck does not expect a significant impairment to the value of intangible assets related to marketed products or inventories as a result of the cyber-attack.

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

Hurricane Maria

In September 2017, Hurricane Maria made direct landfall on Puerto Rico. The Company has one plant in Puerto Rico that makes a limited number of its pharmaceutical products, and the Company also works with contract manufacturers on the island. Merck's plant did not sustain substantial damage, and production activities at the plant have resumed, although the operations at the plant are currently reliant on alternative sources of power and water. The Company is making progress despite the significant damage to the island's infrastructure; however, supply chains within Puerto Rico are not yet restored. Based on Merck's current assessment, the Company expects an immaterial impact to sales in 2017 and 2018.

Operating Results

Sales

Worldwide sales were \$10.3 billion for the third quarter of 2017, a decrease of 2% compared with the third quarter of 2016 including a 1% favorable effect from foreign exchange. The sales decline was primarily attributable to the effects of generic and biosimilar competition for certain products including *Zetia* (ezetimibe), which lost U.S. market exclusivity in December 2016, *Vytorin* (ezetimibe and simvastatin), which lost U.S. market exclusivity in April 2017, *Cubicin* (daptomycin for injection) due to U.S. patent expiration in June 2016, *Remicade* (infliximab) and *Cancidas* (caspofungin acetate), as well as lower sales of products within Diversified Brands including *Singulair* (montelukast), *Nasonex* (mometasone furoate monohydrate), and *Dulera* Inhalation Aerosol (mometasone furoate/formoterol fumarate dihydrate). Lower combined sales of *Isentress/Isentress HD* (raltegravir) also contributed to the revenue decline in the third quarter. Additionally, sales in the third quarter of 2017 were reduced by approximately \$240 million due to a borrowing the Company made from the CDC Pediatric Vaccine Stockpile of doses of *Gardasil 9* as discussed below. Also, as anticipated, the Company was unable to fulfill orders for certain other products in certain markets due to the cyber-attack, which had an unfavorable effect on sales for the third quarter of 2017 of approximately \$135 million. Sales in the third quarter of 2017 as compared with the third quarter of 2016 were also unfavorably affected by approximately \$150 million of additional sales in Japan in the third quarter of 2016 resulting from the timing of shipments in anticipation of the implementation of a resource planning system.

These declines were partially offset by higher sales from the ongoing launches of *Keytruda*, *Zepatier* and *Bridion* (sugammadex) Injection. Additionally, sales in the third quarter of 2017 benefited from the December 31, 2016 termination of Sanofi Pasteur MSD (SPMSD), a joint venture between Merck and Sanofi Pasteur S.A. (Sanofi), which marketed vaccines in most major European markets. In 2017, Merck began recording vaccine sales in the markets that were previously part of the SPMSD joint venture resulting in incremental vaccine sales of approximately \$130 million during the third quarter of 2017. Higher sales of Animal Health products also partially offset the revenue decline in the third quarter of 2017.

Worldwide sales were \$29.7 billion for the first nine months of 2017, essentially flat as compared with sales in the first nine months of 2016 including a 1% unfavorable effect from foreign exchange. Sales were unfavorably affected by generic and biosimilar competition for *Zetia*, *Vytorin*, *Cubicin*, *Remicade* and *Cancidas*, as well as by lower sales of products within Diversified Brands, the diabetes franchise of *Januvia* and *Janumet* (sitagliptin/metformin HCl) and *Isentress/Isentress HD*. Sales in the first nine months of 2017 were also unfavorably affected by the CDC stockpile borrowing and June cyber-attack by the amounts noted above. These declines were offset by higher sales of *Keytruda*, *Zepatier*, *Bridion*, *Adempas* (riociguat), and Animal Health products. Incremental vaccine sales of approximately \$265 million as a result of the termination of SPMSD as noted above also offset the revenue decline in the first nine months of 2017.

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 and, 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 2017. The Company anticipates these pricing actions and other austerity measures will continue to negatively affect revenue performance for the remainder of 2017.

Sales of the Company's products were as follows:

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Primary Care and Women's Health				
Cardiovascular				
<i>Zetia</i>	\$ 320	\$ 671	\$ 1,021	\$ 1,985
<i>Ytorin</i>	142	273	565	843
<i>Atozet</i>	59	39	171	96
<i>Adempas</i>	70	48	221	120
Diabetes				
<i>Januvia</i>	1,012	1,006	2,799	2,976
<i>Janumet</i>	513	548	1,572	1,624
General Medicine and Women's Health				
<i>NuvaRing</i>	214	195	573	571
<i>Implanon/Nexplanon</i>	155	148	503	446
<i>Follistim AQ</i>	72	101	232	268
Hospital and Specialty				
Hepatitis				
<i>Zepatier</i>	468	164	1,363	326
HIV				
<i>Isentress/Isentress HD</i>	310	372	896	1,050
Hospital Acute Care				
<i>Bridion</i>	185	139	495	343
<i>Noxafil</i>	162	147	458	434
<i>Invanz</i>	159	152	445	409
<i>Cancidas</i>	94	142	327	406
<i>Cubicin</i>	91	320	290	969
<i>Primaxin</i>	73	77	206	231
Immunology				
<i>Remicade</i>	214	311	651	999
<i>Simponi</i>	219	193	602	581
Oncology				
<i>Keytruda</i>	1,047	356	2,512	919
<i>Emend</i>	137	137	413	405
<i>Temodar</i>	68	78	198	216
Diversified Brands				
Respiratory				
<i>Singulair</i>	161	239	550	705
<i>Nasonex</i>	42	94	266	425
<i>Dulera</i>	59	97	210	331
Other				
<i>Cozaar/Hyzaar</i>	128	131	360	389
<i>Arcoxia</i>	80	114	272	342
<i>Fosamax</i>	53	68	180	217
Vaccines ⁽¹⁾				
<i>Gardasil/Gardasil 9</i>	675	860	1,675	1,631
<i>ProQuad/M-M-R II/Varivax</i>	519	496	1,273	1,236
<i>Pneumovax 23</i>	229	175	558	403
<i>Zostavax</i>	234	190	547	464
<i>RotaTeq</i>	179	171	525	489
Other pharmaceutical ⁽²⁾	1,013	1,191	3,172	3,398
Total Pharmaceutical segment sales	9,156	9,443	26,101	26,247
Other segment sales ⁽³⁾	1,100	977	3,188	2,862
Total segment sales	10,256	10,420	29,289	29,109
Other ⁽⁴⁾	69	116	400	583
	\$ 10,325	\$ 10,536	\$ 29,689	\$ 29,692

⁽¹⁾ On December 31, 2016, Merck and Sanofi terminated their equally-owned joint venture, SPMSD, which marketed vaccines in most major European markets. Accordingly, vaccine sales in 2017 include sales in the European markets that were previously part of SPMSD. Amounts for 2016 do not include sales of vaccines sold through SPMSD, the results of which are reflected in equity income from affiliates which is included in Other (income) expense, net. Amounts for 2016 do, however, include supply sales to SPMSD.

⁽²⁾ Other pharmaceutical primarily reflects sales of other human health pharmaceutical products, including products within the franchises not listed separately.

⁽³⁾ Represents the non-reportable segments of Animal Health, Healthcare Services and Alliances.

