

Merck & Co., Inc.  
Form 10-Q  
August 08, 2016

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, 2016

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, 2016: 2,765,208,203

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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company

(Do not check if a smaller reporting company)

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

## Part I - Financial Information

## Item 1. Financial Statements

## MERCK &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,	
	2016	2015	2016	2015
Sales	\$9,844	\$9,785	\$19,156	\$19,210
Costs, Expenses and Other				
Materials and production	3,578	3,754	7,150	7,323
Marketing and administrative	2,458	2,624	4,776	5,226
Research and development	2,151	1,670	3,810	3,407
Restructuring costs	134	191	225	273
Other (income) expense, net	19	739	67	793
	8,340	8,978	16,028	17,022
Income Before Taxes	1,504	807	3,128	2,188
Taxes on Income	295	119	789	542
Net Income	1,209	688	2,339	1,646
Less: Net Income Attributable to Noncontrolling Interests	4	1	9	7
Net Income Attributable to Merck & Co., Inc.	\$1,205	\$687	\$2,330	\$1,639
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	\$0.44	\$0.24	\$0.84	\$0.58
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	\$0.43	\$0.24	\$0.83	\$0.57
Dividends Declared per Common Share	\$0.46	\$0.45	\$0.92	\$0.90

## 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,	
	2016	2015	2016	2015
Net Income Attributable to Merck & Co., Inc.	\$1,205	\$687	\$2,330	\$1,639
Other Comprehensive Income (Loss) Net of Taxes:				
Net unrealized (loss) gain on derivatives, net of reclassifications	(91 )	(176 )	(293 )	76
Net unrealized gain (loss) on investments, net of reclassifications	63	(14 )	126	32
Benefit plan net (loss) gain and prior service (cost) credit, net of amortization	(108 )	42	(136 )	77
Cumulative translation adjustment	244	(17 )	365	(194 )
	108	(165 )	62	(9 )
Comprehensive Income Attributable to Merck & Co., Inc.	\$1,313	\$522	\$2,392	\$1,630

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, 2016	December 31, 2015
Assets		
Current Assets		
Cash and cash equivalents	\$6,608	\$8,524
Short-term investments	5,226	4,903
Accounts receivable (net of allowance for doubtful accounts of \$167 in 2016 and \$165 in 2015) (excludes accounts receivable of \$10 in 2016 and 2015 classified in Other assets)	6,916	6,484
Inventories (excludes inventories of \$1,195 in 2016 and \$1,569 in 2015 classified in Other assets - see Note 5)	5,248	4,700
Other current assets	3,928	5,140
Total current assets	27,926	29,751
Investments	11,879	13,039
Property, Plant and Equipment, at cost, net of accumulated depreciation of \$16,005 in 2016 and \$15,923 in 2015	11,987	12,507
Goodwill	17,809	17,723
Other Intangibles, Net	20,315	22,602
Other Assets	6,559	6,055
	\$96,475	\$101,677
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	\$644	\$2,583
Trade accounts payable	2,514	2,533
Accrued and other current liabilities	9,255	11,216
Income taxes payable	1,213	1,560
Dividends payable	1,292	1,309
Total current liabilities	14,918	19,201
Long-Term Debt	23,642	23,829
Deferred Income Taxes	6,091	6,535
Other Noncurrent Liabilities	8,378	7,345
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 2016 and 2015		
Other paid-in capital	39,911	40,222
Retained earnings	45,121	45,348
Accumulated other comprehensive loss	(4,086 )	(4,148 )
	82,734	83,210
Less treasury stock, at cost:		
811,476,036 shares in 2016 and 795,975,449 shares in 2015	39,377	38,534
Total Merck & Co., Inc. stockholders' equity	43,357	44,676
Noncontrolling Interests	89	91
Total equity	43,446	44,767

\$96,475 \$101,677

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,	
	2016	2015
<b>Cash Flows from Operating Activities</b>		
Net income	\$2,339	\$1,646
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	3,111	3,245
Intangible asset impairment charges	567	73
Foreign currency devaluation related to Venezuela	—	715
Equity income from affiliates	(38 )	(147 )
Dividends and distributions from equity affiliates	7	7
Deferred income taxes	(120 )	(383 )
Share-based compensation	148	146
Other	197	689
Net changes in assets and liabilities	(2,438 )	(1,010 )
<b>Net Cash Provided by Operating Activities</b>	<b>3,773</b>	<b>4,981</b>
<b>Cash Flows from Investing Activities</b>		
Capital expenditures	(654 )	(474 )
Purchases of securities and other investments	(6,355 )	(8,621 )
Proceeds from sales of securities and other investments	7,388	12,628
Acquisition of Cubist Pharmaceuticals, Inc., net of cash acquired	—	(7,598 )
Acquisitions of other businesses, net of cash acquired	(157 )	—
Dispositions of businesses, net of cash divested	—	25
Other	21	(40 )
<b>Net Cash Provided by (Used in) Investing Activities</b>	<b>243</b>	<b>(4,080 )</b>
<b>Cash Flows from Financing Activities</b>		
Net change in short-term borrowings	(9 )	(1,529 )
Proceeds from issuance of debt	8	7,940
Payments on debt	(2,351 )	(2,905 )
Purchases of treasury stock	(1,573 )	(1,724 )
Dividends paid to stockholders	(2,579 )	(2,582 )
Proceeds from exercise of stock options	381	377
Other	(109 )	(19 )
<b>Net Cash Used in Financing Activities</b>	<b>(6,232 )</b>	<b>(442 )</b>
Effect of Exchange Rate Changes on Cash and Cash Equivalents	300	(978 )
<b>Net Decrease in Cash and Cash Equivalents</b>	<b>(1,916 )</b>	<b>(519 )</b>
Cash and Cash Equivalents at Beginning of Year	8,524	7,441
<b>Cash and Cash Equivalents at End of Period</b>	<b>\$6,608</b>	<b>\$6,922</b>

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 26, 2016.

The results of operations of any interim period are not necessarily indicative of the results of operations for the full year. In the Company's opinion, all adjustments necessary for a fair statement of these interim statements have been included and are of a normal and recurring nature. Certain reclassifications have been made to prior year amounts to conform to the current presentation.

## Recently Adopted Accounting Standards

In the first quarter of 2016, the Company adopted accounting guidance issued by the Financial Accounting Standards Board (FASB) in April 2015, which requires debt issuance costs to be presented as a direct deduction from the carrying amount of that debt on the balance sheet as opposed to being presented as a deferred charge. Approximately \$100 million of debt issuance costs were reclassified in the first quarter of 2016 as a result of the adoption of the new standard. Prior period amounts have been recast to conform to the new presentation.

In the second quarter of 2016, the Company elected to early adopt an accounting standards update issued by the FASB in March of 2016 intended to simplify the accounting and reporting for employee share-based payment transactions. Among other provisions, the new standard requires that excess tax benefits and deficiencies that arise upon vesting or exercise of share-based payments be recognized in the income statement (as opposed to existing guidance under which tax effects are recorded to Other paid-in-capital in certain instances). This aspect of the new guidance was adopted prospectively; accordingly, the Company recognized \$29 million of excess tax benefits in Taxes on income arising from share-based payments in the second quarter of 2016. The new guidance also amended the presentation of certain share-based payment items in the statement of cash flows. Cash flows related to excess income tax benefits are now classified as an operating activity (formerly included as a financing activity). The Company elected to adopt this aspect of the new guidance prospectively. The standard also clarified that cash payments made to taxing authorities on the employees' behalf for shares withheld should be presented as a financing activity. This aspect of the guidance was adopted retrospectively; accordingly, the Company reclassified \$112 million of such payments from operating activities to financing activities in the Condensed Consolidated Statement of Cash Flows for the six months ended June 30, 2015 to conform to the current presentation. The Company has elected to continue to estimate the impact of forfeitures when determining the amount of compensation cost to be recognized each period rather than account for them as they occur.

## Recently Issued Accounting Standards

In May 2014, the 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. In August 2015, the FASB approved a one-year deferral of the effective date making this guidance effective for interim and annual periods beginning in 2018. Reporting entities may choose to adopt the standard as of the original effective date. The Company is currently assessing the impact of adoption on its consolidated financial statements.

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 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 within its scope. 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



## Notes to Condensed Consolidated Financial Statements (unaudited)

2020, with earlier application permitted in 2019. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

## 2. Acquisitions, Divestitures, Research Collaborations and License Agreements

The Company continues its strategy of establishing external alliances to complement its internal research capabilities, including research collaborations, licensing preclinical and clinical compounds to drive both near- and long-term growth. The Company supplements its internal research with a licensing and external alliance strategy focused on the entire spectrum of collaborations from early research to late-stage compounds, as well as access to new technologies. These arrangements often include upfront payments, as well as expense reimbursements or payments to the third party, and milestone, royalty or profit share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development. The Company also reviews its pipeline to examine candidates which may provide more value through out-licensing and, as part of its portfolio assessment process, may also divest certain products.

