

Merck & Co., Inc.  
Form 10-Q  
August 08, 2017

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 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 July 31, 2017: 2,727,354,340  
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.

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

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## Part I - Financial Information

## Item 1. Financial Statements

## MERCK &amp; CO., INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENT OF INCOME

(Unaudited, \$ in millions except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Sales	\$9,930	\$9,844	\$19,365	\$19,156
Costs, Expenses and Other				
Materials and production	3,080	3,578	6,095	7,150
Marketing and administrative	2,438	2,458	4,849	4,776
Research and development	1,749	2,151	3,545	3,810
Restructuring costs	166	134	317	225
Other (income) expense, net	58	19	117	67
	7,491	8,340	14,923	16,028
Income Before Taxes	2,439	1,504	4,442	3,128
Taxes on Income	488	295	935	789
Net Income	1,951	1,209	3,507	2,339
Less: Net Income Attributable to Noncontrolling Interests	5	4	11	9
Net Income Attributable to Merck & Co., Inc.	\$1,946	\$1,205	\$3,496	\$2,330
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	\$0.71	\$0.44	\$1.28	\$0.84
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	\$0.71	\$0.43	\$1.27	\$0.83
Dividends Declared per Common Share	\$0.47	\$0.46	\$0.94	\$0.92

## MERCK &amp; CO., INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

(Unaudited, \$ in millions)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Net Income Attributable to Merck & Co., Inc.	\$1,946	\$1,205	\$3,496	\$2,330
Other Comprehensive Income (Loss) Net of Taxes:				
Net unrealized loss on derivatives, net of reclassifications	(143 )	(91 )	(375 )	(293 )
Net unrealized gain on investments, net of reclassifications	35	63	78	126
Benefit plan net gain (loss) and prior service credit (cost), net of amortization	47	(108 )	73	(136 )
Cumulative translation adjustment	47	244	356	365
	(14 )	108	132	62
Comprehensive Income Attributable to Merck & Co., Inc.	\$1,932	\$1,313	\$3,628	\$2,392

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



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

	June 30, 2017	December 31, 2016
Assets		
Current Assets		
Cash and cash equivalents	\$7,786	\$6,515
Short-term investments	4,181	7,826
Accounts receivable (net of allowance for doubtful accounts of \$200 in 2017 and \$195 in 2016)	7,439	7,018
Inventories (excludes inventories of \$1,076 in 2017 and \$1,117 in 2016 classified in Other assets - see Note 5)	5,407	4,866
Other current assets	3,354	4,389
Total current assets	28,167	30,614
Investments	12,138	11,416
Property, Plant and Equipment, at cost, net of accumulated depreciation of \$16,375 in 2017 and \$15,749 in 2016	12,094	12,026
Goodwill	18,358	18,162
Other Intangibles, Net	16,119	17,305
Other Assets	5,928	5,854
	\$92,804	\$95,377
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	\$3,181	\$568
Trade accounts payable	2,934	2,807
Accrued and other current liabilities	9,363	10,274
Income taxes payable	1,979	2,239
Dividends payable	1,301	1,316
Total current liabilities	18,758	17,204
Long-Term Debt	21,706	24,274
Deferred Income Taxes	4,560	5,077
Other Noncurrent Liabilities	8,068	8,514
Merck & Co., Inc. Stockholders' Equity		
Common stock, \$0.50 par value		
Authorized - 6,500,000,000 shares	1,788	1,788
Issued - 3,577,103,522 shares in 2017 and 2016		
Other paid-in capital	39,776	39,939
Retained earnings	45,046	44,133
Accumulated other comprehensive loss	(5,094)	(5,226)
	81,516	80,634
Less treasury stock, at cost:		
849,974,743 shares in 2017 and 828,372,200 shares in 2016	42,053	40,546
Total Merck & Co., Inc. stockholders' equity	39,463	40,088
Noncontrolling Interests	249	220
Total equity	39,712	40,308
	\$92,804	\$95,377

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

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

	Six Months Ended June 30,	
	2017	2016
Cash Flows from Operating Activities		
Net income	\$3,507	\$2,339
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	2,355	3,111
Intangible asset impairment charges	131	567
Deferred income taxes	(272 )	(120 )
Share-based compensation	156	148
Other	63	166
Net changes in assets and liabilities	(2,337 )	(2,438 )
Net Cash Provided by Operating Activities	3,603	3,773
Cash Flows from Investing Activities		
Capital expenditures	(732 )	(654 )
Purchases of securities and other investments	(6,280 )	(6,355 )
Proceeds from sales of securities and other investments	9,363	7,388
Acquisitions of businesses, net of cash acquired	(347 )	(157 )
Other	62	21
Net Cash Provided by Investing Activities	2,066	243
Cash Flows from Financing Activities		
Net change in short-term borrowings	(24 )	(9 )
Payments on debt	(301 )	(2,351 )
Purchases of treasury stock	(2,153 )	(1,573 )
Dividends paid to stockholders	(2,601 )	(2,579 )
Proceeds from exercise of stock options	408	381
Other	(86 )	(101 )
Net Cash Used in Financing Activities	(4,757 )	(6,232 )
Effect of Exchange Rate Changes on Cash and Cash Equivalents	359	300
Net Increase (Decrease) in Cash and Cash Equivalents	1,271	(1,916 )
Cash and Cash Equivalents at Beginning of Year	6,515	8,524
Cash and Cash Equivalents at End of Period	\$7,786	\$6,608

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

## Notes to Condensed Consolidated Financial Statements (unaudited)

## 1. Basis of Presentation

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

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. Early adoption is not permitted. The Company is currently assessing the impact of adoption on its consolidated financial statements.

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 is currently evaluating the effect of the standard 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 does not anticipate the adoption of the new guidance will have a material effect 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 is currently evaluating the effect of the standard 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

## Notes to Condensed Consolidated Financial Statements (unaudited)

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 is currently evaluating the impact of adoption 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 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 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 BRCA-mutated ovarian cancer in multiple lines of treatment. 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. 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 will make 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. The Company will record an aggregate charge of \$2.35 billion in Research and development expenses in the third quarter of 2017 related to these 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

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

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 \$297 million related to currently marketed products, net deferred tax liabilities of \$95 million, other net assets of \$1 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 \$180 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 through which fair value is estimated based on market participant expectations of each asset's discounted projected net cash flows. 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 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 in July of 2016, which was accrued for and recorded in Research and development expenses in the second quarter of 2016. 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 cost 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 in-process research and development (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 in the first six months of 2016, 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.

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

## 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 non-facility related restructuring actions under these programs are substantially complete; the remaining activities primarily relate to ongoing facility rationalizations. The Company recorded total pretax costs of \$210 million and \$351 million in the second quarter of 2017 and 2016, respectively, and \$425 million and \$547 million for the first six months of 2017 and 2016, respectively, related to restructuring program activities. Since inception of the programs through June 30, 2017, Merck has recorded total pretax accumulated costs of approximately \$13.0 billion and eliminated approximately 41,920 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 \$300 million of additional pretax costs. The Company estimates that approximately two-thirds of the cumulative pretax costs will result in 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 June 30, 2017				Six Months Ended June 30, 2017			
	Separation Costs	Accelerated Depreciation	Other	Total	Separation Costs	Accelerated Depreciation	Other	Total
Materials and production	\$—	\$ (4)	\$ 37	\$ 33	\$—	\$ 47	\$ 49	\$ 96
Marketing and administrative	—	2	—	2	—	2	1	3
Research and development	—	8	1	9	—	6	3	9
Restructuring costs	118	—	48	166	202	—	115	317
	\$118	\$ 6	\$ 86	\$ 210	\$202	\$ 55	\$ 168	\$ 425
(\$ in millions)	Three Months Ended June 30, 2016				Six Months Ended June 30, 2016			
	Separation Costs	Accelerated Depreciation	Other	Total	Separation Costs	Accelerated Depreciation	Other	Total
Materials and production	\$—	\$ 29	\$ 37	\$ 66	\$—	\$ 51	\$ 62	\$ 113
Marketing and administrative	—	4	83	87	—	7	83	90
Research and development	—	64	—	64	—	119	—	119
Restructuring costs	85	—	49	134	111	—	114	225
	\$85	\$ 97	\$ 169	\$ 351	\$ 111	\$ 177	\$ 259	\$ 547

Separation costs are associated with actual headcount reductions, as well as those headcount reductions which were probable and could be reasonably estimated. In the second quarter of 2017 and 2016, approximately 475 positions and 585 positions, respectively, and for the first six months of 2017 and 2016, approximately 1,020 positions and 1,055 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.

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

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

(\$ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
Restructuring reserves January 1, 2017	\$ 395	\$ —	\$ 146	\$ 541
Expense	202	55	168	425
(Payments) receipts, net	(167 )	—	(234 )	(401 )
Non-cash activity	—	(55 )	50	(5 )
Restructuring reserves June 30, 2017 <sup>(1)</sup>	\$ 430	\$ —	\$ 130	\$ 560

<sup>(1)</sup> The remaining cash outlays are expected to be substantially completed by the end of 2017.

#### 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.

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

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 \$339 million and \$29 million for the first six 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 June 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.

Debt Instrument	June 30, 2017		
	Par Value of Debt	Number of Interest Rate Swaps Held	Total Notional Swap 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.