⁽⁴⁾ 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 2017 and 2016 also includes \$60 million and \$75 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 directly 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 \$2.9 billion and \$2.6 billion for the three months ended September 30, 2017 and 2016, respectively, and by \$8.2 billion and \$7.1 billion for the nine months ended September 30, 2017 and 2016, 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

Primary Care and Women's Health

Cardiovascular

Combined global sales of *Zetia* (marketed in most countries outside the United States as *Ezetrol*), *Vytorin* (marketed outside the United States as *Inegy*), and *Atozet* (ezetimibe and atorvastatin) (marketed in certain countries outside of the United States), medicines for lowering LDL cholesterol, were \$521 million in the third quarter of 2017 and \$1.8 billion for the first nine months of 2017, declines of 47% and 40%, respectively, compared with the same periods of 2016. Foreign exchange favorably affected global sales performance by 1% in the third quarter of 2017. The sales declines primarily reflect lower volumes and pricing of *Zetia* and *Vytorin* in the United States from generic competition. By agreement, a generic manufacturer launched a generic version of *Zetia* in the United States in December 2016. The U.S. patent and exclusivity periods for *Zetia* and *Vytorin* otherwise expired in April 2017. Accordingly, the Company is experiencing rapid and substantial declines in U.S. *Zetia* and *Vytorin* sales from generic competition and expects the declines to continue. The Company will lose market exclusivity in major European markets for *Ezetrol* in April 2018 and for *Inegy* in April 2019 and anticipates sales declines in these markets thereafter. Sales of *Ezetrol* and *Inegy* in these markets were \$389 million and \$327 million, respectively, for the first nine months of 2017.

Pursuant to a collaboration with Bayer AG (Bayer), Merck acquired lead commercial rights for Adempas, a novel 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 equally share profits under the collaboration. In 2016, Merck began promoting and distributing Adempas in Europe. Transition from Bayer in other Merck territories will continue in 2017. Merck recorded sales of \$70 million and \$48 million for Adempas in the third quarter of 2017 and 2016, respectively, and \$221 million and \$120 million for the first nine months of 2017 and 2016, respectively, which 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.

Diabetes

Worldwide combined sales of *Januvia* and *Janumet*, medicines that help lower blood sugar levels in adults with type 2 diabetes, were \$1.5 billion in the third quarter of 2017, a decline of 2% compared with the third quarter of 2016, and were \$4.4 billion in the first nine months of 2017, a decline of 5% compared with the same period of 2016. The declines were driven primarily by ongoing pricing pressure partially offset by continued volume growth globally.

In April 2017, Merck announced that the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) regarding Merck's supplemental New Drug Applications for *Januvia*, *Janumet* and *Janumet XR* (sitagliptin and metformin HCl extended-release). With these applications, Merck is seeking to include data from TECOS (Trial Evaluating Cardiovascular Outcomes with Sitagliptin) in the prescribing information of sitagliptin-containing medicines. Merck has reviewed the letter and is discussing next steps with the FDA.

General Medicine and Women's Health

Worldwide sales of *NuvaRing* (etonogestrel/ethinyl estradiol vaginal ring), a vaginal contraceptive product, were \$214 million in the third quarter of 2017, an increase of 10% compared with the third quarter of 2016 including a 2% favorable effect from foreign exchange. The increase was driven by higher sales in the United States reflecting higher pricing. Global sales of *NuvaRing* were \$573 million in the first nine months of 2017, essentially flat as compared with the same period of 2016.

Worldwide sales of *Implanon/Nexplanon* (etonogestrel implant), single-rod subdermal contraceptive implants, grew 5% to \$155 million in the third quarter of 2017 and increased 13% to \$503 million in the first nine months of 2017 compared with the same periods of 2016 driven by higher sales in the United States from volume growth and, for the year-to-date period, also from higher pricing. Foreign exchange favorably affected global sales performance by 1% for the third quarter of 2017.

Hospital and Specialty

Hepatitis

Global sales of *Zepatier* were \$468 million in the third quarter of 2017 compared with \$164 million in the third quarter of 2016 and were \$1.4 billion in the first nine months of 2017 compared with \$326 million in the first nine months of 2016. Sales growth in both periods primarily reflects higher sales in Europe, the United States and Japan as the Company continues to launch *Zepatier* globally. In January 2016, the FDA approved *Zepatier* for the treatment of chronic HCV genotype (GT) 1 or GT4 infection

in adults. *Zepatier* is indicated for use with ribavirin in certain patient populations. *Zepatier* became available in the United States in February 2016. *Zepatier* was approved by the European Commission (EC) in July 2016, became available in European markets in late November 2016 and has launched across these markets during 2017. The Company has also launched *Zepatier* in other international markets. The Company anticipates that future sales of *Zepatier* will be unfavorably affected by increasing competition and declining patient volumes.

HIV

Combined global sales of *Isentress/Isentress HD*, HIV integrase inhibitors for use in combination with other antiretroviral agents for the treatment of HIV-1 infection, were \$310 million in the third quarter of 2017, a decline of 17% compared with the third quarter of 2016, and were \$896 million in the first nine months of 2017, a decline of 15% compared with the first nine months of 2016. Foreign exchange favorably affected global sales performance by 1% in the third quarter of 2017 and unfavorably affected global sales performance by 1% in the first nine months of 2017. The sales declines primarily reflect lower demand in the United States due to competitive pressures. Lower volumes and pricing in Europe due to competition also had an unfavorable effect on sales in the year-to-date period. In May 2017, the FDA approved *Isentress HD*, a 1200 mg once-daily dose of *Isentress*, to be administered orally as two 600 mg tablets, in combination with other antiretroviral agents, for the treatment of HIV-1 infection in adults, and pediatric patients weighing at least 40 kg, who are treatment-naïve or whose virus has been suppressed on an initial regimen of *Isentress* 400 mg given twice daily. In July 2017, the EC granted marketing authorization of the once-daily dose of *Isentress* (*Isentress* 600 mg as it is known outside the United States) in combination with other antiretroviral medicinal products, for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 40 kg. Regulatory reviews are underway for once-daily versions of *Isentress* in other countries and regions around the world.

Hospital Acute Care

Worldwide sales of *Bridion*, for the reversal of two types of neuromuscular blocking agents used during surgery, were \$185 million in the third quarter of 2017, an increase of 33% compared with the third quarter of 2016. Global sales of *Bridion* were \$495 million in the first nine months of 2017, an increase of 44% compared with the same period of 2016 including a 1% unfavorable effect from foreign exchange. Sales growth in both periods primarily reflects volume growth in the United States.

Global sales of *Invanz* (ertapenem sodium), for the treatment of certain infections, were \$159 million in the third quarter of 2017, an increase of 5% compared with the third quarter of 2016, driven by volume growth in certain international markets. Worldwide sales of *Invanz* were \$445 million in the first nine months of 2017, an increase of 9% compared with the same period of 2016, primarily reflecting higher pricing in the United States. Foreign exchange favorably affected global sales performance by 2% and 1% in the third quarter and first nine months of 2017, respectively. The patent that provides U.S. market exclusivity for *Invanz* will expire on November 15, 2017 and the Company anticipates a significant decline in U.S. *Invanz* sales thereafter. U.S. sales of *Invanz* were \$268 million in the first nine months of 2017.

Global sales of *Cancidas*, an anti-fungal product sold primarily outside of the United States, were \$94 million in the third quarter of 2017 and \$327 million for the first nine months of 2017, declines of 34% and 19%, respectively, compared with the same periods of 2016. Foreign exchange favorably affected global sales performance by 1% in the third quarter of 2017 and unfavorably affected global sales performance by 1% in the first nine months of 2017. The sales declines were driven primarily by generic competition in certain European markets. The EU compound patent for *Cancidas* expired in April 2017. Accordingly, the Company is experiencing significant declines in *Cancidas* sales in those European markets from generic competition and expects the declines to continue.