In July 2016, Merck acquired Afferent Pharmaceuticals (Afferent), a privately held pharmaceutical company focused on the development of therapeutic candidates targeting the P2X3 receptor for the treatment of common, poorly-managed, neurogenic conditions. Afferent's lead investigational candidate, MK-7264 (formerly AF-219), is a selective, non-narcotic, orally-administered P2X3 antagonist currently being evaluated in a Phase 2b clinical trial for the treatment of refractory, chronic cough as well as in a Phase 2 clinical trial in idiopathic pulmonary fibrosis with cough. Merck acquired all outstanding stock of Afferent in exchange for a payment of \$500 million in cash. In addition, former Afferent shareholders are eligible to receive a total of up to an additional \$750 million contingent upon the attainment of certain clinical development and commercial milestones for multiple indications and candidates, including MK-7264. The Company is in the process of determining the preliminary fair value of assets acquired, liabilities assumed and total consideration transferred for this business acquisition. The transaction closed on July 26, 2016; accordingly, the results of operations of the acquired business will be included in the Company's results of operations beginning after that date.

In July 2016, Merck, through its wholly owned subsidiary Healthcare Services & Solutions, LLC, acquired a majority ownership interest in The StayWell Company LLC (StayWell), a portfolio company of Vestar Capital Partners (Vestar). StayWell is a health engagement company that helps its clients engage and educate people to improve health and business results. Under the terms of the transaction, Merck paid \$150 million for a majority ownership interest. Merck has an option to buy, and Vestar has an option to require Merck to buy, an additional ownership interest at a future date. The Company is in the process of determining the preliminary fair value of assets acquired and liabilities assumed for this business acquisition. The transaction closed on July 1, 2016; accordingly, the results of operations of the acquired business will be included in the Company's results of operations beginning after that date.

Also in July 2016, Merck announced it had executed an agreement to acquire 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 more than 100 products spanning parasiticides, anti-infectives and vaccines that include products for livestock, horses, and companion animals. Under the terms of the agreement, Merck will acquire approximately 93% of the shares of Vallée in exchange for a payment estimated to be approximately \$400 million, based on exchange rates at the time of the announcement. This agreement is subject to regulatory review and certain closing conditions.

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 collaboration will combine Merck's established leadership in immuno-oncology with Moderna's mRNA vaccine technology and GMP manufacturing capabilities to advance individually tailored cancer vaccines for patients across a spectrum of cancers. Moderna and Merck will develop personalized cancer vaccines that utilize Moderna's mRNA vaccine technology to encode a patient's specific neoantigens, unique mutations present in that specific patient's tumor. 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 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 will each have the ability to combine mRNA-based personalized cancer vaccines with other (non-PD-1) agents. Merck and Moderna have an existing collaboration and license agreement focused on the discovery and development of mRNA-based infectious disease vaccines and passive immunity treatments.

As previously disclosed, in 2014, the Company entered into a worldwide clinical development collaboration with Bayer AG (Bayer) to market and develop soluble guanylate cyclase (sGC) modulators, including Bayer's Adempas (riociguat). The arrangement provided for potential future milestone payments of up to \$1.1 billion based upon the achievement of agreed-upon

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

sales goals. During the second quarter of 2016, the Company determined it was probable that, in 2017, Adempas sales would exceed the threshold triggering a \$350 million milestone payment from Merck to Bayer. Accordingly, in the second quarter of 2016, the Company recorded a \$350 million liability and a corresponding intangible asset and also recognized \$50 million of cumulative amortization expense within Materials and production costs. The remaining intangible asset of \$300 million will be amortized over the remaining estimated useful life of the asset of 10.5 years as supported by projected future cash flows, subject to impairment testing. Additional potential future milestone payments of \$775 million have not yet been accrued as they are not deemed by the Company to be probable at this time.

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. Total purchase consideration in the transaction of \$227 million included a cash payment of \$150 million and future additional milestone payments of up to \$250 million that are contingent upon certain clinical and regulatory milestones being achieved, which the Company determined had a fair value of \$77 million at the acquisition date. The transaction was accounted for as an acquisition of a business; accordingly, the assets acquired and liabilities assumed were recorded at their respective fair values as of the acquisition date. Merck recognized intangible assets for in-process research and development (IPR&D) of \$155 million and net deferred tax assets of \$26 million. The excess of the consideration transferred over the fair value of net assets acquired of \$46 million was recorded as goodwill that was allocated to the Pharmaceutical segment and is not deductible for tax purposes. The fair value of the identifiable intangible assets related to IPR&D was determined using an income approach, through which fair value is estimated based upon the asset's probability-adjusted future net cash flows, which reflects the stage of development of the project and the associated probability of successful completion. The net cash flows were then discounted to present value using a discount rate of 10.5%. The fair value of the contingent consideration was determined utilizing a probability-weighted estimated cash flow stream adjusted for the expected timing of each payment also utilizing a discount rate of 10.5%. Actual cash flows are likely to be different than those assumed. This transaction closed on January 11, 2016; accordingly, the results of operations of the acquired business have been included in the Company's results of operations beginning after that date. Pro forma financial information has not been included because IOmet's historical financial results are not significant when compared with the Company's financial results.

Also 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.

In February 2015, Merck and NGM Biopharmaceuticals, Inc. (NGM), a privately held biotechnology company, entered into a multi-year collaboration to research, discover, develop and commercialize novel biologic therapies across a wide range of therapeutic areas. The collaboration includes multiple drug candidates currently in preclinical development at NGM, including NP201, which is being evaluated for the treatment of diabetes, obesity and nonalcoholic steatohepatitis. NGM will lead the research and development of the existing preclinical candidates and have the autonomy to identify and pursue other discovery stage programs at its discretion. Merck will have the option to license all resulting NGM programs following human proof-of-concept trials. If Merck exercises this option, Merck will lead global product development and commercialization for the resulting products, if approved. Under the terms of the agreement, Merck made an upfront payment to NGM of \$94 million, which is included in Research and development expenses, and purchased a 15% equity stake in NGM for \$106 million. Merck committed up to \$250 million to fund all of NGM's efforts under the initial five-year term of the collaboration, with the potential for additional funding if certain conditions are met. Prior to Merck initiating a Phase 3 study for a licensed program, NGM may elect to either receive milestone and royalty payments or, in certain cases, to co-fund development and participate in a global cost and revenue share arrangement of up to 50%. The agreement also provides NGM with the option to participate in the co-promotion of any co-funded program in the United States. Merck will have the option to extend the research agreement for two additional two-year terms. Each party has certain termination rights under the

agreement in the event of an uncured material breach by the other party. Additionally, Merck has certain termination rights in the event of the occurrence of certain defined conditions. Upon a termination event, depending on the circumstances, the parties have varying rights and obligations with respect to the continued development and commercialization of compounds discovered under the agreement and certain related payment obligations.

Acquisition of Cubist Pharmaceuticals, Inc.

In January 2015, Merck acquired Cubist Pharmaceuticals, Inc. (Cubist), a leader in the development of therapies to treat serious infections caused by a broad range of bacteria. This transaction closed on January 21, 2015; accordingly, the results of operations of the acquired business have been included in the Company's results of operations beginning after that date. During the first six months of 2015, the Company incurred \$324 million of transaction costs directly related to the acquisition of Cubist including share-based compensation costs, severance costs and legal and advisory fees which are reflected in Marketing and administrative expenses. Of this amount, \$226 million was recorded in the first quarter of 2015 and \$98 million was recorded in the second quarter of 2015, but should have been recorded in the first quarter of 2015 which was the period the acquisition closed.

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

The following unaudited supplemental pro forma data presents consolidated information as if the acquisition of Cubist had been completed on January 1, 2014:

	Three Months Ended June 30, 2015	Six Months Ended June 30, 2015
(\$ in millions, except per share amounts)		
Sales	\$ 9,785	\$ 19,296
Net income attributable to Merck & Co., Inc.	764	1,811
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	0.27	0.64
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	0.27	0.63

The unaudited supplemental pro forma data reflects the historical information of Merck and Cubist adjusted to include additional amortization expense based on the fair value of assets acquired, additional interest expense that would have been incurred on borrowings used to fund the acquisition, transaction costs associated with the acquisition, and the related tax effects of these adjustments. The pro forma data should not be considered indicative of the results that would have occurred if the acquisition had been consummated on January 1, 2014, nor are they indicative of future results.

### 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 \$351 million and \$328 million in the second quarter of 2016 and 2015, respectively, and \$547 million and \$553 million for the first six months of 2016 and 2015, respectively, related to restructuring program activities. Since inception of the programs through June 30, 2016, Merck has recorded total pretax accumulated costs of approximately \$12.0 billion and eliminated approximately 39,330 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 \$1.0 billion 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, 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

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(\$ in millions)	Three Months Ended June 30, 2015				Six Months Ended June 30, 2015			
	Separate Costs	Accelerated Depreciation	Other	Total	Separate Costs	Accelerated Depreciation	Other	Total
Materials and production	\$—	\$ 17	\$88	\$105	\$—	\$ 30	\$180	\$210
Marketing and administrative	—	14	3	17	—	48	5	53
Research and development	—	16	(1 )	15	—	16	1	17
Restructuring costs	59	—	132	191	88	—	185	273
	\$59	\$ 47	\$222	\$328	\$88	\$ 94	\$371	\$553

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

Separation costs are associated with actual headcount reductions, as well as those headcount reductions which were probable and could be reasonably estimated. In the second quarter of 2016 and 2015, approximately 585 positions and 860 positions, respectively, and for the first six months of 2016 and 2015, approximately 1,055 positions and 1,950 positions, respectively, were eliminated under the restructuring program activities. These position eliminations were comprised of actual headcount reductions and the elimination of contractors and vacant positions.