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

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)	Balance Sheet Caption	June 30, 2017			December 31, 2016		
		Fair Value of Derivatives Asset	Fair Value of Derivatives Liability	Notional	Fair Value of Derivatives Asset	Fair Value of Derivatives Liability	Notional
<b>Derivatives Designated as Hedging Instruments</b>							
Interest rate swap contracts	Other assets	\$ 21	\$ —	\$ 2,700	\$ 20	\$ —	\$ 2,700
Interest rate swap contracts	Accrued and other current liabilities	—	4	1,000	—	—	—
Interest rate swap contracts	Other noncurrent liabilities	—	19	2,500	—	29	3,500
Foreign exchange contracts	Other current assets	154	—	4,223	616	—	6,063
Foreign exchange contracts	Other assets	31	—	1,388	129	—	2,075
Foreign exchange contracts	Accrued and other current liabilities	—	58	1,692	—	1	48
Foreign exchange contracts	Other noncurrent liabilities	—	—	—	—	1	12
		\$ 206	\$ 81	\$ 13,503	\$ 765	\$ 31	\$ 14,398
<b>Derivatives Not Designated as Hedging Instruments</b>							
Foreign exchange contracts	Other current assets	\$ 134	\$ —	\$ 5,586	\$ 230	\$ —	\$ 8,210
Foreign exchange contracts	Accrued and other current liabilities	—	120	5,807	—	103	2,931
		\$ 134	\$ 120	\$ 11,393	\$ 230	\$ 103	\$ 11,141
		\$ 340	\$ 201	\$ 24,896	\$ 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:

(\$ in millions)	June 30, 2017		December 31, 2016	
	Asset	Liability	Asset	Liability
Gross amounts recognized in the consolidated balance sheet	\$340	\$ 201	\$995	\$ 134
Gross amount subject to offset in master netting arrangements not offset in the consolidated balance sheet	(132 )	(132 )	(131 )	(131 )
Cash collateral received	(65 )	—	(529 )	—
Net amounts	\$143	\$ 69	\$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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Derivatives designated in a fair value hedging relationship				

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Interest rate swap contracts

Amount of gain recognized in Other (income) expense, net on derivatives <sup>(1)</sup> \$(22) \$(48) \$(7) \$(198)

Amount of loss recognized in Other (income) expense, net on hedged item <sup>(1)</sup> 20 47 4 194

Derivatives designated in foreign currency cash flow hedging relationships

Foreign exchange contracts

Amount of gain reclassified from AOCI to Sales (49 ) (65 ) (144) (207 )

Amount of loss recognized in OCI on derivatives 169 75 432 242

Derivatives not designated in a hedging relationship

Foreign exchange contracts

Amount of gain recognized in Other (income) expense, net on derivatives <sup>(2)</sup> (3 ) (140) (49) (116 )

<sup>(1)</sup> There was \$2 million and \$1 million of ineffectiveness on the hedge during the second quarter of 2017 and 2016, respectively, and \$3 million and \$4 million, respectively, of ineffectiveness on the hedge during the first six months of 2017 and 2016, respectively.

<sup>(2)</sup> 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.

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

At June 30, 2017, the Company estimates \$50 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 AOCI to Sales. The amount ultimately reclassified to Sales may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity.

## Investments in Debt and Equity Securities

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

(\$ in millions)	June 30, 2017				December 31, 2016			
	Fair Value	Amortized Cost	Gross Gains	Unrealized Losses	Fair Value	Amortized Cost	Gross Gains	Unrealized Losses
Corporate notes and bonds	\$10,469	\$10,460	\$28	\$(19)	\$10,577	\$10,601	\$15	\$(39)
U.S. government and agency securities	2,009	2,018	—	(9)	2,232	2,244	1	(13)
Commercial paper	1,607	1,607	—	—	4,330	4,330	—	—
Asset-backed securities	1,399	1,399	2	(2)	1,376	1,380	1	(5)
Mortgage-backed securities	710	714	1	(5)	796	801	1	(6)
Foreign government bonds	569	571	—	(2)	519	521	—	(2)
Equity securities	376	285	92	(1)	349	281	71	(3)
	\$17,139	\$17,054	\$123	\$(38)	\$20,179	\$20,158	\$89	\$(68)

Available-for-sale debt securities included in Short-term investments totaled \$4.2 billion at June 30, 2017. Of the remaining debt securities, \$10.8 billion mature within five years. At June 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.

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

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

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

	Fair Value Measurements Using				Fair Value Measurements Using			
	Quoted Prices				Quoted Prices			
	In	Significant	Significant	Total	In	Significant	Significant	Total
	Active	Other	Unobservable		Active	Other	Unobservable	
	Markets	Observable	Inputs		Markets	Observable	Inputs	
	for	Inputs	(Level 3)		for	Inputs	(Level 3)	
	Identical	Assets	(Level 3)		Identical	Assets	(Level 3)	
	(Level	(Level 2)			(Level	(Level 2)		
	1)				1)			
(\$ in millions)	June 30, 2017				December 31, 2016			
Assets								
Investments								
Corporate notes and bonds	\$—	\$ 10,305	\$ —	\$ 10,305	\$—	\$ 10,389	\$ —	\$ 10,389
U.S. government and agency securities	67	1,649	—	1,716	29	1,890	—	1,919
Commercial paper	—	1,607	—	1,607	—	4,330	—	4,330
Asset-backed securities <sup>(1)</sup>	—	1,314	—	1,314	—	1,257	—	1,257
Mortgage-backed securities <sup>(1)</sup>	—	596	—	596	—	628	—	628
Foreign government bonds	—	568	—	568	—	518	—	518
Equity securities	213	—	—	213	201	—	—	201
	280	16,039	—	16,319	230	19,012	—	19,242
Other assets								
U.S. government and agency securities	—	293	—	293	—	313	—	313
Corporate notes and bonds	—	164	—	164	—	188	—	188
Mortgage-backed securities <sup>(1)</sup>	—	114	—	114	—	168	—	168
Asset-backed securities <sup>(1)</sup>	—	85	—	85	—	119	—	119
Foreign government bonds	—	1	—	1	—	1	—	1
Equity securities	163	—	—	163	148	—	—	148
	163	657	—	820	148	789	—	937
Derivative assets <sup>(2)</sup>								
Purchased currency options	—	180	—	180	—	644	—	644
Forward exchange contracts	—	139	—	139	—	331	—	331
Interest rate swaps	—	21	—	21	—	20	—	20
	—	340	—	340	—	995	—	995
Total assets	\$443	\$ 17,036	\$ —	\$ 17,479	\$378	\$ 20,796	\$ —	\$ 21,174
Liabilities								
Other liabilities								
Contingent consideration	\$—	\$ —	\$ 1,002	\$ 1,002	\$—	\$ —	\$ 891	\$ 891
Derivative liabilities <sup>(2)</sup>								
Forward exchange contracts	—	178	—	178	—	93	—	93
Interest rate swaps	—	23	—	23	—	29	—	29
Written currency options	—	—	—	—	—	12	—	12
	—	201	—	201	—	134	—	134
Total liabilities	\$—	\$ 201	\$ 1,002	\$ 1,203	\$—	\$ 134	\$ 891	\$ 1,025

<sup>(1)</sup> 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) 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 six months of 2017. As of June 30, 2017, Cash and cash equivalents of \$7.8 billion included \$6.7 billion of cash equivalents (which would be considered Level 2 in the fair value hierarchy).

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

## Contingent Consideration

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

	Six Months Ended June 30,	
(\$ in millions)	2017	2016
Fair value January 1	\$891	\$590
Changes in fair value <sup>(1)</sup>	108	19
Additions	3	77
Payments	—	(25 )
Fair value June 30 <sup>(2)</sup>	\$1,002	\$661

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

<sup>(2)</sup> Amount at June 30, 2017, includes \$308 million recorded as a current liability for amounts expected to be paid within the next 12 months, including \$100 million related to the acquisition of IOMET (see Note 2).

The additions to contingent consideration in the first six months of 2016 relate to the acquisition of IOMET (see Note 2). The payments of contingent consideration in the first six months of 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 June 30, 2017, was \$26.0 billion compared with a carrying value of \$24.9 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 June 30, 2017, the Company's total net accounts receivable outstanding for more than one year were approximately \$160 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 June 30, 2017 and December 31, 2016, the Company had received cash collateral of \$65 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 June 30, 2017 or December 31, 2016.





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

## 5. Inventories

Inventories consisted of:

(\$ in millions)	June 30, 2017	December 31, 2016
Finished goods	\$1,396	\$ 1,304
Raw materials and work in process	4,654	4,222
Supplies	175	155
Total (approximates current cost)	6,225	5,681
Increase to LIFO costs	258	302
	\$6,483	\$ 5,983

Recognized as:

Inventories	\$5,407	\$ 4,866
Other assets	1,076	1,117

Amounts recognized as Other assets are comprised almost entirely of raw materials and work in process inventories. At June 30, 2017 and December 31, 2016, these amounts included \$1.0 billion of inventories not expected to be sold within one year. In addition, these amounts included \$80 million at June 30, 2017 and December 31, 2016 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 six months of 2017 and 2016.

During the second quarter and first six 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 June 30, 2017 was \$25 million.

During the second quarter and first six months of 2016, the Company recorded intangible asset impairment charges of \$95 million and \$347 million, respectively. During the second quarter of 2016, the Company wrote off amounts that had been capitalized in connection with in-licensed products that, for business reasons, the Company returned to the licensor. The remaining impairment charges of \$252 million in the first six months of 2016 related 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.

Also, during the second quarter and first six months of 2016, the Company recorded \$195 million and \$220 million, respectively, of IPR&D impairment charges within Research and development expenses. Of these amounts, \$112 million related to an in-licensed program that, for business reasons, was returned to the licensor. The remaining IPR&D impairment charges primarily related 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.



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

## 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 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 June 30, 2017, approximately 4,180 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 4,165 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.

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

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 also dismissed without prejudice another approximately 540 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. The deadline for Merck to file a petition for a writ of certiorari to the U.S. Supreme Court is August 22, 2017.