Sales of *Cubicin*, an I.V. antibiotic for complicated skin and skin structure infections or bacteremia when caused by designated susceptible organisms, were \$91 million in the third quarter of 2017, a decline of 71% compared with the third quarter of 2016, and were \$290 million in the first nine months of 2017, a decline of 70% compared with the same period in 2016. Foreign exchange favorably affected sales performance by 1% in the third quarter of 2017. The U.S. composition patent for *Cubicin* expired in June 2016. Accordingly, the Company is experiencing a rapid and substantial decline in U.S. *Cubicin* sales from generic competition and expects the decline to continue. The Company anticipates it will lose market exclusivity for *Cubicin* in Europe later in 2017 or early in 2018.

Immunology

Sales of *Remicade*, a treatment for inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were \$214 million in the third quarter of 2017 and \$651 million in the first nine months of 2017, declines of 31% and 35%, respectively, compared with the same periods of 2016. Foreign exchange favorably affected sales performance by 3% in the third quarter of 2017 and unfavorably affected sales performance by 1% in the first nine months of 2017. 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.

Sales of *Simponi* (golimumab), a once-monthly subcutaneous treatment for certain inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were \$219 million in the third quarter of 2017, growth of 13% compared with

the third quarter of 2016, and were \$602 million in the first nine months of 2017, an increase of 4% compared with the same period of 2016. Foreign exchange favorably affected sales performance by 4% in the third quarter of 2017 and unfavorably affected sales performance by 1% in the first nine months of 2017. Sales growth in both periods is primarily attributable to volume growth in Europe.

Oncology

Global sales of *Keytruda*, an anti-PD-1 (programmed death receptor-1) therapy, were \$1.0 billion in the third quarter of 2017 compared with \$356 million in the third quarter of 2016 and were \$2.5 billion in the first nine months of 2017 compared with \$919 million in the first nine months of 2016. Sales growth in both periods was driven by volume growth in all markets, particularly in the United States, as the Company continues to launch *Keytruda* with new indications globally. During the first nine months of 2017, Merck has launched six new indications for *Keytruda* in the United States, four in Europe and three in Japan. U.S. sales of *Keytruda* grew to \$604 million and \$1.5 billion in the third quarter and first nine months of 2017, respectively, compared with \$188 million and \$481 million for the third quarter and first nine months of 2016, respectively. Sales in the United States continue to build across the multiple approved indications, in particular for the treatment of non-small-cell lung cancer (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 melanoma and head and neck cancer, combined with the launch in bladder cancer, also contributed to growth in the third quarter and first nine months of 2017. Sales growth in international markets reflects positive performance in the melanoma indications, as well as a greater contribution from the treatment of patients with NSCLC as reimbursement is established in additional markets in the first- and second-line settings.

In September 2017, the FDA approved *Keytruda* for the treatment of patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1 (Combined Positive Score ≥ 1) as determined by an FDA-approved test, with disease progression on or after two or more prior lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy and if appropriate, HER2/neu-targeted therapy.

In May 2017, the FDA approved *Keytruda* in combination with pemetrexed and carboplatin for the first-line treatment of metastatic nonsquamous NSCLC, irrespective of PD-L1 expression. The National Cancer Care Network also recommended the combination for treatment of patients with metastatic nonsquamous NSCLC. *Keytruda* is the only anti-PD-1 approved in the first-line setting as both monotherapy and combination therapy for appropriate patients with metastatic NSCLC. In October 2016, *Keytruda* was approved by the FDA as monotherapy in the first-line setting for patients with metastatic NSCLC whose tumors have high PD-L1 expression (tumor proportion score [TPS] of $\geq 50\%$) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations. *Keytruda* as monotherapy is also indicated for the second-line or greater treatment setting for patients with metastatic NSCLC whose tumors express PD-L1 (TPS $\geq 1\%$) as determined by an FDA-approved test, with disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving *Keytruda*. In December 2016, *Keytruda* was approved in Japan for the treatment of certain patients with PD-L1-positive unresectable advanced/recurrent NSCLC in the first- and second-line treatment settings. Additionally, in January 2017, the EC approved *Keytruda* for the first-line treatment of metastatic NSCLC in adults whose tumors have high PD-L1 expression (TPS of 50% or more) with no EGFR or ALK positive tumor mutations.

Also in May 2017, the FDA approved *Keytruda* for the treatment of certain patients with locally advanced or metastatic urothelial carcinoma, a type of bladder cancer. In the first-line setting, *Keytruda* is approved for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are ineligible for cisplatin-containing chemotherapy. In the second-line setting, *Keytruda* is approved for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. In September 2017, the EC approved *Keytruda* for use as monotherapy for the treatment of locally advanced or metastatic urothelial carcinoma in adults who have received prior platinum-containing chemotherapy, as well as adults who are not eligible for cisplatin-containing chemotherapy.

Additionally in May 2017, the FDA approved *Keytruda* for a first-of-its-kind indication: the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options or colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. With this unique indication, *Keytruda* is the first cancer therapy approved for use based on a biomarker, regardless of tumor type.

In March 2017, the FDA approved *Keytruda* for the treatment of adult and pediatric patients with classical Hodgkin lymphoma (cHL) refractory to treatment, or who have relapsed after three or more prior lines of therapy. In May 2017, the EC approved *Keytruda* for the treatment of adult patients with relapsed or refractory cHL who have failed autologous stem cell transplant and brentuximab vedotin, or who are transplant-ineligible and have failed brentuximab vedotin.

In August 2016, Merck announced that the FDA approved *Keytruda* for the treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) with disease progression on or after platinum-containing chemotherapy. In July 2017, Merck announced that the pivotal Phase 3 KEYNOTE-040 trial investigating *Keytruda* in previously treated patients with recurrent or metastatic HNSCC did not meet its pre-specified primary endpoint of overall survival (OS) (HR, 0.82 [95% CI, 0.67-1.01]; p = 0.03 [one-sided]). The safety profile observed in KEYNOTE-040 was consistent with that observed in previously reported studies of *Keytruda*; no new safety signals were identified. The current indication remains unchanged and clinical trials continue, including KEYNOTE-048, a Phase 3 clinical trial of *Keytruda* in the first-line treatment of recurrent or metastatic HNSCC.

Keytruda is now approved in the United States and in the EU as monotherapy for the treatment of certain patients with NSCLC, melanoma, cHL and urothelial carcinoma. *Keytruda* is also approved in the United States as monotherapy for the treatment of certain patients with HNSCC, gastric or gastroesophageal junction adenocarcinoma and MSI-H or mismatch repair deficient cancer, and in combination with pemetrexed and carboplatin in certain patients with NSCLC. *Keytruda* is also approved in Japan for use in patients with curatively unresectable melanoma and PD-L1-positive unresectable advanced/recurrent NSCLC. The *Keytruda* clinical development program includes studies across a broad range of cancer types (see “Research and Development” below). Pursuant to the settlement of worldwide patent infringement litigation related to *Keytruda* (see Note 7 to the condensed consolidated financial statements), the Company will pay royalties of 6.5% on net sales of *Keytruda* in 2017 through 2023; and 2.5% on net sales of *Keytruda* in 2024 through 2026.

Diversified Brands

Merck’s diversified brands include human health pharmaceutical products that are approaching the expiration of their marketing exclusivity or are no longer protected by patents in developed markets, but continue to be a core part of the Company’s offering in other markets around the world.