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 site, based upon the anticipated date the site will be closed or divested, 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 recorded accelerated depreciation 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 2016 and 2015 includes asset abandonment, shut-down and other related costs, as well as pretax gains and losses resulting from sales of facilities and related assets. Additionally, other activity includes certain employee-related costs associated with pension and other postretirement benefit plans (see Note 11) and share-based compensation.

The following table summarizes the charges and spending relating to restructuring program activities for the six months ended June 30, 2016:

(\$ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
Restructuring reserves January 1, 2016	\$ 592	\$ —	\$ 53	\$ 645
Expense	111	177	259	547
(Payments) receipts, net	(185 )	—	(126)	(311 )
Non-cash activity	—	(177 )	(146)	(323 )
Restructuring reserves June 30, 2016 <sup>(1)</sup>	\$ 518	\$ —	\$ 40	\$ 558

<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 primary objective of the revenue hedging program is to reduce the potential for longer-term unfavorable changes in foreign exchange rates to decrease 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 that are expected to occur over its planning cycle, typically no more than three years into the future. The Company will layer in hedges over time, increasing the portion of third-party and intercompany distributor entity sales hedged as it gets closer to the expected date of the forecasted foreign currency denominated sales. The portion of 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 hedged anticipated sales are a specified component of a portfolio of similarly denominated foreign currency-based sales transactions, each of which responds to the hedged

currency risk in the same manner. The Company manages its anticipated transaction exposure principally with purchased local currency put options, which provide the Company with a right, but not an obligation, to sell foreign currencies in the future at a predetermined price. If the U.S. dollar strengthens relative to the currency of the hedged anticipated sales, total changes in the options' cash flows offset the decline in the expected future U.S. dollar equivalent cash flows of the hedged foreign

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

currency sales. Conversely, if the U.S. dollar weakens, the options' value reduces to zero, but the Company benefits from the increase in the U.S. dollar equivalent value of the anticipated foreign currency cash flows.

In connection with the Company's revenue hedging program, a purchased collar option strategy may be utilized. With a purchased collar option strategy, the Company writes a local currency call option and purchases a local currency put option. As compared to a purchased put option strategy alone, a purchased collar strategy reduces the upfront costs associated with purchasing puts through the collection of premiums by writing call options. If the U.S. dollar weakens relative to the currency of the hedged anticipated sales, the purchased put option value of the collar strategy reduces to zero and the Company benefits from the increase in the U.S. dollar equivalent value of its anticipated foreign currency cash flows; however, this benefit would be capped at the strike level of the written call. If the U.S. dollar strengthens relative to the currency of the hedged anticipated sales, the written call option value of the collar strategy reduces to zero and the changes in the purchased put cash flows of the collar strategy would offset the decline in the expected future U.S. dollar equivalent cash flows of the hedged foreign currency sales.

The Company may also utilize forward contracts in its revenue hedging program. If the U.S. dollar strengthens relative to the currency of the hedged anticipated sales, the increase in the fair value of the forward contracts offsets the decrease in the expected future U.S. dollar cash flows of the hedged foreign currency sales. Conversely, if the U.S. dollar weakens, the decrease in the fair value of the forward contracts offsets the increase in the value of the anticipated foreign currency cash flows.

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 primary objective of the balance sheet risk management program is 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, which enable the Company to buy and sell foreign currencies in the future at fixed exchange rates and economically offset the consequences of changes in foreign exchange from the monetary assets. Merck routinely enters into 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 Company will also minimize the effect of exchange on monetary assets and liabilities by managing operating activities and net asset positions at the local level. The cash flows from these contracts are reported as operating activities in the Condensed Consolidated Statement of Cash Flows.

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

The Company also uses forward exchange contracts to hedge its net investment in foreign operations against movements in exchange rates. The forward contracts are designated as hedges of the net investment in a foreign

operation. The Company hedges a portion of the net investment in certain of its foreign operations and measures ineffectiveness based upon changes in spot foreign exchange rates. 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

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

losses of \$29 million and pretax gains \$247 million for the first six months of 2016 and 2015, 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.

In May 2016, four interest rate swaps with notional amounts of \$250 million each matured. These swaps effectively converted the Company's \$1.0 billion, 0.70% fixed-rate notes due 2016 to variable rate debt. At June 30, 2016, the Company was a party to 26 pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes as detailed in the table below.

(\$ in millions)	June 30, 2016		
	Par Value of Debt	Number of Interest Swaps Held	Total Swap Notional Amount
1.30% notes due 2018	\$1,000	4	\$ 1,000
5.00% notes due 2019	1,250	3	550
1.85% notes due 2020	1,250	5	1,250
3.875% notes due 2021	1,150	5	1,150
2.40% notes due 2022	1,000	4	1,000
2.35% notes due 2022	1,250	5	1,250

The interest rate swap contracts are designated hedges of the fair value changes in the notes attributable to changes in the benchmark London Interbank Offered Rate (LIBOR) swap rate. The fair value changes in the notes attributable to changes in the LIBOR swap rate are recorded in interest expense and offset by the fair value changes in the swap contracts. The cash flows from these contracts are reported as operating activities in the Condensed Consolidated Statement of Cash Flows.

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

(\$ in millions)	Balance Sheet Caption	June 30, 2016			December 31, 2015		
		Asset	Liability	U.S. Dollar Notional	Asset	Liability	U.S. Dollar Notional
Derivatives Designated as Hedging Instruments							
Interest rate swap contracts (noncurrent)	Other assets	\$ 217	\$ —	\$ 6,200	\$ 42	\$ —	\$ 2,700
Interest rate swap contracts (current)	Accrued and other current liabilities	—	—	—	—	1	1,000
Interest rate swap contracts (noncurrent)	Other noncurrent liabilities	—	—	—	—	23	3,500
Foreign exchange contracts (current)	Other current	346	—	4,722	579	—	4,171

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Foreign exchange contracts (noncurrent)	assets Other assets	169	—	2,746	386	—	4,136
Foreign exchange contracts (current)	Accrued and other current liabilities	—	10	438	—	1	77
Foreign exchange contracts (noncurrent)	Other noncurrent liabilities	—	1	150	—	—	—
		\$ 732	\$ 11	\$ 14,256	\$ 1,007	\$ 25	\$ 15,584
Derivatives Not Designated as Hedging Instruments							
Foreign exchange contracts (current)	Other current assets	\$ 180	\$ —	\$ 7,029	\$ 212	\$ —	\$ 8,783
Foreign exchange contracts (noncurrent)	Other assets	—	—	—	18	—	179
Foreign exchange contracts (current)	Accrued and other current liabilities	—	59	3,988	—	37	2,508
Foreign exchange contracts (noncurrent)	Other noncurrent liabilities	—	1	6	—	1	6
		\$ 180	\$ 60	\$ 11,023	\$ 230	\$ 38	\$ 11,476
		\$ 912	\$ 71	\$ 25,279	\$ 1,237	\$ 63	\$ 27,060

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

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, 2016		December 31, 2015	
	Asset	Liability	Asset	Liability
Gross amounts recognized in the consolidated balance sheet	\$912	\$ 71	\$1,237	\$ 63
Gross amount subject to offset in master netting arrangements not offset in the consolidated balance sheet	(47 )	(47 )	(59 )	(59 )
Cash collateral (received) posted	(595 )	—	(862 )	—
Net amounts	\$270	\$ 24	\$316	\$ 4

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, (iii) designated in a foreign currency net investment hedging relationship and (iv) not designated in a hedging relationship:

(\$ in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Derivatives designated in a fair value hedging relationship				
Interest rate swap contracts				
Amount of (gain) loss recognized in Other (income) expense, net on derivatives <sup>(1)</sup>	\$(48)	\$57	\$(198)	\$32
Amount of loss (gain) recognized in Other (income) expense, net on hedged item <sup>(1)</sup>	47	(56 )	194	(34 )
Derivatives designated in foreign currency cash flow hedging relationships				
Foreign exchange contracts				
Amount of gain reclassified from AOCI to Sales	(65 )	(191)	(207 )	(358)
Amount of loss (gain) recognized in OCI on derivatives	75	84	242	(481)
Derivatives designated in foreign currency net investment hedging relationships				
Foreign exchange contracts				
Amount of gain recognized in Other (income) expense, net on derivatives <sup>(2)</sup>	—	(2 )	—	(3 )
Amount of gain recognized in OCI on derivatives	—	(26 )	—	(18 )
Derivatives not designated in a hedging relationship				
Foreign exchange contracts				
Amount of (gain) loss recognized in Other (income) expense, net on derivatives <sup>(3)</sup>	(140)	43	(116 )	(205)
Amount of gain recognized in Sales	—	—	—	(1 )

<sup>(1)</sup> There was \$1 million of ineffectiveness on the hedge during both the second quarter of 2016 and 2015, respectively, and \$4 million and \$2 million of ineffectiveness on the hedge for the first six months of 2016 and 2015, respectively.