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 June 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 540 cases dismissed without prejudice that were also pending the final resolution of the aforementioned appeal have not yet been reinstated.

As of June 30, 2017, approximately 2,820 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 June 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 June 30, 2017, Merck is aware of approximately 1,215 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 1,215 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.

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

As of June 30, 2017, eight 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 is seeking permission to appeal that order on an interlocutory basis and to stay proceedings in the trial court. Trial for three of the product users in Illinois is currently scheduled to begin in November 2017; trial for the fourth product user is scheduled to begin in February 2018.

In addition to the claims noted above, the Company has agreed to toll the statute of limitations for approximately 50 additional claims. The Company intends to continue defending against these lawsuits.

#### Propecia/Proscar

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving Propecia and/or Proscar. As of June 30, 2017, approximately 1,190 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 40 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 James 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

The Company recently received an investigative subpoena from the California Insurance Commissioner's Fraud Liaison Bureau (the Bureau) seeking information from January 1, 2007 to the present related to the pricing and promotion of Cubicin. The Bureau is investigating whether Cubist Pharmaceuticals, Inc., which the Company acquired in 2015, unlawfully induced the presentation of false claims for Cubicin to private insurers under the California Insurance Code False Claims Act. 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.

The UK Competition and Markets Authority (the CMA) issued a Statement of Objections against the Company and MSD Sharp & Dohme Limited (MSD UK) on May 23, 2017. In the Statement of Objections, the CMA alleges that MSD UK abused a dominant position through a discount program for Remicade over the period from March 2015 to February 2016. The Company and MSD UK are contesting the CMA's allegations.

#### 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. The final approval hearing is scheduled for October 5, 2017, following notice of the settlement to the class members.

Sales Force Litigation

As previously disclosed, in May 2013, Ms. Kelli Smith filed a complaint against the Company in the U.S. District Court for the District of New Jersey on behalf of herself and a putative class of female sales representatives and a putative sub-

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

class of female sales representatives with children, claiming (a) discriminatory policies and practices in selection, promotion and advancement, (b) disparate pay, (c) differential treatment, (d) hostile work environment and (e) retaliation under federal and state discrimination laws. Plaintiffs sought and were granted leave to file an amended complaint. In January 2014, plaintiffs filed an amended complaint adding four additional named plaintiffs. In October 2014, the court denied the Company's motion to dismiss or strike the class claims as premature. In September 2015, plaintiffs filed additional motions, including a motion for conditional certification under the Equal Pay Act; a motion to amend the pleadings seeking to add ERISA and constructive discharge claims and a Company subsidiary as a named defendant; and a motion for equitable relief. Merck filed papers in opposition to the motions. On April 27, 2016, the court granted plaintiff's motion for conditional certification but denied plaintiffs' motions to extend the liability period for their Equal Pay Act claims back to June 2009. As a result, the liability period will date back to April 2012, at the earliest. On April 29, 2016, the Magistrate Judge granted plaintiffs' request to amend the complaint to add the following: (i) a Company subsidiary as a corporate defendant; (ii) an ERISA claim and (iii) an individual constructive discharge claim for one of the named plaintiffs. Approximately 700 individuals have opted-in to this action; the opt-in period has closed. On August 1, 2017, plaintiffs filed their motion for class certification. This motion seeks to certify a Title VII pay discrimination class and also seeks final collective action certification of plaintiffs' Equal Pay Act claim.

**Merck KGaA Litigation**

In January 2016, to protect its long-established brand rights in the United States, the Company filed a lawsuit against Merck KGaA, Darmstadt, Germany (KGaA), operating as the EMD Group in the United States, alleging it improperly uses the name "Merck" in the United States. KGaA has filed suit against the Company in France, the United Kingdom (UK), Germany, Switzerland, Mexico, and India alleging breach of the parties' co-existence agreement, unfair competition and/or trademark infringement. In December 2015, the Paris Court of First Instance issued a judgment finding that certain activities by the Company directed towards France did not constitute trademark infringement and unfair competition while other activities were found to infringe. The Company and KGaA appealed the decision, and the appeal was heard in May 2017. In June 2017, the French appeals court held that certain of the activities by the Company directed to France constituted unfair competition or trademark infringement. In January 2016, the UK High Court issued a judgment finding that the Company had breached the co-existence agreement and infringed KGaA's trademark rights as a result of certain activities directed towards the UK based on use of the word MERCK on promotional and information activity. As noted in the UK decision, this finding was not based on the Company's use of the sign MERCK in connection with the sale of products or any material pharmaceutical business transacted in the UK. The Company and KGaA have both appealed this decision, and the appeal was heard in June 2017. The Company is currently awaiting the decision.

**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, Nasonex, 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 lawsuit automatically stays FDA approval of Savior's application until November 2017 or until an adverse court decision, if any, whichever may occur earlier.

Nasonex — In July 2014, a patent infringement lawsuit was filed in the United States against Teva Pharmaceuticals USA, Inc. (Teva Pharma) in respect of Teva Pharma's application to the FDA seeking pre-patent expiry approval to market a generic version of Nasonex. The trial in this matter was held in June 2016. In November 2016, the district court ruled that the patent was valid but not infringed. In March 2017, the parties reached a settlement whereby Teva Pharma can launch its generic version in September 2017, or earlier under certain conditions.

In March 2015, a patent infringement lawsuit was filed in the United States against Amneal Pharmaceuticals LLC (Amneal) in respect of Amneal's application to the FDA seeking pre-patent expiry approval to market a generic version of Nasonex. The trial in this matter was held in June 2016. In January 2017, the district court ruled that the patent was valid but not infringed. The Company has appealed this decision.

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

A previous decision, issued in June 2013, held that the Merck patent in the Teva Pharma and Amneal lawsuits covering mometasone furoate monohydrate was valid, but that it was not infringed by Apotex Corp.'s proposed product. In April 2015, a patent infringement lawsuit was filed against Apotex Inc. and Apotex Corp. (Apotex) in respect of Apotex's now-launched product that the Company believes differs from the generic version in the previous lawsuit.

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. The lawsuit automatically stays FDA approval of Actavis's application until December 2017 or until an adverse court decision, if any, whichever may occur earlier. The trial was held in July 2017 and closing arguments will be held in August 2017. 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. The lawsuit automatically stays FDA approval of Roxane's application until August 2018 or until an adverse court decision, if any, whichever may occur earlier. 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 has appealed 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 appeal will be heard in September 2017.

#### 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 as follows:

- 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.

In October 2015, PDL Biopharma (PDL) filed a lawsuit in the United States against the Company alleging that the manufacture of Keytruda infringed US Patent No. 5,693,761 ('761 patent), which expired in December 2014. This patent claims platform technology used in the creation and manufacture of recombinant antibodies and PDL is seeking damages for pre-expiry infringement of the '761 patent. In April 2017, the parties reached a settlement pursuant to which, in exchange for a lump sum, PDL dismissed its lawsuit with prejudice and granted the Company a fully paid-up non-exclusive license to the '761 patent.

In July 2016, the Company filed a declaratory judgment action in the United States against Genentech and City of Hope seeking a ruling that US Patent No. 7,923,221 (the Cabilly III patent), which claims platform technology used in the creation and manufacture of recombinant antibodies, is invalid and that Keytruda and bezlotoxumab do not infringe the Cabilly III patent. In July 2016, the Company also filed a petition in the USPTO for Inter Partes Review (IPR) of certain claims of US Patent No. 6,331,415 (the Cabilly II patent), which claims platform technology used in the creation and manufacture of recombinant antibodies and is also owned by Genentech and City of Hope, as being invalid. In December 2016, the USPTO denied the petition but allowed the Company to join an IPR filed previously by another party. In May 2017, the parties reached a settlement pursuant to which the Company dismissed its lawsuit with prejudice and moved to terminate the IPR and Genentech and City of Hope granted the Company a fully paid-up non-exclusive license to the Cabilly II and Cabilly III patents.

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

**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 is scheduled for September 2017. 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 is considering its options in Canada, including seeking leave to the Supreme Court 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 June 30, 2017 and December 31, 2016 of approximately \$175 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.

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

## 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	Cost	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.	—	—	—	2,330	—	—	—	—	—	2,330
Other comprehensive income, net of taxes	—	—	—	—	62	—	—	—	—	62
Cash dividends declared on common stock	—	—	—	(2,557)	—	—	—	—	—	(2,557)
Treasury stock shares purchased	—	—	—	—	—	30	(1,573)	—	—	(1,573)
Share-based compensation plans and other	—	—	(311)	—	—	(15)	730	—	—	419
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	9	—	9
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(11)	—	(11)
Balance at June 30, 2016	3,577	\$ 1,788	\$ 39,911	\$ 45,121	\$ (4,086)	811	\$(39,377)	\$ 89		\$ 43,446
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.	—	—	—	3,496	—	—	—	—	—	3,496
Other comprehensive income, net of taxes	—	—	—	—	132	—	—	—	—	132
Cash dividends declared on common stock	—	—	—	(2,583)	—	—	—	—	—	(2,583)
Treasury stock shares purchased	—	—	—	—	—	34	(2,153)	—	—	(2,153)
Share-based compensation plans and other	—	—	(163)	—	—	(12)	646	—	—	483
Acquisition of Vallée	—	—	—	—	—	—	—	25	—	25
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	11	—	11
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(7)	—	(7)
Balance at June 30, 2017	3,577	\$ 1,788	\$ 39,776	\$ 45,046	\$ (5,094)	850	\$(42,053)	\$ 249		\$ 39,712

## 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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Pretax share-based compensation expense	\$82	\$80	\$156	\$148

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Income tax benefit (25 ) (25 ) (47 ) (45 )  
 Total share-based compensation expense, net of taxes \$57 \$55 \$109 \$103

During the first six months of 2017 and 2016, the Company granted 5 million RSUs with a weighted-average grant date fair value of \$63.97 per RSU and 5 million RSUs with a weighted-average grant date fair value of \$54.54 per RSU, respectively. During the first six months of 2017 and 2016, the Company granted 4 million stock options with a weighted-average exercise price of \$63.98 per option and 6 million stock options with a weighted-average exercise price of \$54.61 per option, respectively. The weighted-average fair value of options granted for the first six months of 2017 and 2016 was \$7.05 and \$5.89 per option, respectively, and was determined using the following assumptions:

	Six Months	
	Ended	
	June 30,	
	2017	2016
Expected dividend yield	3.6 %	3.8 %
Risk-free interest rate	2.0 %	1.4 %
Expected volatility	17.9%	19.6%
Expected life (years)	6.1	6.2

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

At June 30, 2017, there was \$633 million of total pretax unrecognized compensation expense related to nonvested stock options, RSU and PSU awards which will be recognized over a weighted-average period of 2.2 years. For segment reporting, share-based compensation costs are unallocated expenses.