Respiratory

Worldwide sales of *Singulair*, a once-a-day oral medicine for the chronic treatment of asthma and for the relief of symptoms of allergic rhinitis, were \$161 million in the third quarter of 2017 and \$550 million for the first nine months of 2017, declines of 33% and 22%, respectively, compared with the same periods of 2016. Foreign exchange unfavorably affected global sales performance by 1% in both the third quarter and first nine months of 2017. The sales declines were largely driven by lower volumes in Japan as a result of generic competition. The patents that provided market exclusivity for *Singulair* in Japan expired in February and October of 2016. As a result, the Company is experiencing a decline in *Singulair* sales in Japan and expects the decline to continue. The Company no longer has market exclusivity for *Singulair* in any major market.

Global sales of *Nasonex*, an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, declined 55% to \$42 million in the third quarter of 2017, and decreased 37% to \$266 million in the first nine months of 2017, compared with the same periods of 2016, driven by lower sales in the United States from ongoing generic competition. Foreign exchange favorably affected global sales performance by 1% in both the third quarter and first nine months of 2017.

Global sales of *Dulera* Inhalation Aerosol, a combination medicine for the treatment of asthma, were \$59 million in the third quarter of 2017, a decline of 39% compared with the third quarter of 2016, and were \$210 million in the first nine months of 2017, a decline of 37% compared with the first nine months of 2016. The declines were driven by lower sales in the United States reflecting competitive pricing pressures. Foreign exchange favorably affected global sales performance by 1% in the third quarter of 2017.

Vaccines

On December 31, 2016, Merck and Sanofi terminated their equally-owned joint venture, SPMSD, which developed and marketed vaccines in Europe. Accordingly, vaccine sales in 2017 include sales of Merck vaccines in the European markets that were previously part of the SPMSD joint venture, whereas sales in periods prior to 2017 do not. Prior to 2017, vaccine sales in these European markets were sold through the SPMSD joint venture, the results of which are reflected in equity income from affiliates included in *Other (income) expense, net* (see Note 11 to the condensed consolidated financial statements). Supply sales to SPMSD, however, are included in vaccine sales in periods prior to 2017. Incremental vaccine sales resulting from the termination of the SPMSD joint venture in the third quarter and first nine months of 2017 were approximately \$130 million and \$265 million, respectively, of which approximately \$65 million and \$155 million, respectively, relate to *Gardasil/Gardasil 9*.

Merck’s sales of *Gardasil* (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant)/*Gardasil 9*, vaccines to help prevent certain cancers and diseases caused by certain types of human papillomavirus (HPV), were \$675 million in the third quarter of 2017, a decline of 22% compared with the third quarter of 2016, driven primarily by lower sales in the United States. 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, 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, and recognized a corresponding liability. The Company anticipates it will replenish the stockpile in the second half of 2018, which will result in the recognition of sales and a reversal of the liability. Additionally, the timing of sales in Brazil also contributed to the sales decline in *Gardasil/Gardasil 9* in the third quarter of 2017 as compared with the third quarter of 2016. These declines were partially offset by higher sales in Europe resulting from the termination of the SPMSD joint venture noted above, as well as higher demand in Asia Pacific. Merck's sales of *Gardasil/Gardasil 9* were \$1.7 billion in the first nine months of 2017, growth of 3% compared with the first nine months of 2016. Sales growth was driven primarily by higher sales in Europe resulting from the termination of the SPMSD joint venture and higher demand in Asia Pacific, partially offset by lower sales in the United States as a result of the CDC stockpile borrowing discussed above. In October 2016, the FDA approved a 2-dose vaccination regimen for *Gardasil 9*, for use in girls and boys 9 through 14 years of age, and the CDC's Advisory Committee on Immunization Practices (ACIP) voted to recommend the 2-dose vaccination regimen for certain 9 through 14 year olds. The Company is beginning to experience an impact from the transition from a 3-dose vaccine regimen to a 2-dose vaccination regimen; however, increased patient starts are helping to offset the negative effects of the transition. *Gardasil* recently received marketing authorization from the China Food and Drug Administration for use in females aged 20 to 45 to prevent cervical cancers and cervical pre-cancers (cervical intraepithelial neoplasia, or CIN1/2/3, and adenocarcinoma in situ or AIS) caused by HPV types 16 and 18.

Merck's 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 \$169 million in the third quarter of 2017 compared with \$150 million in the third quarter of 2016 driven primarily by higher pricing in the United States and volume growth in most international markets. Merck's sales of *ProQuad* were \$402 million in the first nine months of 2017 compared with \$389 million in the first nine months of 2016. The increase reflects volume growth in most international markets. Merck's sales of *M-M-R II* (Measles, Mumps and Rubella Virus Vaccine Live), a vaccine to help protect against measles, mumps and rubella, were \$124 million for the third quarter of 2017 compared with \$115 million for the third quarter of 2016 and were \$303 million in the first nine months of 2017 compared with \$269 million in the first nine months of 2016. The increases were largely attributable to higher sales in Europe resulting from the termination of the SPMSD joint venture. Merck's sales of *Varivax* (Varicella Virus Vaccine Live), a vaccine to help prevent chickenpox (varicella), were \$226 million for the third quarter of 2017 compared with \$232 million for the third quarter of 2016 and were \$568 million in the first nine months of 2017 compared with \$578 million in the first nine months of 2016. The declines are attributable to lower sales in the United States, reflecting lower volumes partially offset by higher pricing, and lower sales in Latin America due to the timing of shipments. These declines were partially offset by higher sales in Europe resulting from the termination of the SPMSD joint venture.

Merck's sales of *Pneumovax 23* (pneumococcal vaccine polyvalent), a vaccine to help prevent pneumococcal disease, were \$229 million in the third quarter of 2017, an increase of 31% compared with the third quarter of 2016. Merck's sales of *Pneumovax 23* were \$558 million in the first nine months of 2017, an increase of 38% compared with the first nine months of 2016 including a 1% unfavorable effect from foreign exchange. Sales growth in both periods was driven primarily by volume growth and higher pricing in the United States, as well as in Europe resulting from the termination of the SPMSD joint venture.

Merck's sales of *Zostavax* (Zoster Vaccine Live), a vaccine to help prevent shingles (herpes zoster) in adults 50 years of age and older, were \$234 million in the third quarter of 2017, an increase of 23% compared with the third quarter of 2016, and were \$547 million in the first nine months of 2017, an increase of 18% compared with the first nine months of 2016 including a 1% favorable effect from foreign exchange. Sales growth in both periods was driven largely by volume growth in Europe resulting from the termination of the SPMSD joint venture. Volume growth in the Asia Pacific region also contributed to sales growth, particularly in the year-to-date period. Sales in United States were down slightly in both periods as lower demand was largely offset by higher pricing. In October 2017, the ACIP voted to recommend a competitor's vaccine as the preferred vaccine for the prevention of shingles over *Zostavax*. The Company anticipates the ACIP recommendation, if approved by the CDC, will have a material unfavorable effect on U.S. sales of *Zostavax* in future periods.

Merck's sales of *RotaTeq* (Rotavirus Vaccine, Live Oral, Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and children, were \$179 million in the third quarter of 2017, growth of 4% compared with the third quarter of 2016 driven primarily by higher sales in Europe resulting from the termination of the SPMSD joint venture. Merck's sales of *RotaTeq* were \$525 million in the first nine months of 2017, an increase of 7% compared with the first nine months of 2016. The increase was driven primarily by higher sales in Europe, as well as higher pricing and volumes in the United States.

Other Segments

The Company's other segments are the Animal Health, Healthcare Services and Alliances segments, which are not material for separate reporting.