<sup>(2)</sup> There was no ineffectiveness on the hedge. Represents the amount excluded from hedge effectiveness testing.

<sup>(3)</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.

At June 30, 2016, the Company estimates \$121 million of pretax net unrealized gains on derivatives maturing within the next 12 months that hedge foreign currency denominated sales over that same period will be reclassified from AOCI to Sales. The amount ultimately reclassified to Sales may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity.



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

## Investments in Debt and Equity Securities

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

(\$ in millions)	June 30, 2016				December 31, 2015			
	Fair Value	Amortized Cost	Gross Gains	Unrealized Losses	Fair Value	Amortized Cost	Gross Gains	Unrealized Losses
Corporate notes and bonds	\$10,640	\$ 10,552	\$ 92	\$ (4 )	\$10,259	\$ 10,299	\$ 7	\$ (47 )
U.S. government and agency securities	2,357	2,345	12	—	1,761	1,767	—	(6 )
Commercial paper	2,031	2,031	—	—	2,977	2,977	—	—
Asset-backed securities	1,402	1,398	5	(1 )	1,284	1,290	—	(6 )
Mortgage-backed securities	784	779	6	(1 )	694	697	1	(4 )
Foreign government bonds	511	508	3	—	607	586	22	(1 )
Equity securities	394	306	90	(2 )	534	409	125	—
	\$18,119	\$ 17,919	\$ 208	\$ (8 )	\$18,116	\$ 18,025	\$ 155	\$ (64 )

Available-for-sale debt securities included in Short-term investments totaled \$5.2 billion at June 30, 2016. Of the remaining debt securities, \$10.6 billion mature within five years. At June 30, 2016 and December 31, 2015, 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, 2016				December 31, 2015			
Assets								
Investments								
Corporate notes and bonds	\$—	\$ 10,505	\$ —	\$ 10,505	\$—	\$ 10,259	\$ —	\$ 10,259
Commercial paper	—	2,031	—	2,031	—	2,977	—	2,977
U.S. government and agency securities	32	1,792	—	1,824	—	1,761	—	1,761
Asset-backed securities <sup>(1)</sup>	—	1,296	—	1,296	—	1,284	—	1,284
Mortgage-backed securities <sup>(1)</sup>	—	700	—	700	—	694	—	694
Foreign government bonds	—	510	—	510	—	607	—	607
Equity securities	239	—	—	239	360	—	—	360
	271	16,834	—	17,105	360	17,582	—	17,942
Other assets <sup>(2)</sup>								
U.S. government and agency securities	—	533	—	533	—	—	—	—
Corporate notes and bonds	—	135	—	135	—	—	—	—
Asset-backed securities <sup>(1)</sup>	—	106	—	106	—	—	—	—
Mortgage-backed securities <sup>(1)</sup>	—	84	—	84	—	—	—	—
Foreign government bonds	—	1	—	1	—	—	—	—
Equity securities	155	—	—	155	155	19	—	174
	155	859	—	1,014	155	19	—	174
Derivative assets <sup>(3)</sup>								
Purchased currency options	—	548	—	548	—	1,041	—	1,041
Interest rate swaps	—	217	—	217	—	42	—	42
Forward exchange contracts	—	147	—	147	—	154	—	154
	—	912	—	912	—	1,237	—	1,237
Total assets	\$426	\$ 18,605	\$ —	\$ 19,031	\$515	\$ 18,838	\$ —	\$ 19,353
Liabilities								
Other liabilities								
Contingent consideration	\$—	\$ —	\$ 661	\$ 661	\$—	\$ —	\$ 590	\$ 590
Derivative liabilities <sup>(3)</sup>								
Forward exchange contracts	—	70	—	70	—	38	—	38
Written currency options	—	1	—	1	—	1	—	1
Interest rate swaps	—	—	—	—	—	24	—	24
	—	71	—	71	—	63	—	63
Total liabilities	\$—	\$ 71	\$ 661	\$ 732	\$—	\$ 63	\$ 590	\$ 653

<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 credit card, auto loan, and home equity 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 increase in investments included in Other assets reflects certain assets previously restricted for retiree benefits that became available to fund certain other health and welfare benefits during the second quarter of 2016 (see Note 11).

(3) The fair value determination of derivatives includes the impact of the credit risk of counterparties to the derivatives and the Company's own credit risk, the effects of which were not significant.

There were no transfers between Level 1 and Level 2 during the first six months of 2016. As of June 30, 2016, Cash and cash equivalents of \$6.6 billion included \$6.0 billion of cash equivalents (considered Level 2 in the fair value hierarchy).

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

## Contingent Consideration

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

	Six Months Ended June 30,	
(\$ in millions)	2016	2015
Fair value January 1	\$590	\$428
Changes in fair value <sup>(1)</sup>	19	76
Additions	77	123
Payments	(25 )	(50 )
Fair value June 30	\$661	\$577

<sup>(1)</sup> Recorded in Research and development expenses and Materials and production costs.

The Company recognized liabilities for contingent consideration related to the acquisition of IOmet in the first six months of 2016 and the acquisition of Cubist for the first six months of 2015, reflected as “Additions” in the table above (see Note 2). The payments of contingent consideration reflected in the table above for 2016 relate to the first commercial sale of Zerbaxa in the European Union and for 2015 relate to the first commercial sale of Zerbaxa in the United States.

## 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, 2016, was \$26.2 billion compared with a carrying value of \$24.3 billion and at December 31, 2015, was \$27.0 billion compared with a carrying value of \$26.4 billion. Fair value was estimated using recent observable market prices and would be considered Level 2 in the fair value hierarchy.

## Concentrations of Credit Risk

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

The majority of the Company’s accounts receivable arise from product sales in the United States and Europe and are primarily due from drug wholesalers and retailers, hospitals, government agencies, managed health care providers and pharmacy benefit managers. The Company monitors the financial performance and creditworthiness of its customers so that it can properly assess and respond to changes in their credit profile. The Company also continues to monitor 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, 2016, the Company’s total net accounts receivable outstanding for more than one year were approximately \$115 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, 2016 and December 31, 2015, the Company had received cash collateral of \$595 million and \$862 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, 2016 or December 31, 2015.



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

## 5. Inventories

Inventories consisted of:

(\$ in millions)	June 30, 2016	December 31, 2015
Finished goods	\$1,437	\$ 1,343
Raw materials and work in process	4,480	4,374
Supplies	169	168
Total (approximates current cost)	6,086	5,885
Increase to LIFO costs	357	384
	\$6,443	\$ 6,269

Recognized as:

Inventories	\$5,248	\$ 4,700
Other assets	1,195	1,569

Amounts recognized as Other assets are comprised almost entirely of raw materials and work in process inventories. At June 30, 2016 and December 31, 2015, these amounts included \$1.1 billion and \$1.5 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included \$69 million and \$63 million at June 30, 2016 and December 31, 2015, respectively, of inventories produced in preparation for product launches.

## 6. Other Intangibles

In connection with acquisitions, the Company measures the fair value of marketed products and research and development pipeline programs and capitalizes these amounts.

During the second quarter and first six months of 2016, the Company recorded \$95 million and \$347 million, respectively, of intangible asset impairment charges within Materials and production costs. During the second quarter of 2016, the Company wrote-off \$95 million that had been capitalized in connection with in-licensed products Grastek and Ragwitek, allergy immunotherapy tablets that, for business reasons, the Company has determined it will return to the licensor. The remaining \$252 million of impairment charges in the year-to-date period relate to Zontivity, a product marketed by the Company 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 relates to a charge for an in-licensed program for house dust mite allergies that, for business reasons, will be returned to the licensor. The remaining IPR&D impairment charges for the second quarter and first six months of 2016 primarily relate to deprioritized pipeline programs that were deemed to have no alternative use during the period, including a \$79 million impairment charge for MK-8342B, an investigational candidate for contraception. During the second quarter and first six months of 2015, the Company recorded \$59 million and \$61 million, respectively, of IPR&D impairment charges. Of these amounts, \$50 million relates to the surotomycin clinical development program obtained in connection with the acquisition of Cubist. During the second quarter of 2015, the Company received unfavorable efficacy data from a clinical trial for surotomycin. The evaluation of this data, combined with an assessment of the commercial opportunity of surotomycin, resulted in the IPR&D impairment charge noted above. The Company may recognize additional non-cash impairment charges in the future related to other marketed products or pipeline programs and such charges could be material.

## 7. Joint Ventures and Other Equity Method Affiliates

Equity income from affiliates reflects the performance of the Company's joint ventures and other equity method affiliates including Sanofi Pasteur MSD (SPMSD) and certain investment funds. Equity income from affiliates was \$4 million and \$2 million for the second quarter of 2016 and 2015, respectively, and \$38 million and \$147 million for the

first six months of 2016 and 2015, respectively, and is included in Other (income) expense, net (see Note 12).