## 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				Six Months Ended			
	June 30,		June 30,		June 30,		June 30,	
	2017	2016	2017	2016	2017	2016	2017	2016
	U.S.	International	U.S.	International	U.S.	International	U.S.	International
Service cost	\$77	\$ 63	\$73	\$ 62	\$154	\$ 124	\$146	\$ 120
Interest cost	113	42	113	52	226	83	226	105
Expected return on plan assets	(218)	(97 )	(210)	(97 )	(436 )	(191 )	(420 )	(193 )
Amortization of unrecognized prior service credit	(13 )	(3 )	(14 )	(3 )	(27 )	(5 )	(27 )	(6 )
Net loss amortization	44	24	29	21	89	47	57	43
Termination benefits	3	1	1	—	8	2	5	—
Curtailments	1	(1 )	—	—	4	(1 )	—	1
	\$7	\$ 29	\$(8)	\$ 35	\$18	\$ 59	\$(13)	\$ 70

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		Six Months Ended	
	June 30,	June 30,	June 30,	June 30,
	2017	2016	2017	2016
Service cost	\$14	\$13	\$28	\$27
Interest cost	20	21	40	42
Expected return on plan assets	(20 )	(34 )	(39 )	(69 )
Amortization of unrecognized prior service credit	(24 )	(26 )	(49 )	(53 )
Termination benefits	—	—	1	1
Curtailments	(2 )	(1 )	(5 )	(2 )
	\$(12)	\$(27)	\$(24)	\$(54)

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		Six Months Ended	
	June 30,	June 30,	June 30,	June 30,
	2017	2016	2017	2016
Interest income	\$(96)	\$(78)	\$(194)	\$(157)
Interest expense	193	171	375	343
Exchange losses	19	37	11	76
Equity (income) loss from affiliates	(5 )	(4 )	8	(38 )

Other, net

(53 ) (107) (83 ) (157 )  
\$58 \$19 \$117 \$67

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

The change in equity (income) loss from affiliates in the first six months of 2017 as compared with the same period of 2016 was driven primarily by lower equity income from certain research investment funds, as well as by the termination of the SPMSD joint venture on December 31, 2016.

Other, net (as reflected in the table above) in the second quarter and first six months of 2016 includes a gain of \$115 million related to the settlement of certain patent litigation.

Interest paid for the six months ended June 30, 2017 and 2016 was \$343 million and \$321 million, respectively.

#### 12. Taxes on Income

The effective income tax rates of 20.0% and 19.6% for the second quarter of 2017 and 2016, respectively, and 21.0% and 25.2% for the first six 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. The effective income tax rates for the second quarter and first six months of 2017 also include a benefit of \$88 million related to the settlement of a state income tax issue. The effective income tax rates for the second quarter and first six months of 2016 also reflect the beneficial impact of orphan drug federal income tax credits, primarily for Keytruda, recorded in the second quarter.

The Company is under examination by numerous tax authorities in various jurisdictions globally. The ultimate finalization of the Company's examinations with relevant taxing authorities can include formal administrative and legal proceedings, which could have a significant impact on the timing of the reversal of unrecognized tax benefits. The Company believes that its reserves for uncertain tax positions are adequate to cover existing risks or exposures. However, there is one item that is currently under discussion with the Internal Revenue Service relating to the 2006 through 2008 examination. The Company has concluded that its position should be sustained upon audit. However, if this item were to result in an unfavorable outcome or settlement, it could have a material adverse impact on the Company's financial position, liquidity and results of operations.

#### 13. Earnings Per Share

The calculations of earnings per share are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
(\$ and shares in millions except per share amounts)				
Net income attributable to Merck & Co., Inc.	\$1,946	\$1,205	\$3,496	\$2,330
Average common shares outstanding	2,734	2,768	2,739	2,771
Common shares issuable <sup>(1)</sup>	18	21	20	21
Average common shares outstanding assuming dilution	2,752	2,789	2,759	2,792
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	\$0.71	\$0.44	\$1.28	\$0.84
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	\$0.71	\$0.43	\$1.27	\$0.83

<sup>(1)</sup> Issuable primarily under share-based compensation plans.

For the three months ended June 30, 2017 and 2016, 5 million and 13 million, respectively, and for the first six months of 2017 and 2016, 4 million and 12 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.

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

14. Other Comprehensive Income (Loss)

Changes in AOCI by component are as follows:

(\$ in millions)	Three Months Ended June 30,				
	Derivatives	Investments	Employee Benefit Plans	Cumulative Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
Balance April 1, 2016, net of taxes	\$202	\$ 104	\$ (2,435 )	\$ (2,065 )	\$ (4,194 )
Other comprehensive income (loss) before reclassification adjustments, pretax	(75 )	76	(183 )	255	73
Tax	27	(5 )	68	(11 )	79
Other comprehensive income (loss) before reclassification adjustments, net of taxes	(48 )	71	(115 )	244	152
Reclassification adjustments, pretax	(66 ) <sup>(1)</sup>	(10 ) <sup>(2)</sup>	7 <sup>(3)</sup>	—	(69 )
Tax	23	2	—	—	25
Reclassification adjustments, net of taxes	(43 )	(8 )	7	—	(44 )
Other comprehensive income (loss), net of taxes	(91 )	63	(108 )	244	108
Balance June 30, 2016, net of taxes	\$111	\$ 167	\$ (2,543 )	\$ (1,821 )	\$ (4,086 )
Balance April 1, 2017, net of taxes	\$106	\$ 40	\$ (3,180 )	\$ (2,046 )	\$ (5,080 )
Other comprehensive income (loss) before reclassification adjustments, pretax	(169 )	26	29	(25 )	(139 )
Tax	59	3	(3 )	72	131
Other comprehensive income (loss) before reclassification adjustments, net of taxes	(110 )	29	26	47	(8 )
Reclassification adjustments, pretax	(50 ) <sup>(1)</sup>	8 <sup>(2)</sup>	27 <sup>(3)</sup>	—	(15 )
Tax	17	(2 )	(6 )	—	9
Reclassification adjustments, net of taxes	(33 )	6	21	—	(6 )
Other comprehensive income (loss), net of taxes	(143 )	35	47	47	(14 )
Balance June 30, 2017, net of taxes	\$(37 )	\$ 75	\$ (3,133 )	\$ (1,999 )	\$ (5,094 )
	Six Months Ended June 30,				
					Accumulated
(\$ in millions)	Derivatives	Investments	Employee Benefit Plans	Cumulative Translation Adjustment	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	(242 )	130	(218 )	354	24
Tax	85	11	67	11	174
Other comprehensive income (loss) before reclassification adjustments, net of taxes	(157 )	141	(151 )	365	198
Reclassification adjustments, pretax	(209 ) <sup>(1)</sup>	(21 ) <sup>(2)</sup>	14 <sup>(3)</sup>	—	(216 )
Tax	73	6	1	—	80
Reclassification adjustments, net of taxes	(136 )	(15 )	15	—	(136 )
Other comprehensive income (loss), net of taxes	(293 )	126	(136 )	365	62
Balance June 30, 2016, net of taxes	\$111	\$ 167	\$ (2,543 )	\$ (1,821 )	\$ (4,086 )

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Balance January 1, 2017, net of taxes	\$338	\$ (3 )	\$ (3,206 )	\$ (2,355 )	\$ (5,226 )
Other comprehensive income (loss) before reclassification adjustments, pretax	(432 )	113	25	238	(56 )
Tax	151	(4 )	6	118	271
Other comprehensive income (loss) before reclassification adjustments, net of taxes	(281 )	109	31	356	215
Reclassification adjustments, pretax	(145 ) <sup>(1)</sup>	(49 ) <sup>(2)</sup>	55	<sup>(3)</sup> —	(139 )
Tax	51	18	(13 )	—	56
Reclassification adjustments, net of taxes	(94 )	(31 )	42	—	(83 )
Other comprehensive income (loss), net of taxes	(375 )	78	73	356	132
Balance June 30, 2017, net of taxes	\$(37 )	\$ 75	\$ (3,133 )	\$ (1,999 )	\$ (5,094 )

<sup>(1)</sup> Relates to foreign currency cash flow hedges that were reclassified from AOCI to Sales.

<sup>(2)</sup> Represents net realized (gains) losses on the sales of available-for-sale investments that were reclassified from AOCI to Other (income) expense, net.

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

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

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.