Animal Health

Animal Health includes pharmaceutical and vaccine products for the prevention, treatment and control of disease in all major farm and companion animal species. 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 2017, an increase of 16% compared with sales of \$865 million in the third quarter of 2016. Worldwide sales of Animal Health products were \$2.9 billion in the first nine months of 2017, an increase of 12%, compared with sales of \$2.6 billion for the first nine months of 2016. Foreign exchange favorably affected global sales performance by 2% and 1% in the third quarter and first nine months of 2017, respectively. Sales growth in both periods primarily reflects higher sales of companion animal products, driven largely by the *Bravecto* line of products that kill fleas and ticks in dogs and cats for up to 12 weeks, and by companion animal vaccines. Sales growth in both periods also reflects higher sales of ruminant products, including the impact of the Vallée S.A. acquisition in March (see Note 2 to the condensed consolidated financial statements), swine and poultry products.

Costs, Expenses and Other

Materials and Production

Materials and production costs were \$3.3 billion for the third quarter of 2017, a decline of 4% compared with the third quarter of 2016, and were \$9.4 billion in the first nine months of 2017, a decline of 11% compared with the first nine months of 2016. Costs in the third quarter of 2017 and 2016 include \$765 million and \$772 million, respectively, and for the first nine months of 2017 and 2016 include \$2.3 billion and \$2.9 billion, respectively, of expenses for the amortization of intangible assets recorded in connection with business acquisitions. Additionally, costs for the first nine months of 2017 and 2016 include \$47 million and \$347 million, respectively, of intangible asset impairment charges related to marketed products (see Note 6 to the condensed consolidated financial statements). The Company may recognize additional non-cash impairment charges in the future related to intangible assets that were measured at fair value and capitalized in connection with business acquisitions and such charges could be material. Costs in the first nine months of 2017 also include a \$76 million intangible asset impairment charge related to a licensing agreement. Included in materials and production costs are expenses associated with restructuring activities which amounted to \$25 million and \$36 million in the third quarter of 2017 and 2016, respectively, and \$121 million and \$149 million for the first nine months of 2017 and 2016, 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 68.3% in the third quarter of 2017 compared with 67.6% in the third quarter of 2016. Gross margin in both periods reflects a 7.7 percentage point net unfavorable impact from the amortization of intangible assets, intangible asset impairment charges and restructuring costs as noted above. The improvement in gross margin reflects the favorable effects of product mix, partially offset by manufacturing-related costs resulting from the cyber-attack. Gross margin was 68.4% in the first nine months of 2017 compared with 64.4% in the first nine months of 2016. The improvement in gross margin in the year-to-date period was driven primarily by a lower net impact from the amortization of intangible assets, intangible asset impairment charges and restructuring costs as noted above, which reduced gross margin by 8.7 percentage points in the first nine months of 2017 compared with 11.6 percentage points in the first nine months of 2016. The gross margin improvement in the first nine months of 2017 is also attributable to the favorable effects of product mix. Costs related to the cyber-attack partially offset the gross margin improvement in the year-to-date period.

Marketing and Administrative

Marketing and administrative (M&A) expenses were \$2.4 billion in the third quarter of 2017, essentially flat as compared with the third quarter of 2016. Higher administrative costs, including costs associated with the Company operating its vaccines business in the European markets that were previously part of the SPMSD joint venture and remediation costs related to the cyber-attack, as well as the unfavorable effects of foreign exchange and higher promotional expenses related to product launches were offset by lower acquisition and divestiture-related costs and lower selling costs. M&A expenses increased 1% to \$7.3 billion in the first nine months of 2017 compared with the same period of 2016. The increase was driven primarily by higher administrative costs and promotional expenses, partially offset by lower restructuring and acquisition and divestiture-related costs and lower selling expenses. M&A expenses for the first nine months of 2017 and 2016 include \$3 million and \$91 million, respectively, of restructuring costs, related primarily to accelerated depreciation for facilities to be closed or divested. Separation costs associated with sales force reductions have been incurred and are reflected in *Restructuring costs* as discussed below. M&A expenses also include acquisition and divestiture-related costs of \$11 million and \$36 million in the third quarter of 2017 and 2016, respectively, and \$40 million and \$56 million in the first nine months of 2017 and 2016, respectively, consisting of integration, transaction, and certain other costs related to business acquisitions and divestitures.

Research and Development

Research and development (R&D) expenses were \$4.4 billion for the third quarter of 2017 compared with \$1.7 billion for the third quarter of 2016. The increase was driven primarily by a charge related to the formation of an oncology collaboration with AstraZeneca, higher in-process research and development (IPR&D) impairment charges, and increased investment in early drug development. R&D expenses were \$7.9 billion for the first nine months of 2017 compared with \$5.5 billion in the same period of 2016. The increase was driven primarily by the charge related to the AstraZeneca collaboration noted above, higher licensing costs and IPR&D impairment charges, partially offset by lower restructuring costs.

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 \$1.1 billion in both the third quarter of 2017 and 2016, and were \$3.4 billion and \$3.2 billion for the first nine months of 2017 and 2016, 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 \$645 million and \$525 million for the third quarter of 2017 and 2016, respectively, and were approximately \$1.9 billion for both the first nine months of 2017 and 2016. Additionally, 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 2 to the condensed consolidated financial statements). R&D expenses also include IPR&D impairment charges of \$245 million for the third quarter of 2017, and \$253 million and \$225 million for the first nine months of 2017 and 2016, respectively (see Note 6 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. R&D expenses also reflect accelerated depreciation and asset abandonment costs associated with restructuring activities of \$2 million and \$14 million in the third quarter of 2017 and 2016, respectively, and \$11 million and \$133 million for the first nine months of 2017 and 2016, respectively (see Note 3 to the condensed consolidated financial statements).

Restructuring Costs

The Company incurs substantial costs for restructuring program activities related to Merck's productivity and cost reduction initiatives, as well as in connection with the integration of certain acquired businesses. 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 \$153 million and \$161 million for the third quarter of 2017 and 2016, respectively, and were \$470 million and \$386 million for the first nine months of 2017 and 2016, respectively. Separation costs were incurred 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 205 positions and 300 positions in the third quarter of 2017 and 2016, respectively, and 1,225 and 1,355 positions for the first nine months of 2017 and 2016, 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* as discussed above. The Company recorded aggregate pretax costs of \$180 million and \$212 million in the third quarter of 2017 and 2016, respectively, and \$605 million and \$759 million for the first nine months of 2017 and 2016, respectively, related to restructuring program activities (see Note 3 to the condensed consolidated financial statements). The Company expects to substantially complete the remaining actions under the programs by the end of 2017 and incur approximately \$250 million of additional pretax costs.

Other (Income) Expense, Net

Other (income) expense, net was \$86 million of income in the third quarter of 2017 compared with \$22 million of expense in the third quarter of 2016 and was \$30 million of expense in the first nine months of 2017 compared with \$88 million of expense in the first nine months of 2016. For details on the components of *Other (income) expense, net*, see Note 11 to the condensed consolidated financial statements.

Segment Profits

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Pharmaceutical segment profits	\$ 5,929	\$ 6,162	\$ 16,722	\$ 16,698
Other non-reportable segment profits	482	389	1,442	1,129
Other	(6,211)	(3,664)	(13,522)	(11,812)
Income before income taxes	\$ 200	\$ 2,887	\$ 4,642	\$ 6,015

Segment profits are comprised of segment sales less standard costs, certain operating expenses directly incurred by the segment, components of equity income or loss from affiliates and certain depreciation and amortization expenses. For internal

management reporting presented to the chief operating decision maker, Merck does not allocate materials and production costs, other than standard costs, the majority of research and development expenses 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 of liabilities related to 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, including a charge related to the formation of a collaboration with AstraZeneca, are reflected in “Other” in the above table. Also included in “Other” are miscellaneous corporate profits (losses), as well as operating profits (losses) related to third-party manufacturing sales.