**Sanofi Pasteur MSD**

In March 2016, Merck and Sanofi Pasteur announced their intention to end their joint vaccines operations in Europe. The joint venture SPMSD, owned equally by Sanofi Pasteur and Merck, was created in 1994 to develop and commercialize vaccines

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

originating from both companies' pipelines to improve and promote public health in 19 European countries. Sanofi Pasteur and Merck expect the project to be completed by the end of 2016, subject to local labor laws and regulations and regulatory approvals. Upon concluding the joint venture, Merck plans to integrate its European vaccine business into its operations, manage its product portfolio and pursue its growth strategy in Europe. Joint venture vaccine sales were \$202 million and \$175 million for the second quarter of 2016 and 2015, respectively, and were \$383 million and \$337 million for the first six months of 2016 and 2015, respectively.

#### AstraZeneca LP

In 1998, Merck and Astra completed the restructuring of the ownership and operations of their existing joint venture whereby Merck acquired Astra's interest in KBI Inc. (KBI) and contributed KBI's operating assets to a new U.S. limited partnership, Astra Pharmaceuticals L.P. (the Partnership). Astra contributed the net assets of its wholly owned subsidiary, Astra USA, Inc., to the Partnership. The Partnership, renamed AstraZeneca LP (AZLP) upon Astra's 1999 merger with Zeneca Group Plc, became the exclusive distributor of the products for which KBI retained rights. In connection with AstraZeneca's 2014 exercise of its option to purchase Merck's interest in KBI, the Company deferred \$327 million of the exercise price, which reflected an estimate of the fair value of Merck's interest in Nexium and Prilosec. This amount, which is subject to a true-up in 2018 based on actual sales from closing in 2014 to June 2018, was deferred and recognized over time in Other (income) expense, net as the contingency was eliminated as sales occurred. The deferred income amount has been fully amortized based on the sales performance of Nexium and Prilosec subsequent to the 2014 option exercise. Beginning in the first quarter of 2016, the Company is recognizing income and a corresponding receivable for amounts that will be due to Merck from AstraZeneca based on the sales performance of Nexium and Prilosec subject to the true-up in June 2018. The Company recognized \$54 million of such income in the first six months of 2016.

#### 8. Contingencies

The Company is involved in various claims and legal proceedings of a nature considered normal to its business, including product liability, intellectual property, and commercial litigation, as well as certain additional matters including 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.

#### Vioxx Litigation

##### Product Liability Lawsuits

As previously disclosed, Merck is a defendant in approximately 30 putative class action lawsuits alleging economic injury as a result of the purchase of Vioxx. All but one of those cases are coordinated in a multidistrict litigation in the U.S. District Court for the Eastern District of Louisiana (the Vioxx MDL) before Judge Eldon E. Fallon. Merck has reached a resolution, approved by Judge Fallon, of these class actions. Under the settlement, Merck will pay up to \$23 million to resolve all properly documented claims submitted by class members, approved attorneys' fees and expenses,

and approved settlement notice costs and certain other administrative expenses. The court entered an order approving the settlement in January 2014 and the claims review process was recently completed. Merck is also a defendant in lawsuits (together with the above-referenced lawsuits, the Vioxx Product Liability Lawsuits) brought by state Attorneys General of three states — Alaska, Montana and Utah. The lawsuits are pending in state courts. These

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

actions allege that Merck misrepresented the safety of Vioxx and seek recovery for expenditures on Vioxx by government-funded health care programs, such as Medicaid, and/or penalties for alleged Consumer Fraud Act violations. Trial has been scheduled in the Montana case for September 12, 2016, and trial has been set in the Alaska case for January 9, 2017. A motion for judgment on the pleadings in the Montana case is currently pending. Merck's motion to dismiss in Utah and motion for judgment on the pleadings in Alaska were both recently denied.

#### Shareholder Lawsuits

As previously disclosed, in addition to the Vioxx Product Liability Lawsuits, various putative class actions and individual lawsuits have been filed against Merck and certain former employees alleging that the defendants violated federal securities laws by making alleged material misstatements and omissions with respect to the cardiovascular safety of Vioxx (Vioxx Securities Lawsuits). The Vioxx Securities Lawsuits are coordinated in a multidistrict litigation in the U.S. District Court for the District of New Jersey before Judge Stanley R. Chesler. As previously disclosed, Merck has reached a resolution of the Vioxx securities class action for which a reserve was recorded in 2015 and under which Merck created a settlement fund in 2016 of \$830 million (the Settlement Class Fund) and agreed to pay an additional amount for approved attorneys' fees and expenses up to \$232 million (the Fee/Expense Fund). On June 28, 2016, the court approved the settlement and awarded attorneys' fees and expenses in the amount of \$222 million; the remaining amount of the Fee/Expense Fund will be added to the Settlement Class Fund. The Company paid the total settlement amount into escrow in April 2016. After available funds under certain insurance policies, Merck's net cash payment for the settlement and fees was approximately \$680 million. The settlement covers all claims relating to Vioxx by settlement class members who purchased Merck securities between May 21, 1999, and October 29, 2004. The settlement is not an admission of wrongdoing and, as part of the settlement agreement, defendants continue to deny the allegations.

In addition, Merck has reached a resolution of the above referenced 13 individual securities lawsuits filed by foreign and domestic institutional investors, which were also consolidated with the Vioxx Securities Lawsuits.

As a result of these settlements, Merck has resolved all of the Vioxx Securities Lawsuits.

#### Insurance

As a result of the previously disclosed insurance arbitration, the Company's insurers paid insurance proceeds of approximately \$380 million in connection with the settlement of the class action. The Company also has Directors and Officers insurance coverage applicable to the Vioxx Securities Lawsuits with remaining stated upper limits of approximately \$145 million, which the Company has not received. There are disputes with the insurers about the availability of the Company's Directors and Officers insurance coverage for these claims. The amounts actually recovered under the Directors and Officers policies discussed in this paragraph may be less than the stated upper limits.

#### International Lawsuits

As previously disclosed, in addition to the lawsuits discussed above, Merck has been named as a defendant in litigation relating to Vioxx in Brazil and Europe (collectively, the Vioxx International Lawsuits). The litigation in these jurisdictions is generally in procedural stages and Merck expects that the litigation may continue for a number of years.

#### Reserves

The Company has an immaterial reserve with respect to certain Vioxx Product Liability Lawsuits and also has an immaterial remaining reserve relating to the previously disclosed Vioxx litigation for the non-participating states with which litigation is continuing. The Company has established no other liability reserves for, and believes that it has meritorious defenses to, the remaining Vioxx Product Liability Lawsuits and Vioxx International Lawsuits and will vigorously defend against them.

#### Other 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, 2016, approximately 4,400 cases are filed and pending against Merck in either federal or state court, including one case which seeks class action certification, as well as damages and/or medical monitoring. In approximately 20 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 4,380 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.

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

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 claims of approximately 20 non-participants' will remain once the settlement is complete. The ONJ Master Settlement Agreement has no effect on the cases alleging Femur Fractures discussed below.

**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 (the Femur Fracture MDL). Judge Pisano presided over the Femur Fracture MDL until March 2015, at which time the Femur Fracture MDL was reassigned from Judge Pisano to Judge Freda L. Wolfson following Judge Pisano's retirement. In the only bellwether case tried to date in the Femur Fracture MDL, Glynn v. Merck, the jury returned a verdict in Merck's favor. In addition, in June 2013, the Femur Fracture MDL court granted Merck's motion for judgment as a matter of law in the Glynn case and held that the plaintiff's failure to warn claim was preempted by federal law.

In August 2013, the Femur Fracture MDL court entered an order requiring plaintiffs in the Femur Fracture MDL to show cause why those cases asserting claims for a femur fracture injury that took place prior to September 14, 2010, should not be dismissed based on the court's preemption decision in the Glynn case. Pursuant to the show cause order, in March 2014, the Femur Fracture MDL court dismissed with prejudice approximately 650 cases on preemption grounds. Plaintiffs in approximately 515 of those cases are appealing that decision to the U.S. Court of Appeals for the Third Circuit. In June 2015, the Femur Fracture MDL court dismissed without prejudice another approximately 520 cases pending plaintiffs' appeal of the preemption ruling to the Third Circuit. On June 30, 2016, the Third Circuit heard oral argument on plaintiffs' appeal of the preemption ruling and the parties await the decision.

In June 2014, Judge Pisano 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 have appealed Judge Pisano's decision to the Third Circuit. In August 2014, Merck filed a motion requesting that Judge Pisano 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.

As of June 30, 2016, approximately 20 cases were pending in the Femur Fracture MDL, excluding the 515 cases dismissed with prejudice on preemption grounds that are pending appeal and the 520 cases dismissed without prejudice that are also pending the aforementioned appeal.

As of June 30, 2016, approximately 3,020 cases alleging Femur Fractures have been filed in New Jersey state court and are pending before Judge Jessica Mayer 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 recently begun selecting the next group of cases to be reviewed through fact discovery.

As of June 30, 2016, approximately 295 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 has appealed that verdict to the California appellate court. 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.

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

**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, 2016, approximately 1,140 product user claims have been served on Merck 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). As of June 30, 2016, 12 product users have claims pending against Merck in state courts other than the 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 1,140 served product user claims, these rulings resulted in the dismissal of approximately 1,100 product user claims.