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

Sales of the Company's products were as follows:

(\$ in millions)	Three Months		Six Months	
	Ended		Ended	
	June 30,		June 30,	
	2017	2016	2017	2016
Primary Care and Women's Health				
Cardiovascular				
Zetia	\$367	\$702	\$701	\$1,314
Vytorin	182	293	423	570
Atozet	63	33	112	56
Adempas	67	40	151	72
Diabetes				
Januvia	948	1,064	1,787	1,970
Janumet	563	569	1,059	1,075
General Medicine and Women's Health				
NuvaRing	199	200	359	376
Implanon/Nexplanon	178	164	349	298
Follistim AQ	79	73	160	167
Hospital and Specialty				
Hepatitis				
Zepatier	517	112	895	161
HIV				
Isentress/Isentress HD	282	338	587	678
Hospital Acute Care				
Bridion	163	113	310	204
Noxafil	155	143	296	288
Invanz	150	143	286	257
Cancidas	112	131	233	263
Cubicin	103	357	198	649
Primaxin	71	81	133	154
Immunology				
Remicade	208	339	437	688
Simponi	199	199	383	387
Oncology				
Keytruda	881	314	1,465	563
Emend	143	143	276	268
Temodar	65	73	130	139
Diversified Brands				
Respiratory				
Singulair	203	229	389	465
Nasonex	85	101	224	331
Dulera	69	121	151	234
Other				
Cozaar/Hyzaar	119	132	231	258
Arcoxia	89	117	192	228
Fosamax	66	73	127	148
Vaccines <sup>(1)</sup>				
Gardasil/Gardasil 9	469	393	1,001	770
ProQuad/M-M-R II/Varivax	399	383	754	739

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RotaTeq	123	130	347	318
Pneumovax 23	166	120	329	228
Zostavax	160	149	313	274
Other pharmaceutical <sup>(2)</sup>	1,116	1,128	2,156	2,214
Total Pharmaceutical segment sales	8,759	8,700	16,944	16,804
Other segment sales <sup>(3)</sup>	1,056	980	2,089	1,885
Total segment sales	9,815	9,680	19,033	18,689
Other <sup>(4)</sup>	115	164	332	467
	\$9,930	\$9,844	\$19,365	\$19,156

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

<sup>(1)</sup> 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.

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

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

Other is primarily comprised of miscellaneous corporate revenues, including revenue hedging activities, as well as

<sup>(4)</sup> third-party manufacturing sales. Other in the first six months of 2017 and 2016 also includes \$50 million and \$75 million, respectively, related to the sale of the marketing rights to certain products.



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

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

(\$ in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Segment profits:				
Pharmaceutical segment	\$5,613	\$5,420	\$10,793	\$10,537
Other segments	508	386	961	739
Total segment profits	6,121	5,806	11,754	11,276
Other profits	43	93	186	320
Unallocated:				
Interest income	96	78	194	157
Interest expense	(193 )	(171 )	(375 )	(343 )
Equity income from affiliates	5	(6 )	(7 )	14
Depreciation and amortization	(332 )	(438 )	(702 )	(864 )
Research and development	(1,527 )	(1,833 )	(3,126 )	(3,206 )
Amortization of purchase accounting adjustments	(779 )	(1,027 )	(1,557 )	(2,161 )
Restructuring costs	(166 )	(134 )	(317 )	(225 )
Other unallocated, net	(829 )	(864 )	(1,608 )	(1,840 )
	\$2,439	\$1,504	\$4,442	\$3,128

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.

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

### Recent Developments

#### Global Oncology Collaboration

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 BRCA-mutated ovarian cancer in multiple lines of treatment. 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. As part of the agreement, Merck will make 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. The Company will record an aggregate charge of \$2.35 billion in Research and development expenses in the third quarter of 2017 related to these 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).

#### 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. While the Company does not yet know the magnitude of the impact of the disruption, which remains ongoing in certain operations, it continues to work to minimize the effects.

The Company is in the process of restoring its manufacturing operations. To date, Merck has largely restored its packaging operations and has mostly restored its formulation operations. The Company is in the process of restoring its Active Pharmaceutical Ingredient operations but is not yet producing bulk 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). In addition, Merck does not currently expect a significant impact to sales of its other top products; however, the Company anticipates that it will have temporary delays in fulfilling orders for certain other products in certain markets. Merck does not currently expect a significant impairment to the value of intangible assets related to marketed products or inventories. Full resumption of affected operations will take time and the Company will incur expenditures related to remediation efforts.

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.

### Operating Results

#### Sales

Worldwide sales were \$9.9 billion for the second quarter of 2017, an increase of 1% compared with the second quarter of 2016. Worldwide sales were \$19.4 billion for the first six months of 2017, an increase of 1% compared with the first six months of 2016. Foreign exchange unfavorably affected global sales performance by 1% in both the second quarter and first six months of 2017. Sales growth in both periods was driven primarily by higher sales in the oncology franchise largely from Keytruda, the ongoing launch of hepatitis C virus (HCV) treatment Zepatier, and growth in vaccine products including Gardasil (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant)/Gardasil 9 (Human Papillomavirus 9-valent Vaccine, Recombinant) and Pneumovax 23 (pneumococcal vaccine polyvalent). Sales in the second quarter and first six months 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. Also contributing to sales growth in the second quarter and first six months of 2017 were higher sales of Bridion (sugammadex) Injection, Adempas

(riociguat), and Animal Health products, particularly Bravecto (fluralaner).

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Partially offsetting revenue growth in the second quarter and first six months of 2017 were declines 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) and Remicade (infliximab), as well as lower sales of products within Diversified Brands including Dulera Inhalation Aerosol (mometasone furoate/formoterol fumarate dihydrate), Singulair (montelukast) and Nasonex (mometasone furoate monohydrate). Declines in the diabetes franchise of Januvia and Janumet (sitagliptin/metformin HCl) and lower combined sales of Isentress/Isentress HD (raltegravir) also offset revenue growth in the second quarter and first six 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 six 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.

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Sales of the Company's products were as follows:

(\$ in millions)	Three Months		Six Months	
	Ended		Ended	
	June 30,		June 30,	
	2017	2016	2017	2016
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Cardiovascular				
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Simponi	199	199	383	387
Oncology				
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Emend	143	143	276	268
Temodar	65	73	130	139
Diversified Brands				
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Singulair	203	229	389	465
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Dulera	69	121	151	234
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Arcoxia	89	117	192	228
Fosamax	66	73	127	148
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Gardasil/Gardasil 9	469	393	1,001	770

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Pneumovax 23	166	120	329	228
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	\$9,930	\$9,844	\$19,365	\$19,156

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

<sup>(1)</sup> 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.

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

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

Other is primarily comprised of miscellaneous corporate revenues, including revenue hedging activities, as well as <sup>(4)</sup> third-party manufacturing sales. Other in the first six months of 2017 and 2016 also includes \$50 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, which includes indirect customer discounts that occur when a contracted customer purchases directly through an intermediary wholesale purchaser, known as chargebacks, as well as indirectly in the form of rebates 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 \$2.8 billion and \$2.3 billion for the three months ended June 30, 2017 and 2016, respectively, and by \$5.3 billion and \$4.5 billion for the six months ended June 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 \$612 million in the second quarter of 2017 and \$1.2 billion for the first six months of 2017, declines of 40% and 36%, respectively, compared with the same periods of 2016. The sales declines primarily reflect lower volumes 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 and the Company is experiencing rapid and substantial declines in U.S. Zetia and Vytorin sales. The Company has market exclusivity in major European markets for Ezetrol until April 2018 and for Inegy until April 2019.

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. 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 \$67 million and \$40 million for Adempas in the second quarter of 2017 and 2016, respectively, and \$151 million and \$72 million for the first six 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 second quarter of 2017, a decline of 8% compared with the second quarter of 2016, and were \$2.8 billion in the first six months of 2017, a decline of 7% compared with the same period of 2016. Foreign exchange unfavorably affected global sales performance by 1% in both the second quarter and first six months of 2017. The declines primarily reflect lower sales in the United States driven by continued pricing pressure and lower customer inventory levels that were partially offset by continued volume growth. Lower demand and pricing in Europe also contributed to the sales declines. These declines were partially offset by volume growth in Asia Pacific and Latin America.

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.

In July 2017, Merck announced that the FDA granted tentative approval for Lusduna Nexvue (insulin glargine injection), a follow-on biologic basal insulin for the treatment of people with type 1 and type 2 diabetes. Lusduna Nexvue is being developed by Merck with funding from Samsung Bioepis Co., Ltd (Samsung Bioepis). With the tentative approval, Lusduna Nexvue has met all required regulatory standards for follow-on biologics of clinical and nonclinical safety, efficacy and quality, but is subject to an automatic stay due to a lawsuit from Sanofi claiming patent infringement. Under the Hatch-Waxman Act, the initiation of Sanofi's lawsuit in September 2016 automatically invoked a stay on final FDA approval of Lusduna Nexvue for a period of up to 30 months, or in the event a court finds

in favor of Merck, whichever comes sooner. Lusduna was approved in the European Union (EU) in January 2017.

**General Medicine and Women's Health**

Worldwide sales of NuvaRing (etonogestrel/ethinyl estradiol vaginal ring), a vaginal contraceptive product, were \$199 million in the second quarter of 2017, essentially flat as compared with the second quarter of 2016. Global sales of NuvaRing declined 4% in the first six months of 2017 to \$359 million driven primarily by lower sales in the United States reflecting the timing of customer purchases, partially offset by higher pricing. In August 2016, the U.S. District Court ruled that the Company's delivery system patent for NuvaRing is invalid. The Company is appealing this verdict to the U.S. Court of Appeals for the Federal Circuit. However, given the U.S. District Court's decision, there may be generic entrants into the U.S. market in advance of the



April 2018 patent expiration. If this should occur, the Company anticipates a significant decline in U.S. NuvaRing sales thereafter. U.S. sales of NuvaRing were \$265 million for the first six months of 2017. As a result of the unfavorable U.S. District Court decision, the Company evaluated the intangible asset related to NuvaRing for impairment and concluded that it was not impaired. The intangible asset value for NuvaRing was \$228 million at June 30, 2017.