Pharmaceutical segment profits declined 4% in the third quarter of 2017 driven primarily by lower sales partially offset by the favorable effects of product mix. Pharmaceutical segment profits were essentially flat in the first nine months of 2017 compared with the same period of 2016 primarily reflecting lower sales offset by the favorable effects of product mix.

Taxes on Income

The effective income tax rates of 125.5% and 24.2% for the third quarter of 2017 and 2016, respectively, and 25.5% and 24.7% for the first nine months of 2017 and 2016, 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 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 includes a benefit of \$88 million related to the settlement of a state income tax issue. The effective income tax rate for the first nine months of 2016 also reflects the beneficial impact of orphan drug federal income tax credits, primarily for *Keytruda*.

In the third quarter of 2017, the Internal Revenue Service 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 provision 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 (Loss) Income and (Loss) Earnings per Common Share

Net (loss) income attributable to Merck & Co., Inc. was \$(56) million for the third quarter of 2017 compared with \$2.2 billion for the third quarter of 2016 and was \$3.4 billion for the first nine months of 2017 compared with \$4.5 billion for the first nine months of 2016. (Loss) earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders (EPS) for the third quarter of 2017 were \$(0.02) compared with \$0.78 in the third quarter of 2016 and were \$1.25 in the first nine months of 2017 compared with \$1.62 for the first nine months of 2016.

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:

(\$ in millions except per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Pretax income as reported under GAAP	\$ 200	\$ 2,887	\$ 4,642	\$ 6,015
Increase (decrease) for excluded items:				
Acquisition and divestiture-related costs	1,032	834	2,797	3,602
Restructuring costs	180	212	605	759
Aggregate charge related to the formation of an oncology collaboration with AstraZeneca	2,350	—	2,350	—
Other	—	(6)	(9)	(6)
	3,762	3,927	10,385	10,370
Taxes on income as reported under GAAP	251	699	1,186	1,487
Estimated tax benefit on excluded items ⁽¹⁾	218	235	593	801
Net benefit related to the settlement of certain federal income tax issues	234	—	234	—
Benefit related to settlement of state income tax issue	—	—	88	—
	703	934	2,101	2,288
Non-GAAP net income	3,059	2,993	8,284	8,082
Less: Net income attributable to noncontrolling interests	5	4	16	13
Non-GAAP net income attributable to Merck & Co., Inc.	\$ 3,054	\$ 2,989	\$ 8,268	\$ 8,069
EPS assuming dilution as reported under GAAP	\$ (0.02)	\$ 0.78	\$ 1.25	\$ 1.62
EPS difference ⁽²⁾	1.13	0.29	1.75	1.27
Non-GAAP EPS assuming dilution	\$ 1.11	\$ 1.07	\$ 3.00	\$ 2.89

⁽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 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 3 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 2017 is an aggregate charge related to the formation of an oncology collaboration with AstraZeneca (see Note 2 to the condensed consolidated financial statements), a net benefit related to the settlement of certain federal income tax issues and a benefit related to the settlement of a state income tax issue (see Note 12 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. *Keytruda* is currently approved as monotherapy for the treatment of certain patients with NSCLC, melanoma, cHL, HNSCC, urothelial carcinoma, gastric or gastroesophageal junction adenocarcinoma, and MSI-H or mismatch repair deficient cancer, and in combination with pemetrexed and carboplatin in certain patients with NSCLC (see “Pharmaceutical Segment” above).

Keytruda has received Breakthrough Therapy designation from the FDA for the treatment of patients with primary mediastinal B-cell lymphoma that is refractory to or has relapsed after two prior lines of therapy. *Keytruda* has also recently received Breakthrough Therapy designation in combination with axitinib as a first-line treatment for patients with advanced or metastatic renal cell carcinoma; for the treatment of high-risk early-stage triple-negative breast cancer in combination with neoadjuvant chemotherapy; and for the treatment of Merkel cell carcinoma. 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.

Merck is amending the KEYNOTE-189 study to include overall survival as a co-primary endpoint. The updated completion date is February 2019 and there will be opportunities for the Company to conduct interim analyses. KEYNOTE-189 is a Phase 3 study of platinum-pemetrexed chemotherapy with or without *Keytruda* in patients with first-line metastatic nonsquamous NSCLC.

In July 2017, Merck announced that the FDA has placed a full clinical hold on KEYNOTE-183 and KEYNOTE-185 and a partial clinical hold on Cohort 1 of KEYNOTE-023, three combination studies of *Keytruda* with lenalidomide or pomalidomide versus lenalidomide or pomalidomide alone in the blood cancer multiple myeloma. This decision follows a review of data by the Data Monitoring Committee in which more deaths were observed in the *Keytruda* arms of KEYNOTE-183 and KEYNOTE-185 and which led to the pause in new patient enrollment, as announced on June 12, 2017. The FDA has determined that the data available at the present time indicate that the risks of *Keytruda* plus pomalidomide or lenalidomide outweigh any potential benefit for patients with multiple myeloma. All patients enrolled in KEYNOTE-183 and KEYNOTE-185 and those in the *Keytruda*/lenalidomide/dexamethasone cohort in KEYNOTE-023 have discontinued investigational treatment with *Keytruda*. This clinical hold does not apply to other studies with *Keytruda*.

In October 2017, Merck announced it has withdrawn its European application for *Keytruda* in combination with pemetrexed and carboplatin as a first-line treatment for metastatic nonsquamous NSCLC. The application was based on findings from KEYNOTE-021, Cohort G.

The *Keytruda* clinical development program consists of more than 600 clinical trials, including more than 400 trials that combine *Keytruda* with other cancer treatments. These studies encompass more than 30 cancer types including: bladder, colorectal, esophageal, gastric, head and neck, hepatocellular, Hodgkin lymphoma, non-Hodgkin lymphoma, melanoma, nasopharyngeal, NSCLC, ovarian, 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 June 2017, Merck in partnership with Pfizer Inc. (Pfizer) announced that two Phase 3 studies (VERTIS MET and VERTIS SITA) of ertugliflozin, an investigational oral SGLT-2 inhibitor in development to help improve glycemic control in adults with type 2 diabetes, met their primary endpoints. In the studies, both doses of ertugliflozin tested (5 mg and 15 mg daily) achieved statistically significant reductions in A1C, a measure of average blood glucose over a two- to three-month timeframe, when added to metformin or in initial co-administration with sitagliptin. The results of these studies, along with 52-week extension data from three other studies in the VERTIS clinical development program of ertugliflozin, were presented at the 77th Scientific Sessions of the American Diabetes Association. Marketing applications for ertugliflozin and for two fixed-dose combination products (ertugliflozin and *Januvia*, ertugliflozin and metformin) are under review with the FDA and the EMA. The Prescription Drug User Fee Act (PDUFA) action date from the FDA is in December 2017 for the three New Drug Applications. Under the terms of the collaboration agreement with Pfizer, Merck made a \$90 million milestone payment to Pfizer in the first nine months of 2017 recorded in *Research and development* expenses.

In 2017, Merck filed regulatory applications for the approval of MK-8228, letermovir, in the United States and EU. Letermovir is an investigational, once-daily, antiviral candidate administered orally or by intravenous infusion for the prophylaxis of clinically-significant cytomegalovirus (CMV) infection and disease. Letermovir has received Orphan Drug Status and Breakthrough Therapy designation in the United States and in the EU it has received accelerated assessment. In October 2016, Merck announced that the pivotal Phase 3 clinical study of letermovir met its primary endpoint. The global, multicenter, randomized, placebo-controlled study evaluated the efficacy and safety of letermovir in adult (18 years and older) CMV-seropositive recipients of an allogeneic hematopoietic stem cell transplant. On November 2, 2017, letermovir received its first approval in Canada. Letermovir will be marketed under the global trademark *Prevymis*.