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

In addition to the claims noted above, the Company has agreed, as of June 30, 2016, to toll the statute of limitations for approximately 45 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, 2016, approximately 1,360 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 50 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 Mayer in Middlesex County. In addition, there is one matter pending in state court in Massachusetts and one matter pending in state court in New York. The Company intends to defend against these lawsuits.

**Governmental Proceedings**

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

**Patent Litigation**

From time to time, generic manufacturers of pharmaceutical products file Abbreviated New Drug Applications with the U.S. Food and Drug Administration (FDA) seeking to market generic forms of the Company’s products prior to the expiration of relevant patents owned by the Company. To protect its patent rights, the Company may file patent infringement lawsuits against such generic companies. 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: Cancidas, Cubicin, 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 generic 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.

**Cancidas** — In February 2014, a patent infringement lawsuit was filed in the United States against Xellia Pharmaceuticals ApS (Xellia) with respect to Xellia’s application to the FDA seeking pre-patent expiry approval to market a generic version of Cancidas. In June 2015, the district court found that Xellia infringed the Company’s patent

and ordered that Xellia's application not be approved until the patent expires in September 2017 (including pediatric exclusivity). Xellia appealed this decision, and the appeal was heard in March 2016. In May 2016, the parties reached a settlement whereby Xellia can launch its generic version in August 2017, or earlier under certain conditions. In August 2014, a patent infringement lawsuit was filed in the United States against Fresenius Kabi USA, LLC (Fresenius) in respect of Fresenius's application to the FDA seeking pre-patent expiry approval to market a generic version of Cancidas. The lawsuit automatically stays FDA approval of Fresenius's application until December 2016 or until an adverse court decision, if any, whichever may occur earlier.

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

**Cubicin** — In March 2012, a patent infringement lawsuit was filed in the United States against Hospira, Inc. (Hospira), with respect to Hospira's application to the FDA seeking pre-patent expiry approval to market a generic version of Cubicin. A trial was held in February 2014 and, in December 2014, the district court found the composition patent, which expired in June 2016, to be valid and infringed. Later patents, expiring in September 2019 and November 2020, were found to be invalid. Hospira appealed the finding that the composition patent is not invalid and the Company cross-appealed the finding that the later patents are invalid. In November 2015, the U.S. Court of Appeals for the Federal Circuit affirmed the lower court decision. In May 2016, the United States Supreme Court declined to review this decision. As of June 2016, there is no longer any patent impediment to the approval of Hospira's application. As a result of the Hospira decision and the expiration of the composition patent in June 2016, there is no longer any patent impediment to the approval of a number of generic manufacturers' applications to the FDA for generic versions of Cubicin.

**Invanz** — In July 2014, a patent infringement lawsuit was filed in the United States against Hospira in respect of Hospira's application to the FDA seeking pre-patent expiry approval to market a generic version of Invanz. The lawsuit automatically stays FDA approval of Hospira's application until November 2016 or until an adverse court decision, if any, whichever may occur earlier. The trial in this matter was held in April 2016 and the Company is awaiting the court's decision. 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 lawsuit automatically stays FDA approval of Teva Pharma's application until November 2016 or until an adverse court decision, if any, whichever may occur earlier. The trial in this matter was held in June 2016 and the Company is preparing post-trial submissions. 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 lawsuit automatically stays FDA approval of Amneal's application until August 2017 or until an adverse court decision, if any, whichever may occur earlier. The trial in this matter was held in June 2016 and the Company is preparing post-trial submissions.

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 application to the FDA seeking pre-patent expiry approval to market a generic version of Nasonex 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.

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. Since Par did not challenge an earlier expiring patent at issue in other pertinent litigation, if that patent is upheld, Par's application to the FDA will not be approved until at least that patent expires in July 2019. If that patent is not upheld, the lawsuit automatically stays FDA approval of Roxane's application until August 2018 or until an adverse court decision in this litigation, if any, whichever may occur earlier.

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 and the Company is awaiting the court's 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.

The Company had been involved in ongoing litigation in Canada with Apotex concerning the Company's patents related to lovastatin, alendronate, and norfloxacin. All of the litigation has now been either settled or concluded. As a consequence of the conclusion of all of this litigation, in the second quarter of 2016, the Company recorded a net gain of \$115 million included in Other (income) expense, net (see Note 12).

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

## 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. The Company believes that the '878 patent is invalid and filed an opposition in the European Patent Office (EPO) seeking its revocation. In June 2014, the Opposition Division of the EPO found the claims in the '878 patent are valid. The Company received the Opposition Division's written opinion in September 2014 and the Company submitted its substantive appeal in February 2015. In April 2014, the Company, and three other companies, opposed another European patent (EP 2 161 336) ('336) owned by BMS and Ono that it believes is invalid. The '336 patent, as granted, broadly claimed anti-PD-1 antibodies that could include Keytruda. In February 2015 and May 2016, BMS and Ono submitted requests to amend the claims of the '336 patent. During a hearing in July 2016, the EPO allowed the May 2016 amendment and, as a result, the claims of the '336 patent no longer broadly claim anti-PD-1 antibodies such as Keytruda.

In May 2014, the Company filed a lawsuit in the UK seeking revocation of the UK national versions of both the '878 and '336 patents. In July 2014, Ono and BMS sued the Company seeking a declaration that the '878 patent would be infringed in the UK by the marketing of Keytruda. The Company has sought a declaration from the UK court that Keytruda will not infringe the '336 patent in the UK. BMS and Ono notified the Company of their request to amend the claims of the EPO '336 patent and of their intention to seek permission from the court to similarly amend the UK national version so that the claims of the '336 patent would no longer broadly claim anti-PD-1 antibodies such as Keytruda. A trial was held in the UK in July 2015. At that trial, the issues of validity and infringement of the '878 patent were heard at the same time by the court. In October 2015, the court issued its judgment, finding the '878 patent valid and infringed. Merck appealed this judgment. The appeal is scheduled to be heard in March 2017. BMS and Ono have concurrently started a proceeding to determine the amount of damages and royalties the Company would pay should the appeal be denied. A hearing in that proceeding is scheduled for October 2017.

In February 2015, the Company filed lawsuits in the Netherlands seeking revocation of the Dutch national versions of both the '878 and '336 patents. BMS and Ono amended the claims of the '336 patent so that the claims of the '336 patent no longer broadly claim anti-PD-1 antibodies such as Keytruda. Trial regarding the validity and infringement of the '878 patent was held in January 2016. In June 2016, the District Court in The Hague issued its judgment finding the Dutch '878 patent valid and infringed. Merck will appeal this judgment.

In December 2015, BMS and Ono filed lawsuits against the Company in France, Ireland, Switzerland and Germany alleging infringement of the '878 patent. In January 2016, BMS and Ono filed a lawsuit against the Company in Spain alleging infringement of the '878 patent. In France, BMS and Ono filed for preliminary relief seeking payment of damages while the case is pending. A hearing on this preliminary relief was held in February 2016 and BMS's and Ono's request for preliminary relief was denied. Dates for trials regarding the validity and infringement of the Irish, French, Swiss and Spanish national versions of the '878 patent have not yet been scheduled. A trial concerning the infringement of the German version of the '878 patent is currently scheduled to begin in March 2017.

The Company continues to believe the '878 patent is invalid.

The Company can file lawsuits seeking revocation of the '878 patents in other national courts in Europe at any time, and Ono and BMS can file patent infringement actions against the Company in other national courts in Europe at or around the time the Company launches Keytruda. If a national court determines that the Company infringed a valid claim in the '878 patent, Ono and BMS may be entitled to monetary damages, including royalties on future sales of Keytruda, and potentially could seek an injunction to prevent the Company from marketing Keytruda in that country. The United States Patent and Trademark Office (USPTO) granted US Patent Nos. 8,728,474 to Ono and 8,779,105 to Ono and BMS in May 2014. These patents are equivalent to the '878 and '336 patents, respectively. In September 2014, BMS and Ono filed a lawsuit in the United States alleging that, by marketing Keytruda, the Company will infringe US Patent No. 8,728,474. BMS and Ono are not seeking to prevent or stop the marketing of Keytruda in the United States. The trial in this matter is currently scheduled to begin in April 2017. The Company believes that the 8,728,474 patent and the 8,779,105 patent are both invalid. In June 2015 and July 2015, Ono filed lawsuits in the United States alleging that, by marketing Keytruda, the Company will infringe US Patent Nos. 9,067,999 and 9,073,994, which are patents



related to the 8,728,474 patent. The Company believes the 9,067,999 and 9,073,994 patents are also invalid. In June 2016, the Company filed petitions for Inter Partes Review (IPR) in the USPTO alleging that the 9,067,999 and 9,073,994 patents are invalid.

In April 2016, the Company filed a declaratory judgment action in the United States against BMS and Ono seeking a ruling that US Patent Nos. 8,779,105 and 9,084,776 are invalid and/or not infringed by the sale of Keytruda. These patents are equivalents of the '336 patent, as originally granted. In June 2016, Ono and BMS filed a counterclaim that the Company's marketing, making, using, selling, offering for sale, and/or importing Keytruda in the United States for the treatment of certain cancers, including melanoma and non-small-cell lung cancer, infringes these patents.