Worldwide sales of Implanon/Nexplanon (etonogestrel implant), single-rod subdermal contraceptive implants, grew 9% to \$178 million in the second quarter of 2017 and increased 17% to \$349 million in the first six months of 2017 compared with the same periods of 2016 primarily reflecting higher pricing and volume growth in the United States. Foreign exchange unfavorably affected global sales performance by 1% for the first six months of 2017.

#### Hospital and Specialty

##### Hepatitis

Global sales of Zepatier were \$517 million in the second quarter of 2017 compared with \$112 million in the second quarter of 2016 and were \$895 million in the first six months of 2017 compared with \$161 million in the first six months of 2016. Sales growth in both periods primarily reflects higher sales in the United States, Europe 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 recommended 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 and became available in European markets in late November 2016.

Launches are expected to continue across the EU in 2017. The Company has also launched Zepatier in Japan and in other international markets. Sales in the United States in the first six months of 2017 reflect an approximately \$40 million favorable adjustment to rebate accruals due to mix of business. The Company will continue to focus on expanding Zepatier's utilization globally, but anticipates that uptake may be affected by the ongoing decline in overall patient volumes in many markets and by increased competition.

##### 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 \$282 million in the second quarter of 2017, a decline of 17% compared with the second quarter of 2016, and were \$587 million in the first six months of 2017, a decline of 13% compared with the first six months of 2016. Foreign exchange unfavorably affected global sales performance by 2% in the second quarter of 2017. The declines reflect lower demand in the United States and Europe due to competitive pressures, as well as lower volumes in Brazil. 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 will be 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 \$163 million in the second quarter of 2017, an increase of 44% compared with the second quarter of 2016. Global sales of Bridion were \$310 million in the first six months of 2017, an increase of 52% 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 \$150 million in the second quarter of 2017, growth of 5% compared with the second quarter of 2016, and were \$286 million in the first six months of 2017, an increase of 11% compared with the same period of 2016. Sales growth in both periods primarily reflects higher pricing in the United States. The patent that provides U.S. market exclusivity for Invanz will expire in November 2017 and the Company anticipates a significant decline in U.S. Invanz sales thereafter. U.S. sales of Invanz

were \$175 million in the first six months of 2017.

Global sales of Cancidas (casposfungin acetate), an anti-fungal product, were \$112 million in the second quarter of 2017 and \$233 million for the first six months of 2017, declines of 14% and 12%, respectively, compared with the same periods of 2016. Foreign exchange unfavorably affected global sales performance by 1% and 3% for the second quarter and first six months of 2017, respectively. The declines were driven primarily by generic competition in certain European markets. The EU compound patent for Cancidas expired in April 2017 and the Company anticipates declines in Cancidas sales in those European markets will continue.

Sales of Cubicin, an I.V. antibiotic for complicated skin and skin structure infections or bacteremia when caused by designated susceptible organisms, were \$103 million in the second quarter of 2017, a decline of 71% compared with the second quarter of 2016, and were \$198 million in the first six months of 2017, a decline of 69% compared with the same period in 2016.

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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.

In October 2016, Merck announced that the FDA approved Zinplava Injection 25 mg/mL. Zinplava is indicated to reduce recurrence of Clostridium difficile infection (CDI) in patients 18 years of age or older who are receiving antibacterial drug treatment of CDI and are at high risk for CDI recurrence. Zinplava became available in the United States in February 2017. Zinplava was approved by the EC in January 2017 and became available in the EU in March 2017.

#### Immunology

Sales of Remicade, a treatment for inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were \$208 million in the second quarter of 2017 and \$437 million in the first six months of 2017, declines of 39% and 37%, respectively, compared with the same periods of 2016. Foreign exchange unfavorably affected sales performance by 3% in both the second quarter and first six 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.

In July 2017, Merck launched Renflexis (infliximab-abda), a biosimilar of Remicade, in the United States. Renflexis was approved by the FDA in April 2017 for all eligible indications. Renflexis is the first medicine available in the United States under a global biosimilars development and commercialization agreement between Merck and Samsung Bioepis.

Sales of Simponi (golimumab), a once-monthly subcutaneous treatment for certain inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were \$199 million in the second quarter of 2017, essentially flat as compared with the second quarter of 2016, and were \$383 million in the first six months of 2017, a decline of 1% compared with the same period of 2016. Foreign exchange unfavorably affected global sales performance by 3% and 4% for the second quarter and first six months of 2017, respectively. Excluding the unfavorable effect of foreign exchange, sales performance in both periods was driven primarily by higher volumes.

#### Oncology

Global sales of Keytruda, an anti-PD-1 (programmed death receptor-1) therapy, were \$881 million in the second quarter of 2017 compared with \$314 million in the second quarter of 2016 and were \$1.5 billion in the first six months of 2017 compared with \$563 million in the first six 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. 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). During the second quarter of 2017, Keytruda received four new indications in the United States and an additional indication in Europe.

In May 2017, the FDA approved Keytruda in combination with pemetrexed and carboplatin, a commonly used chemotherapy regimen, 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. 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.

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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 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 July 2017, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending the approval of Keytruda for the treatment of certain patients with locally advanced or metastatic urothelial carcinoma. The recommendation will now be reviewed by the EC for marketing authorization in the EU. A final decision is expected in the third quarter of 2017.

Also 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. Keytruda is now approved in the United States and in the EU as monotherapy for the treatment of certain patients with NSCLC, melanoma and cHL. Keytruda is also approved in the United States as monotherapy for the treatment of certain patients with HNSCC, urothelial carcinoma, and MSI-H or mismatch repair deficient cancer, and in combination with pemetrexed and carboplatin in certain patients with 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.

Global sales of Emend (aprepitant), for the prevention of chemotherapy-induced and post-operative nausea and vomiting, were \$143 million in the second quarter of 2017, essentially flat compared with the second quarter of 2016 including a 1% unfavorable effect from foreign exchange. Sales performance reflects higher volumes in Japan that were offset by volume declines in the United States. Worldwide sales of Emend were \$276 million in the first six months of 2017, an increase of 3% compared with the same period of 2016, driven primarily by volume growth in Japan, partially offset by volume declines in the United States and Europe.

#### 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 \$203 million in the second quarter of 2017 and \$389 million for the first six months of 2017, declines of 11% and 16%, respectively, compared with the same periods of 2016. Foreign exchange unfavorably affected global sales performance by 1% in the second quarter of 2017. The sales declines were largely driven by lower volumes in Japan. 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 16% to \$85 million in the second quarter of 2017 and decreased 32% to \$224 million in the first six months of 2017 compared with the same periods of 2016. Foreign exchange favorably affected global sales performance by 1% in the first six

months of 2017. The sales declines were driven by lower volumes in the United States from ongoing generic competition.

Global sales of Dulera Inhalation Aerosol, a combination medicine for the treatment of asthma, were \$69 million in the second quarter of 2017, a decline of 43% compared with the second quarter of 2016, and were \$151 million in the first six months of 2017, a decline of 35% compared with the first six months of 2016. The declines were driven by lower sales in the United States reflecting competitive pricing pressures.

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## 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 second quarter and first six months of 2017 were approximately \$70 million and \$135 million, respectively, of which approximately \$40 million and \$90 million, respectively, relate to Gardasil/Gardasil 9.

Merck's sales of Gardasil/Gardasil 9, vaccines to help prevent certain cancers and diseases caused by certain types of human papillomavirus (HPV), were \$469 million in the second quarter of 2017, an increase of 19% compared with the second quarter of 2016 including a 1% unfavorable effect from foreign exchange. Sales growth was driven primarily by higher sales in Europe resulting from the termination of the SPMSD joint venture noted above, higher demand in Asia Pacific, and timing in Brazil. U.S. sales of Gardasil/Gardasil 9 were relatively flat in the second quarter of 2017 compared to the second quarter of 2016 as lower volumes from the timing of public sector purchases were offset by higher pricing. Merck's sales of Gardasil/Gardasil 9 were \$1.0 billion in the first six months of 2017, growth of 30% compared with the first six months of 2016. Sales growth was driven primarily by higher sales in Europe resulting from the termination of the SPMSD joint venture, higher sales in the United States, largely reflecting demand and pricing, as well as higher demand in Asia Pacific and timing in Brazil. 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 U.S. Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices 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. 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 \$130 million in the second quarter of 2017 compared with \$117 million in the second quarter of 2016 driven by higher volumes and pricing in the United States. Merck's sales of ProQuad were \$233 million in the first six months of 2017 compared with \$239 million in the first six months of 2016. The decline was driven primarily by the effects of public sector purchasing in the United States, as well as \$29 million of sales in 2016 to the U.S. Center for Disease Control and Prevention Pediatric Vaccine Stockpile. 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 \$86 million for the second quarter of 2017 compared with \$78 million for the second quarter of 2016 and were \$178 million in the first six months of 2017 compared with \$154 million in the first six months of 2016. The increases were driven primarily by 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 \$183 million for the second quarter of 2017 compared with \$188 million for the second quarter of 2016 and were \$343 million in the first six months of 2017 compared with \$346 million in the first six months of 2016. The declines reflect lower sales in Latin America and the United States, partially offset by higher sales in Europe resulting from the termination of the SPMSD joint venture.