In July 2017, Merck and AstraZeneca entered a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza (olaparib) for multiple cancer types. Lynparza is an oral, poly (ADP-ribose) polymerase (PARP) inhibitor currently approved for certain types of ovarian cancer. The companies will develop and commercialize Lynparza, both as monotherapy and in combination trials with other potential medicines. Independently, Merck and AstraZeneca will develop and commercialize Lynparza in combinations with their respective PD-1 and PD-L1 medicines, *Keytruda* (pembrolizumab) and *Imfinzi* (durvalumab). 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 including thyroid cancer (see Note 2 to the condensed consolidated financial statements). In October 2017, Merck and AstraZeneca announced that the FDA accepted and granted priority review for a supplemental New Drug Application for the use of Lynparza tablets in patients with germline BRCA-mutated, HER2-negative metastatic breast cancer who have been previously treated with chemotherapy either in the neoadjuvant, adjuvant or metastatic settings. The PDUFA action date is in the first quarter of 2018. A New Drug Application was also submitted to Japan's Pharmaceuticals and Medical Devices Agency.

Also in July 2017, Merck announced the presentation of results from the DRIVE-AHEAD study, the second of two pivotal Phase 3 clinical trials evaluating the efficacy and safety of doravirine, the Company's investigational, non-nucleoside reverse transcriptase inhibitor, for the treatment of HIV-1 infection. At 48 weeks, the study showed that a once-daily single tablet, fixed-dose combination of doravirine (DOR), lamivudine (3TC), and tenofovir disoproxil fumarate (TDF) met its primary efficacy endpoint of non-inferiority based on the proportion of participants achieving levels of HIV-1 RNA less than 50 copies/mL at 48 weeks of treatment, compared to a fixed-dose combination of efavirenz (EFV), emtricitabine (FTC), and TDF, in treatment-naïve adults infected with HIV-1. The study also met its primary safety endpoint, showing that treatment with DOR/3TC/TDF resulted in fewer patients reporting several pre-specified neuropsychiatric adverse events compared to EFV/FTC/TDF by week 48. Based on these findings, the Company plans to file regulatory applications for DOR both as a single-entity tablet and as a fixed-dose combination tablet (DOR/3TC/TDF) in the fourth quarter of 2017.

In October 2017, Merck announced that it will not submit applications for regulatory approval for anacetrapib, the Company's investigational cholesteryl ester transfer protein (CETP) inhibitor. The decision follows a thorough review of the clinical profile of anacetrapib, including discussions with external experts.

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 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 currently marketed by the Company for the treatment of chronic HCV infection. As a result of this decision, the Company recorded an IPR&D impairment charge (see Note 6 to the condensed consolidated financial statements).

The chart below reflects the Company's research pipeline as of November 1, 2017. 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
Asthma MK-1029 Cancer MK-3475 <i>Keytruda</i> Advanced Solid Tumors Ovarian PMBCL (Primary Mediastinal Large B-Cell Lymphoma) Prostate Cough, including cough with Idiopathic Pulmonary Fibrosis MK-7264 Diabetes Mellitus MK-8521 Pneumoconjugate Vaccine V114 Schizophrenia MK-8189	Alzheimer's Disease MK-8931 (verubecestat) (December 2013) Bacterial Infection MK-7655A (relebactam+imipenem/cilastatin) (October 2015) Cancer MK-3475 <i>Keytruda</i> Breast (October 2015) Colorectal (November 2015) Esophageal (December 2015) Gastric (May 2015) (EU) Head and Neck (November 2014) (EU) Hepatocellular (May 2016) Nasopharyngeal (April 2016) Renal (October 2016) Small-Cell Lung (May 2017) MK-7339 Lynparza ⁽¹⁾ Pancreatic (December 2014) Prostate (April 2017) MK-5618 (selumetinib) ⁽¹⁾ Thyroid (June 2013) Ebola Vaccine V920 (March 2015) Heart Failure MK-1242 (vericiguat) (September 2016) ⁽¹⁾ Herpes Zoster V212 (inactivated VZV vaccine) (December 2010) HIV MK-1439 (doravirine) (December 2014) MK-1439A (doravirine/lamivudine/tenofovir disoproxil fumarate) (June 2015)	New Molecular Entities/Vaccines CMV Prophylaxis in Transplant Patients MK-8228 (letermovir) (U.S./EU) Diabetes Mellitus MK-0431J (sitagliptin+ipragliflozin) (Japan) ⁽¹⁾ MK-8835 (ertugliflozin) (U.S./EU) ⁽¹⁾ MK-8835A (ertugliflozin+sitagliptin) (U.S./EU) ⁽¹⁾ MK-8835B (ertugliflozin+metformin) (U.S./EU) ⁽¹⁾ Pediatric Hexavalent Combination Vaccine V419 (U.S.) ⁽²⁾ Certain Supplemental Filings Cancer MK-7339 Lynparza ⁽¹⁾ <ul style="list-style-type: none"> Second-Line Metastatic Breast Cancer (U.S.) Footnotes: ⁽¹⁾ Being developed in a collaboration. ⁽²⁾ V419 is an investigational pediatric hexavalent 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. Both companies are reviewing the CRL and plan to have further communication with the FDA.

Selected Joint Venture and Affiliate Information

Sanofi Pasteur MSD

On December 31, 2016, Merck and Sanofi terminated their equally-owned joint venture, SPMSD, which developed and marketed vaccines in Europe. Total vaccine sales reported by SPMSD were \$351 million and \$725 million in the third quarter and first nine months of 2016, respectively, which included \$61 million and \$161 million, respectively, of sales of *Gardasil/Gardasil 9*. The Company recorded the results from its interest in SPMSD in *Other (income) expense, net* (see Note 11 to the condensed consolidated financial statements).

Liquidity and Capital Resources

(\$ in millions)	September 30, 2017	December 31, 2016
Cash and investments	\$ 23,401	\$ 25,757
Working capital	8,452	13,410
Total debt to total liabilities and equity	29.4%	26.0%

Cash provided by operating activities was \$2.4 billion in the first nine months of 2017 compared with \$6.7 billion in the first nine months of 2016. The decline reflects a \$2.8 billion payment related to the settlement of certain federal income tax issues (see Note 12 to the condensed consolidated financial statements), a \$1.6 billion upfront payment related to the formation of a collaboration with AstraZeneca (see Note 2 to the condensed consolidated financial statements), and a \$625 million payment made by the Company related to the settlement of worldwide *Keytruda* patent litigation (see Note 7 to the condensed consolidated financial statements). Cash provided by operating activities in the first nine months of 2016 includes a net payment of approximately \$680 million to fund the *Vioxx* shareholder class action litigation settlement not covered by insurance proceeds. Cash provided by operating activities continues to be the Company's primary source of funds to finance operating needs, capital expenditures, a portion of treasury stock purchases and dividends paid to shareholders.

Cash provided by investing activities was \$2.7 billion in the first nine months of 2017 compared with a use of cash of \$647 million in the first nine months of 2016. The change was driven primarily by lower purchases of securities and other investments, higher proceeds from the sales of securities and other investments and a lower use of cash for the acquisitions of businesses.