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

In September 2014, the Company filed a lawsuit in Australia seeking revocation of Australian Patent No. 2011203119, which is equivalent to the '336 patent as originally granted. In March 2015, BMS and Ono counterclaimed in this matter alleging that the Company's manufacture and supply of Keytruda to the Australian market will infringe Australian Patent No. 2011203119. A trial on this patent is scheduled for September 2017. Ono and BMS have similar and other patents and applications, which the Company is closely monitoring, pending in the United States, Japan and other countries.

The Company is confident that it will be able to market Keytruda in any country in which it is approved and that it will not be prevented from doing so by the Ono or BMS patents or any pending applications.

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 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 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. The USPTO has six months to decide this petition.

#### Gilead Patent Litigation and Opposition

In August 2013, Gilead Sciences, Inc. (Gilead) filed a lawsuit in the United States 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, Solvadi 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 on August 4, 2016, and the Company is awaiting the court's decision.] The Company will pay 20%, net of legal fees, of damages or royalties, if any, that it is awarded to Ionis Pharmaceuticals, Inc.

The Company, through its Idenix Pharmaceuticals, Inc. subsidiary, has pending litigations 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 EPO. Trial in the United States is currently scheduled for October and December 2016. In the UK, Norway, Australia and Canada, the Company was initially unsuccessful and those cases are currently under appeal. The EPO opposition division revoked the European patent, and the Company is currently analyzing the decision and considering its options. 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, 2016 and December 31, 2015 of approximately \$235 million and \$245 million, respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue

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

to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

9. Equity

(\$ and shares in millions)	Common Stock		Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss		Treasury Stock Shares	Non-Controlling Interests	Total
	Share	Par Value			Loss	Cost			
Balance at January 1, 2015	3,577	\$ 1,788	\$40,423	\$46,021	\$ (4,323)	739	\$(35,262)	\$ 144	\$48,791
Net income attributable to Merck & Co., Inc.	—	—	—	1,639	—	—	—	—	1,639
Cash dividends declared on common stock	—	—	—	(2,557)	—	—	—	—	(2,557)
Treasury stock shares purchased	—	—	—	—	—	29	(1,724)	—	(1,724)
Share-based compensation plans and other	—	—	(317)	—	—	(15)	761	5	449
Other comprehensive loss	—	—	—	—	(9)	—	—	—	(9)
Changes in noncontrolling ownership interests	—	—	8	—	—	—	—	37	45
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	7	7
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(3)	(3)
Balance at June 30, 2015	3,577	\$ 1,788	\$40,114	\$45,103	\$ (4,332)	753	\$(36,225)	\$ 190	\$46,638
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
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
Other comprehensive income	—	—	—	—	62	—	—	—	62
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

10. Share-Based Compensation Plans

The Company has share-based compensation plans under which the Company grants restricted stock units (RSUs) and performance share units (PSUs) to certain management level employees. The Company also issues RSUs to employees of certain of the Company's equity method investees. 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,	
	2016	2015	2016	2015

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Pretax share-based compensation expense	\$80	\$83	\$148	\$146
Income tax benefit	(25 )	(26 )	(45 )	(45 )
Total share-based compensation expense, net of taxes	\$55	\$57	\$103	\$101

Amounts in the table above do not reflect share-based compensation costs to settle non-vested Cubist equity awards attributable to postcombination service that were recognized as transaction expense in 2015 (see Note 2).

During the first six months of 2016 and 2015, the Company granted 5 million RSUs with a weighted-average grant date fair value of \$54.54 per RSU and 4 million RSUs with a weighted-average grant date fair value of \$59.83 per RSU, respectively. During the first six months of 2016 and 2015, the Company granted 6 million stock options with a weighted-average exercise price of \$54.61 per option and 5 million stock options with a weighted-average exercise price of \$59.83 per option, respectively. The weighted-average fair value of options granted for the first six months of 2016 and 2015 was \$5.89 and \$6.47 per option, respectively, and was determined using the following assumptions:

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

	Six Months Ended June 30,	
	2016	2015
Expected dividend yield	3.8 %	4.1 %
Risk-free interest rate	1.4 %	1.7 %
Expected volatility	19.6%	19.9%
Expected life (years)	6.2	6.2

At June 30, 2016, there was \$603 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 2.3 years. For segment reporting, share-based compensation costs are unallocated expenses.

## 11. Pension and Other Postretirement Benefit Plans

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

(\$ in millions)	Three Months Ended June 30,				Six Months Ended June 30,			
	2016		2015		2016		2015	
	U.S.	International	U.S.	International	U.S.	International	U.S.	International
Service cost	\$73	\$ 62	\$83	\$ 63	\$146	\$ 120	\$165	\$ 129
Interest cost	113	52	109	51	226	105	218	104
Expected return on plan assets	(210)	(97 )	(206)	(94 )	(420 )	(193 )	(411 )	(191 )
Net amortization	15	18	43	26	30	37	85	53
Termination benefits	1	—	2	—	5	—	18	1
Curtailments	—	—	(2 )	—	—	1	(8 )	—
Settlements	—	—	—	1	—	—	—	2
	\$ (8 )	\$ 35	\$29	\$ 47	\$ (13 )	\$ 70	\$67	\$ 98

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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
	Service cost	\$13	\$19	\$27
Interest cost	21	27	42	55
Expected return on plan assets	(34 )	(36 )	(69 )	(72 )
Net amortization	(26 )	(15 )	(53 )	(30 )
Termination benefits	—	1	1	5
Curtailments	(1 )	(1 )	(2 )	(7 )
	\$(27)	\$(5)	\$(54)	\$(10)

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 and settlements were recorded on pension and other postretirement benefit plans as reflected in the tables above.

As a result of certain allowable administrative actions that occurred in June 2016, approximately \$990 million of other postretirement benefit plan assets are no longer restricted for retiree benefits and became available to fund certain other health and welfare benefits.



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

## 12. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

	Three Months Ended June 30,		Six Months Ended June 30,	
(\$ in millions)	2016	2015	2016	2015
Interest income	\$(78)	\$(71)	\$(157)	\$(146)
Interest expense	171	174	343	338
Exchange losses	37	716	76	810
Equity income from affiliates	(4 )	(2 )	(38 )	(147 )
Other, net	(107)	(78 )	(157 )	(62 )
	\$19	\$739	\$67	\$793

The higher exchange losses in 2015 compared with 2016 related to the Venezuelan Bolívar. During the second quarter of 2015, upon evaluation of evolving economic conditions in Venezuela and volatility in the country, the Company determined it was unlikely that all outstanding net monetary assets would be settled at the then official (CENCOEX) rate of 6.30 VEF (Bolívar Fuertes) per U.S. dollar. Accordingly, during the second quarter of 2015, the Company recorded a charge of \$715 million to devalue its net monetary assets in Venezuela to an amount that represented the Company's estimate of the U.S. dollar amount that would ultimately be collected. Since January 2010, Venezuela has been designated hyperinflationary and, as a result, local foreign operations are remeasured in U.S. dollars with the impact recorded in results of operations.

The decrease in equity income from affiliates in the first six months of 2016 as compared with the first six months of 2015 was driven primarily by lower equity income from certain research investment funds.

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 (see Note 8). Other, net in the first six months of 2015 includes an expense of \$78 million for a contribution of investments in equity securities to the Merck Foundation. Interest paid for the six months ended June 30, 2016 and 2015 was \$321 million and \$293 million, respectively.

## 13. Taxes on Income

The effective income tax rates of 19.6% and 14.7% for the second quarter of 2016 and 2015, respectively, and 25.2% and 24.8% for the first six months of 2016 and 2015, 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 2016 also reflect the beneficial impact of orphan drug federal income tax credits, primarily for Keytruda, recorded in the quarter. The effective income tax rates for the second quarter and first six months of 2015 reflect the favorable impact of a net benefit of \$370 million related to the settlement of certain federal income tax issues, as well as the unfavorable effect of non-tax deductible foreign exchange losses related to Venezuela (see Note 12) and a \$75 million out of period discrete adjustment related to deferred taxes associated with prior year restructuring activities. Management considered the discrete adjustment to be immaterial to current and prior period financial statements as reported.

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.





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

## 14. Earnings Per Share

The calculations of earnings per share are as follows:

(\$ and shares in millions except per share amounts)	Three Months Ended		Six Months Ended	
	June 30, 2016	June 30, 2015	June 30, 2016	June 30, 2015
Net income attributable to Merck & Co., Inc.	\$1,205	\$687	\$2,330	\$1,639
Average common shares outstanding	2,768	2,826	2,771	2,831
Common shares issuable <sup>(1)</sup>	21	24	21	25
Average common shares outstanding assuming dilution	2,789	2,850	2,792	2,856
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	\$0.44	\$0.24	\$0.84	\$0.58
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	\$0.43	\$0.24	\$0.83	\$0.57

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

For the three months ended June 30, 2016 and 2015, 13 million and 6 million, respectively, and for the first six months of 2016 and 2015, 12 million and 5 million, respectively, of common shares issuable under share-based compensation plans were excluded from the computation of earnings per common share assuming dilution because the effect would have been antidilutive.