Merck's sales of RotaTeq (Rotavirus Vaccine, Live Oral, Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and children, were \$123 million in the second quarter of 2017, a decline of 5% compared with the second quarter of 2016. The decline reflects lower volumes in the United States driven primarily by the effects of public sector purchasing, partially offset by higher sales in Europe resulting from the termination of the SPMSD joint venture. Merck's sales of RotaTeq were \$347 million in the first six months of 2017, an increase of 9% compared with the first six months of 2016. The increase was driven primarily by higher sales in Europe resulting

from the termination of the SPMSD joint venture, as well as higher volumes and pricing in the United States. Merck's sales of Pneumovax 23, a vaccine to help prevent pneumococcal disease, were \$166 million in the second quarter of 2017, an increase of 38% compared with the second quarter of 2016. Merck's sales of Pneumovax 23 were \$329 million in the first six months of 2017, an increase of 44% compared with the first six months of 2016 including a 1% unfavorable effect from foreign exchange. Sales growth in both periods was driven by volume growth in most regions, particularly in the United States.

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 \$160 million in the second quarter of 2017, an increase of 7% compared with the second quarter of 2016, and were \$313 million in the first six months of 2017, an increase of 14% compared with the first six months of 2016. Sales growth in both periods was driven largely by volume growth in the Asia Pacific region, partially offset by lower demand in the United States.

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## 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 \$955 million for the second quarter of 2017, an increase of 6% compared with sales of \$900 million in the second quarter of 2016. Foreign exchange unfavorably affected global sales performance by 1% in the second quarter of 2017. Worldwide sales of Animal Health products were \$1.9 billion in the first six months of 2017, an increase of 10%, compared with sales of \$1.7 billion for the first six months of 2016. Sales growth in both periods primarily reflects higher sales of companion animal products, driven by the Bravecto line of products that kill fleas and ticks in dogs and cats for up to 12 weeks, and higher sales of ruminant products reflecting the impact of the Vallée S.A. acquisition. Sales growth in the year-to-date period also reflects higher sales of swine and poultry products.

### Costs, Expenses and Other

#### Materials and Production

Materials and production costs were \$3.1 billion for the second quarter of 2017, a decline of 14% compared with the second quarter of 2016. Costs in the second quarter of 2017 and 2016 include \$779 million and \$1.0 billion, respectively, and for the first six months of 2017 and 2016 include \$1.6 billion and \$2.1 billion, respectively, of expenses for the amortization of intangible assets recorded in connection with business acquisitions. Additionally, costs for the second quarter and first six months of 2017 include \$47 million and for the second quarter and first six months of 2016 include \$95 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 six 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 \$33 million and \$66 million in the second quarter of 2017 and 2016, respectively, and \$96 million and \$113 million for the first six 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 69.0% in the second quarter of 2017 compared with 63.7% in the second quarter of 2016 and was 68.5% in the first six months of 2017 compared with 62.7% in the first six months of 2016. The improvements in gross margin were driven primarily by lower amortization of intangible assets, intangible asset impairment and restructuring charges as noted above, which reduced gross margin by 8.6 percentage points in the second quarter of 2017 as compared with 12.0 percentage points in the second quarter of 2016 and 9.2 percentage points in the first six months of 2017 as compared with 13.6 percentage points in the first six months of 2016. The gross margin improvement in both periods also reflects the favorable effects of product mix and lower inventory write-offs.

#### Marketing and Administrative

Marketing and administrative (M&A) expenses declined 1% to \$2.4 billion in the second quarter of 2017 compared with the second quarter of 2016 driven primarily by lower restructuring costs and the favorable effects of foreign exchange, partially offset by 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, as well as higher promotional expenses related to product launches. M&A expenses increased 2% to \$4.8 billion in the first six 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 costs and the favorable effects of foreign exchange. M&A expenses for the second quarter of 2017 and 2016 include \$2 million and \$87 million, respectively, and for the first six months of 2017 and 2016 include \$3 million and \$90 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.

Research and Development

Research and development (R&D) expenses were \$1.7 billion for the second quarter of 2017, a decline of 19% compared with the second quarter of 2016 and were \$3.5 billion for the first six months of 2017, a decrease of 7% compared with the same period of 2016. The declines were driven primarily by lower in-process research and development (IPR&D) impairment charges, lower licensing and restructuring costs, partially offset by higher clinical development spending.

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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 second quarter of 2017 and 2016, and were \$2.2 billion and \$2.1 billion for the first six 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 \$610 million and \$770 million for the second quarter of 2017 and 2016, respectively, and were approximately \$1.3 billion and \$1.4 billion for the first six months of 2017 and 2016, respectively. The decrease was driven in part by higher licensing costs in the prior year periods primarily related to a collaboration with Moderna (see Note 2 to the condensed consolidated financial statements). In addition, R&D expenses include IPR&D impairment charges of \$195 million and \$220 million for the second quarter and first six months of 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 \$9 million and \$64 million in the second quarter of 2017 and 2016, respectively, and \$9 million and \$119 million for the first six 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. The non-facility related restructuring actions under these programs are substantially complete; the remaining activities primarily relate to ongoing facility rationalizations. Restructuring costs, primarily representing separation and other related costs associated with these restructuring activities, were \$166 million and \$134 million for the second quarter of 2017 and 2016, respectively, and were \$317 million and \$225 million for the first six 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 475 positions and 585 positions in the second quarter of 2017 and 2016, respectively, and 1,020 and 1,055 positions for the first six 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 \$210 million and \$351 million in the second quarter of 2017 and 2016, respectively, and \$425 million and \$547 million for the first six 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 \$300 million of additional pretax costs.

#### Other (Income) Expense, Net

Other (income) expense, net was \$58 million of expense in the second quarter of 2017 compared with \$19 million of expense in the second quarter of 2016 and was \$117 million of expense in the first six months of 2017 compared with \$67 million of expense in the first six 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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Pharmaceutical segment profits	\$5,613	\$5,420	\$10,793	\$10,537
Other non-reportable segment profits	508	386	961	739
Other	(3,682 )	(4,302 )	(7,312 )	(8,148 )
Income before income taxes	\$2,439	\$1,504	\$4,442	\$3,128

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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 are reflected in "Other" in the above table. Also included in "Other" are miscellaneous corporate profits (losses), as well as operating profits (losses) related to third-party manufacturing sales.

Pharmaceutical segment profits grew 4% in the second quarter of 2017 and grew 2% in the first six months of 2017 compared with the same periods of 2016 primarily reflecting higher sales and the favorable effects of product mix.

#### Taxes on Income

The effective income tax rates of 20.0% and 19.6% for the second quarter of 2017 and 2016, respectively, and 21.0% and 25.2% for the first six 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. The effective income tax rates for the second quarter and first six months of 2017 also include a benefit of \$88 million related to the settlement of a state income tax issue. The effective income tax rates for the second quarter and first six months of 2016 also reflect the beneficial impact of orphan drug federal income tax credits, primarily for Keytruda, recorded in the second quarter.

The Company is under examination by numerous tax authorities in various jurisdictions globally. The ultimate finalization of the Company's examinations with relevant taxing authorities can include formal administrative and legal proceedings, which could have a significant impact on the timing of the reversal of unrecognized tax benefits. The Company believes that its reserves for uncertain tax positions are adequate to cover existing risks or exposures. However, there is one item that is currently under discussion with the Internal Revenue Service relating to the 2006 through 2008 examination. The Company has concluded that its position should be sustained upon audit. However, if this item were to result in an unfavorable outcome or settlement, it could have a material adverse impact on the Company's financial position, liquidity and results of operations.

#### Net Income and Earnings per Common Share

Net income attributable to Merck & Co., Inc. was \$1.9 billion for the second quarter of 2017 compared with \$1.2 billion for the second quarter of 2016 and was \$3.5 billion for the first six months of 2017 compared with \$2.3 billion for the first six months of 2016. Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders (EPS) for the second quarter of 2017 were \$0.71 compared with \$0.43 in the second quarter of 2016 and were \$1.27 in the first six months of 2017 compared with \$0.83 for the first six 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		Six Months	
	Ended		Ended	
	June 30,	June 30,	June 30,	June 30,
	2017	2016	2017	2016
Pretax income as reported under GAAP	\$2,439	\$1,504	\$4,442	\$3,128
Increase (decrease) for excluded items:				
Acquisition and divestiture-related costs	882	1,345	1,765	2,768
Restructuring costs	210	351	425	547
Other	—	—	(9)	—
	3,531	3,200	6,623	6,443
Taxes on income as reported under GAAP	488	295	935	789
Estimated tax benefit on excluded items <sup>(1)</sup>	172	314	375	566
Benefit related to settlement of state income tax issue	88	—	88	—
	748	609	1,398	1,355
Non-GAAP net income	2,783	2,591	5,225	5,088
Less: Net income attributable to noncontrolling interests	5	4	11	9
Non-GAAP net income attributable to Merck & Co., Inc.	\$2,778	\$2,587	\$5,214	\$5,079
EPS assuming dilution as reported under GAAP	\$0.71	\$0.43	\$1.27	\$0.83
EPS difference <sup>(2)</sup>	0.30	0.50	0.62	0.99
Non-GAAP EPS assuming dilution	\$1.01	\$0.93	\$1.89	\$1.82

(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.

Represents the difference between calculated GAAP EPS and calculated non-GAAP EPS, which may be different

(2) 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 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, and MSI-H or mismatch repair deficient cancer, and in combination with pemetrexed and carboplatin in certain patients with NSCLC (see “Pharmaceutical Segment” above).

In May 2017, the FDA accepted for review a supplemental Biologics License Application (sBLA) for Keytruda seeking approval for the treatment of patients with recurrent or locally advanced gastric or gastroesophageal junction adenocarcinoma who have already received two or more lines of chemotherapy. The FDA granted Priority Review with a Prescription Drug User Fee Act (PDUFA) target action date of September 22, 2017.