Cash used in financing activities was \$4.2 billion in the first nine months of 2017 compared with \$7.1 billion in the first nine months of 2016. The decrease in cash used in financing activities was driven primarily by lower payments on debt and an increase in short-term borrowings, partially offset by lower proceeds from the exercise of stock options.

At September 30, 2017, the total of worldwide cash and investments was \$23.4 billion, including \$11.2 billion of cash, cash equivalents and short-term investments and \$12.2 billion of long-term investments. Generally 80%-90% of cash and investments are held by foreign subsidiaries that would be subject to significant tax payments if such cash and investments were repatriated in the form of dividends. The Company records U.S. deferred tax liabilities for certain unremitted earnings, but when amounts earned overseas are expected to be indefinitely reinvested outside of the United States, no accrual for U.S. taxes is provided. The amount of cash and investments held by U.S. and foreign subsidiaries fluctuates due to a variety of factors including the timing and receipt of payments in the normal course of business. Cash provided by operating activities in the United States continues to be the Company's primary source of funds to finance domestic operating needs, capital expenditures, a portion of treasury stock purchases and dividends paid to shareholders. The decline in working capital from December 31, 2016 to September 30, 2017 primarily reflects the reclassification of \$3.0 billion of notes due in the first half of 2018 from long-term debt to short-term debt and the \$1.6 billion upfront payment related to the formation of the AstraZeneca collaboration discussed above.

Capital expenditures totaled \$1.2 billion and \$1.1 billion for the first nine months of 2017 and 2016, respectively.

Dividends paid to stockholders were \$3.9 billion for both the first nine months of 2017 and 2016. In May 2017, the Board of Directors declared a quarterly dividend on the Company's common stock for the third quarter of \$0.47 per share that was paid in July 2017. In July 2017, the Board of Directors declared a quarterly dividend on the Company's common stock for the fourth quarter of \$0.47 per share that was paid in October 2017.

In March 2015, 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 is being 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 2017, the Company purchased \$2.3 billion (36 million shares) for its treasury. As of September 30, 2017, the Company's remaining share repurchase authorization was \$2.7 billion.

In February 2017, \$300 million of floating rate notes matured in accordance with their terms and were repaid. In January 2016, \$850 million of 2.2% notes matured in accordance with their terms and were repaid. In May 2016, \$1.0 billion of 0.70% notes and \$500 million of floating rate notes matured in accordance with their terms and were repaid.

On November 6, 2017, Merck announced the commencement of offers to purchase certain of its outstanding long-term notes (Notes). The offers are being made upon, and are subject to, the terms and conditions set forth in the Offer to Purchase, dated November 6, 2017, which conditions include that Merck will not pay more than \$850 million, plus accrued interest, in the aggregate for the Notes.

The Company has a \$6.0 billion, five-year credit facility that matures in June 2022. The facility provides backup liquidity for the Company's commercial paper borrowing facility and is to be used for general corporate purposes. The Company has not drawn funding from this facility.

Critical Accounting Policies

The Company's significant accounting policies, which include management's best estimates and judgments, are included in Note 2 to the consolidated financial statements for the year ended December 31, 2016 included in Merck's Form 10-K filed on February 28, 2017. 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, 2016.

Recently Issued Accounting Standards

In May 2014, the Financial Accounting Standards Board (FASB) issued amended accounting guidance on revenue recognition that will be applied 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 Company will adopt the new standard on January 1, 2018 and currently plans to use the modified retrospective method. The majority of the Company's business is ship and bill and, on that primary revenue stream, Merck does not expect significant differences. Additionally, the Company has not identified significant changes related to the recognition of revenue for its multiple element arrangements or discount and trade promotion programs when applying the new guidance. However, the Company's analysis is preliminary and subject to change. The Company anticipates the adoption of the new guidance will result in some additional disclosures.

In January 2016, the FASB issued revised guidance for the accounting and reporting of financial instruments. 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 new guidance also simplifies the impairment testing of equity investments without readily determinable fair values and changes certain disclosure requirements. This guidance is effective for interim and annual periods beginning in 2018. The Company is currently assessing the impact of adoption on its consolidated financial statements. The impact of adoption will be recorded as a cumulative-effect adjustment to retained earnings.

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 guidance is effective for interim and annual periods beginning in 2018. Early adoption is permitted. The guidance is to be applied retrospectively to all periods presented but may be applied prospectively if retrospective application would be impracticable. The Company does not anticipate the adoption of the new guidance will have a material effect on its Consolidated Statement of Cash Flows.

In October 2016, the FASB issued guidance on the accounting for the income tax consequences of intra-entity transfers of assets other than inventory. Under existing guidance, the recognition of current and deferred income taxes for an intra-entity asset transfer is prohibited until the asset has been sold to a third party. The new guidance will require 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. The guidance is effective for interim and annual periods beginning in 2018. 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 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 guidance is effective for interim and annual periods beginning in 2018 and should be applied using a retrospective transition method to each period presented. Early adoption is permitted. The Company does not anticipate the adoption of the new guidance will have a material effect on its Consolidated Statement of Cash Flows.

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 new guidance is effective for interim and annual periods in 2018. Entities must use a retrospective transition method to adopt the requirement for separate presentation in the income statement of service costs and other components and a prospective transition method to adopt the requirement to limit the capitalization of benefit costs to the service cost component. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

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 new guidance is effective prospectively for interim and annual periods beginning in 2018. Early adoption is permitted. The Company does not anticipate the adoption of the new guidance will have a material effect on its consolidated financial statements.

In February 2016, the FASB issued new accounting guidance for the accounting and reporting of leases. 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 new guidance will be effective for interim and annual periods beginning in 2019. Early adoption is permitted. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

In August 2017, the FASB issued new guidance on hedge accounting 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 new guidance is effective for interim and annual periods beginning in 2019. Early application is permitted in any interim period. The Company does not anticipate the adoption of the new guidance will have a material effect on its consolidated financial statements and may elect to early adopt this guidance.

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 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 the adoption of the new guidance will have a material effect on its 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, 2017, 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. 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, 2016, as filed on February 28, 2017, the Company discusses in more detail various important risk factors that could cause actual results to differ from expected or historic results. The Company notes these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. One should understand that it is not possible to predict or identify all such factors. Consequently, the reader should not consider any such list to be a complete statement of all potential risks or uncertainties.

PART II - Other Information

Item 1. Legal Proceedings

The information called for by this Item is incorporated herein by reference to Note 7 included in Part I, Item 1, Financial Statements (unaudited) — Notes to Condensed Consolidated Financial Statements.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Issuer purchases of equity securities for the three months ended September 30, 2017 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	—	\$0.00	\$2,902
August 1 - August 31	720,907	\$62.46	\$2,857
September 1 - September 30	1,758,726	\$64.68	\$2,743
Total	2,479,633	\$64.04	\$2,743

⁽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.

Item 6. Exhibits

<u>Number</u>	<u>Description</u>
3.1	— <u>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)</u>
3.2	— <u>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)</u>
31.1	— <u>Rule 13a – 14(a)/15d – 14(a) Certification of Chief Executive Officer</u>
31.2	— <u>Rule 13a – 14(a)/15d – 14(a) Certification of Chief Financial Officer</u>
32.1	— <u>Section 1350 Certification of Chief Executive Officer</u>
32.2	— <u>Section 1350 Certification of Chief Financial Officer</u>
101	— The following materials from Merck & Co., Inc.’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, 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 7, 2017

/s/ Michael J. Holston

MICHAEL J. HOLSTON

Executive Vice President and General Counsel

Date: November 7, 2017

/s/ Rita A. Karachun

RITA A. KARACHUN

Senior Vice President Finance - Global Controller

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