In July 2017, the CHMP of the EMA adopted a positive opinion recommending the approval of Keytruda for the treatment of certain patients with locally advanced or metastatic urothelial carcinoma, a type of bladder cancer. Specifically, Keytruda is recommended for the treatment of locally advanced or metastatic urothelial carcinoma in adult patients who have received prior platinum-containing chemotherapy, as well as adult patients who are not eligible for cisplatin-containing chemotherapy. The recommendation will now be reviewed by the EC for marketing authorization in the EU. A final decision is expected in the third quarter of 2017. Keytruda is also under review in the EU in combination with pemetrexed and carboplatin for the first-line treatment of patients with metastatic or advanced non-squamous NSCLC regardless of PD-L1 expression.

Additionally, 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 new adjuvant 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.

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 will discontinue investigational treatment with Keytruda. This clinical hold does not apply to other studies with Keytruda.

The Keytruda clinical development program consists of more than 550 clinical trials, including more than 300 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 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 six 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 oral or an intravenous infusion once-daily antiviral candidate for the prevention 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.

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 events of 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 in the fourth quarter of 2017.

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In June 2017, Merck announced that the REVEAL (Randomized EValuation of the Effects of Anacetrapib through Lipid modification) outcomes study of anacetrapib, Merck's investigational cholesteryl ester transfer protein (CETP) inhibitor, met its primary endpoint, significantly reducing major coronary events (defined as the composite of coronary death, myocardial infarction, and coronary revascularization) compared to placebo in patients at risk for cardiac events who are already receiving an effective LDL-C lowering regimen. The safety profile of anacetrapib in the early analysis was generally consistent with that demonstrated in previous studies of the drug, including accumulation of anacetrapib in adipose tissue, as has been previously reported. Merck plans to review the results of the trial with external experts, and will consider whether to file new drug applications with the FDA and other regulatory agencies. The results of the REVEAL study will be presented at the European Society of Cardiology meeting in August 2017. The REVEAL study is a randomized, double-blind placebo-controlled clinical trial to assess the efficacy and safety of adding anacetrapib to effective LDL-lowering treatment with atorvastatin for a median duration of at least 4 years among approximately 30,000 patients at high risk of cardiovascular events. The chart below reflects the Company's research pipeline as of August 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 Keytruda) 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	Alzheimer's Disease	New Molecular Entities/Vaccines
MK-1029	MK-8931 (verubecestat) (December 2013)	CMV Prophylaxis in Transplant Patients
Cancer	Atherosclerosis	MK-8228 (letermovir) (U.S./EU)
MK-3475 Keytruda	MK-0859 (anacetrapib) (May 2008)	Diabetes Mellitus
Advanced Solid Tumors	Bacterial Infection	MK-0431J (sitagliptin+ipragliflozin) (Japan) <sup>(1)</sup>
Nasopharyngeal	MK-7655A	MK-8835 (ertugliflozin) (U.S./EU) <sup>(1)</sup>
Ovarian	(relebactam+imipenem/cilastatin) (October 2015)	MK-8835A (ertugliflozin+sitagliptin) (U.S./EU) <sup>(1)</sup>
PMBCL (Primary Mediastinal Large B-Cell Lymphoma)	Cancer	MK-8835B (ertugliflozin+metformin) (U.S./EU) <sup>(1)</sup>
Prostate	MK-3475 Keytruda	Pediatric Hexavalent Combination Vaccine V419 (U.S.) <sup>(2)</sup>
Cough, including cough with Idiopathic Pulmonary Fibrosis	Breast (October 2015)	
MK-7264	Colorectal (November 2015)	
Diabetes Mellitus	Esophageal (December 2015)	
MK-8521	Gastric (May 2015) (EU)	Certain Supplemental Filings
Hepatitis C	Head and Neck (November 2014) (EU)	Cancer
MK-3682B (MK-5172 (grazoprevir)/MK-8408 (ruzasvir)/MK-3682 (uprifosbuvir))	Hepatocellular (May 2016)	Keytruda
MK-3682C (MK-8408 (ruzasvir)/MK-3682 (uprifosbuvir))	Renal (October 2016)	• Combination with carboplatin and pemetrexed in first line non-squamous non-small-cell lung (EU)
MK-3682C (MK-8408 (ruzasvir)/MK-3682 (uprifosbuvir))	Small-Cell Lung (May 2017)	• First line cisplatin-ineligible bladder (EU)
MK-3682C (MK-8408 (ruzasvir)/MK-3682 (uprifosbuvir))	Ebola Vaccine V920 (March 2015)	• Second line metastatic bladder (EU)
MK-3682C (MK-8408 (ruzasvir)/MK-3682 (uprifosbuvir))	Heart Failure	• Third line gastric (U.S.)
Pneumoconjugate Vaccine V114	MK-1242 (vericiguat) (September 2016) <sup>(1)</sup>	
Schizophrenia	Herpes Zoster	
MK-8189		

Footnotes:

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V212 (inactivated VZV vaccine) (December 2010) HIV	(1) Being developed in a collaboration.
MK-1439 (doravirine) (December 2014) MK-1439A (doravirine/lamivudine/tenofovir disoproxil fumarate) (June 2015)	(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 \$202 million and \$383 million in the second quarter and first six months of 2016, respectively, which included \$60 million and \$101 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)	June 30, 2017	December 31, 2016
Cash and investments	\$24,105	\$25,757
Working capital	9,409	13,410
Total debt to total liabilities and equity	26.8	26.0

Cash provided by operating activities was \$3.6 billion in the first six months of 2017 compared with \$3.8 billion in the first six months of 2016. Cash provided by operating activities in the first six months of 2017 reflects 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 six 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 \$2.1 billion in the first six months of 2017 compared with \$243 million in the first six months of 2016. The increase in cash provided by investing activities in 2017 was driven primarily by higher proceeds from the sales of securities and other investments and lower purchases of securities and other investments, partially offset by a higher use of cash to fund acquisitions and higher capital expenditures.

Cash used in financing activities was \$4.8 billion in the first six months of 2017 compared with \$6.2 billion in the first six months of 2016. The decrease in cash used in financing activities was driven primarily by lower payments on debt and higher proceeds from the exercise of stock options, partially offset by higher purchases of treasury stock and dividends paid to shareholders.

At June 30, 2017, the total of worldwide cash and investments was \$24.1 billion, including \$12.0 billion of cash, cash equivalents and short-term investments and \$12.1 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 June 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.

Capital expenditures totaled \$732 million and \$654 million for the first six months of 2017 and 2016, respectively. Dividends paid to stockholders were \$2.6 billion for both the first six 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 is payable in October 2017.

In March 2015, Merck's board of directors authorized additional purchases of up to \$10 billion of Merck's common stock for its treasury. The treasury stock purchase has no time limit and will be made over time in open-market transactions, block transactions on or off an exchange, or in privately negotiated transactions. During the first six months of 2017, the Company purchased \$2.2 billion (34 million shares) for its treasury. As of June 30, 2017, the Company's remaining share repurchase authorization was \$2.9 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. 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.

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### 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.

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. Early adoption is not permitted. The Company is currently assessing the impact of adoption on its consolidated financial statements.

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 is currently evaluating the effect of the standard 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 does not anticipate the adoption of the new guidance will have a material effect 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 is currently evaluating the effect of the standard 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.

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The new guidance is effective prospectively for interim and annual periods beginning in 2018. Early adoption is permitted. The Company is currently evaluating the impact of adoption 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 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 June 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.

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## 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 June 30, 2017 were as follows:

## ISSUER PURCHASES OF EQUITY SECURITIES

Period	Total Number of Shares Purchased <sup>(1)</sup>	Average Price Paid Per Share	(\$ in millions)
			Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs <sup>(1)</sup>
April 1 - April 30	5,448,401	\$62.97	\$3,693
May 1 - May 31	6,218,475	\$63.59	\$3,297
June 1 - June 30	6,123,210	\$64.60	\$2,902
Total	17,790,086	\$63.75	\$2,902

(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

Number Description

3.1 Restated Certificate of Incorporation of Merck & Co., Inc. (November 3, 2009) – Incorporated by reference to Current Report on Form 8-K filed on November 4, 2009 (No. 1-6571)

3.2 By-Laws of Merck & Co., Inc. (effective July 22, 2015) – Incorporated by reference to Current Report on Form 8-K filed on July 28, 2015 (No. 1-6571)

31.1 Rule 13a – 14(a)/15d – 14(a) Certification of Chief Executive Officer

31.2 Rule 13a – 14(a)/15d – 14(a) Certification of Chief Financial Officer

32.1 Section 1350 Certification of Chief Executive Officer

32.2 Section 1350 Certification of Chief Financial Officer

The following materials from Merck & Co., Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 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: August 8, 2017 /s/ Michael J. Holston  
MICHAEL J. HOLSTON  
Executive Vice President and General Counsel

Date: August 8, 2017 /s/ Rita A. Karachun  
RITA A. KARACHUN  
Senior Vice President Finance - Global Controller

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EXHIBIT INDEX

Number Description

- 3.1 Restated Certificate of Incorporation of Merck & Co., Inc. (November 3, 2009) – Incorporated by reference to Current Report on Form 8-K filed on November 4, 2009 (No. 1-6571)
- 3.2 By-Laws of Merck & Co., Inc. (effective July 22, 2015) – Incorporated by reference to Current Report on Form 8-K filed on July 28, 2015 (No. 1-6571)
- 31.1 Rule 13a – 14(a)/15d – 14(a) Certification of Chief Executive Officer
- 31.2 Rule 13a – 14(a)/15d – 14(a) Certification of Chief Financial Officer
- 32.1 Section 1350 Certification of Chief Executive Officer
- 32.2 Section 1350 Certification of Chief Financial Officer

101 The following materials from Merck & Co., Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 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.