## 15. Other Comprehensive Income (Loss)

Changes in AOCI by component are as follows:

(\$ in millions)	Three Months Ended June 30,				Accumulated Other Comprehensive Income (Loss)
	Derivatives	Investments	Employee Benefit Plans	Cumulative Translation Adjustment	
Balance April 1, 2015, net of taxes	\$782	\$ 157	\$(2,951)	\$(2,155)	\$(4,167)
Other comprehensive income (loss) before reclassification adjustments, pretax	(85)	6	9	(41)	(111)
Tax	30	(15)	(1)	24	38
Other comprehensive income (loss) before reclassification adjustments, net of taxes	(55)	(9)	8	(17)	(73)
Reclassification adjustments, pretax	(192)	(6)	54	—	(144)
Tax	71	1	(20)	—	52
Reclassification adjustments, net of taxes	(121)	(5)	34	—	(92)
Other comprehensive income (loss), net of taxes	(176)	(14)	42	(17)	(165)
Balance June 30, 2015, net of taxes	\$606	\$ 143	\$(2,909)	\$(2,172)	\$(4,332)
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)	(10)	7	—	(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

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Balance June 30, 2016, net of taxes	\$111	\$ 167	\$(2,543 )	\$(1,821 )	\$(4,086 )
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## Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

(\$ in millions)	Six Months Ended June 30,			Accumulated	
	Derivatives	Investments	Employee Benefit Plans	Cumulative Translation Adjustment	Other Comprehensive Income (Loss)
Balance January 1, 2015, net of taxes	\$530	\$ 111	\$ (2,986 )	\$ (1,978 )	\$ (4,323 )
Other comprehensive income (loss) before reclassification adjustments, pretax	480	99	15	(94 )	500
Tax	(168 )	(25 )	(4 )	(100 )	(297 )
Other comprehensive income (loss) before reclassification adjustments, net of taxes	312	74	11	(194 )	203
Reclassification adjustments, pretax	(363 ) <sup>(1)</sup>	(62 ) <sup>(2)</sup>	108 <sup>(3)</sup>	—	(317 )
Tax	127	20	(42 )	—	105
Reclassification adjustments, net of taxes	(236 )	(42 )	66	—	(212 )
Other comprehensive income (loss), net of taxes	76	32	77	(194 )	(9 )
Balance June 30, 2015, net of taxes	\$606	\$ 143	\$ (2,909 )	\$ (2,172 )	\$ (4,332 )
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 )

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

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

(3) Includes net amortization of prior service cost and actuarial gains and losses included in net periodic benefit cost (see Note 11).

#### 16. Segment Reporting

The Company's operations are principally managed on a products basis and include the Pharmaceutical, Animal Health, Alliances and Healthcare Services 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 marketed either directly by the Company or through joint ventures. 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 vaccines is sold to the U.S. Centers for Disease Control and Prevention Vaccines for Children program, which is funded by the U.S. government. Additionally, the Company sells vaccines to the Federal government for placement into vaccine stockpiles. The Company also has animal health operations that discover, develop, manufacture and market 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.

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## 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,	
	2016	2015	2016	2015
Primary Care and Women's Health				
Cardiovascular				
Zetia	\$702	\$635	\$1,314	\$1,202
Vytorin	293	320	570	640
Diabetes				
Januvia	1,064	1,044	1,970	1,928
Janumet	569	554	1,075	1,063
General Medicine and Women's Health				
NuvaRing	200	182	376	348
Implanon/Nexplanon	164	124	298	261
Dulera	121	120	234	251
Follistim AQ	73	111	167	193
Hospital and Specialty				
Hepatitis				
Zepatier	112	—	161	—
HIV				
Isentress	338	375	678	760
Hospital Acute Care				
Cubicin	357	293	649	480
Noxafil	143	117	288	228
Cancidas	131	134	263	297
Invanz	143	139	257	271
Bridion	113	87	204	172
Primaxin	81	88	154	153
Immunology				
Remicade	339	455	688	956
Simponi	199	169	387	327
Oncology				
Keytruda	314	110	563	192
Emend	143	134	268	255
Temodar	73	80	139	155
Diversified Brands				
Respiratory				
Singulair	229	212	465	457
Nasonex	101	215	331	504
Other				
Cozaar/Hyzaar	132	189	258	374
Arcoxia	117	115	228	238
Fosamax	73	96	148	190
Zocor	50	63	96	112
Vaccines <sup>(1)</sup>				
Gardasil/Gardasil 9	393	427	770	785
ProQuad/M-M-R II/Varivax	383	358	739	705
RotaTeq	130	89	318	281

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Zostavax	149	149	274	324
Pneumovax 23	120	106	228	216
Other pharmaceutical <sup>(2)</sup>	1,151	1,274	2,246	2,512
Total Pharmaceutical segment sales	8,700	8,564	16,804	16,830
Other segment sales <sup>(3)</sup>	979	911	1,883	1,839
Total segment sales	9,679	9,475	18,687	18,669
Other <sup>(4)</sup>	165	310	469	541
	\$9,844	\$9,785	\$19,156	\$19,210

(1) These amounts do not reflect sales of vaccines sold in most major European markets through the Company's joint venture, SPMSD, the results of which are reflected in equity income from affiliates which is included in Other (income) expense, net. These amounts do, however, reflect supply sales to SPMSD. In March 2016, Merck and Sanofi announced their intent to end the SPMSD joint venture (see Note 7).

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

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

(4) Other is primarily comprised of miscellaneous corporate revenues, including revenue hedging activities, as well as third-party manufacturing sales. Other in the first six months of 2016 also includes \$75 million related to the sale of the U.S. marketing rights to certain products (see Note 2).

## 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		Six Months Ended	
	June 30,		June 30,	
	2016	2015	2016	2015
Segment profits:				
Pharmaceutical segment	\$5,420	\$5,282	\$10,537	\$10,447
Other segments	424	407	809	847
Total segment profits	5,844	5,689	11,346	11,294
Other profits	93	226	320	378
Unallocated:				
Interest income	78	71	157	146
Interest expense	(171 )	(174 )	(343 )	(338 )
Equity income from affiliates	(6 )	(7 )	14	136
Depreciation and amortization	(438 )	(393 )	(864 )	(789 )
Research and development	(1,833 )	(1,460 )	(3,206 )	(3,020 )
Amortization of purchase accounting adjustments	(1,024 )	(1,238 )	(2,158 )	(2,476 )
Restructuring costs	(134 )	(191 )	(225 )	(273 )
Foreign currency devaluation related to Venezuela	—	(715 )	—	(715 )
Other unallocated, net	(905 )	(1,001 )	(1,913 )	(2,155 )
	\$1,504	\$807	\$3,128	\$2,188

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 product intangible asset impairment charges, gains or losses on sales of businesses and other miscellaneous income or expense items.



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

### Business Developments

In January 2016, Merck acquired IOmet Pharma Ltd, 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 (see Note 2 to the condensed consolidated financial statements). This transaction closed on January 11, 2016; accordingly, the results of the acquired business have been included in the Company's results of operations beginning after that date.

In June 2016, Merck and Moderna Therapeutics (Moderna) announced a strategic collaboration and license agreement to develop and commercialize novel messenger RNA (mRNA)-based personalized cancer vaccines (see Note 2 to the condensed consolidated financial statements).

In July 2016, Merck acquired Afferent Pharmaceuticals (Afferent), a privately held pharmaceutical company focused on the development of therapeutic candidates targeting the P2X3 receptor for the treatment of common, poorly-managed, neurogenic conditions (see Note 2 to the condensed consolidated financial statements). This transaction closed on July 26, 2016; accordingly, the results of the acquired business will be included in the Company's results of operations beginning after that date.

Also in July 2016, Merck acquired a majority ownership interest in The StayWell Company LLC (StayWell), a health engagement company that helps its clients engage and educate people to improve health and business results (see Note 2 to the condensed consolidated financial statements). This transaction closed on July 1, 2016; accordingly, the results of operations of the acquired business will be included in the Company's results of operations beginning after that date. Additionally in July 2016, Merck announced it had executed an agreement to acquire a controlling interest in Vallée S.A. (Vallée), a leading privately-held producer of animal health products in Brazil (see Note 2 to the condensed consolidated financial statements).

### Operating Results

#### Sales

Worldwide sales were \$9.8 billion for the second quarter of 2016, an increase of 1% compared with the second quarter of 2015. Foreign exchange unfavorably affected global sales performance by 2% in the second quarter of 2016, which includes a lower benefit from revenue hedging activities as compared with the second quarter of 2015. Sales growth was driven primarily by higher sales of Keytruda (pembrolizumab), Zepatier (elbasvir and grazoprevir), Zetia (ezetimibe), Cubicin (daptomycin for injection), RotaTeq (Rotavirus Vaccine, Live Oral, Pentavalent), Varivax (Varicella Virus Vaccine Live), Implanon/Nexplanon (etonogestrel implant), Januvia (sitagliptin) and Janumet (sitagliptin and metformin HCl), Adempas (riociguat), Simponi (golimumab), as well as higher sales of Animal Health products. Largely offsetting revenue growth in the second quarter were declines in Remicade (infliximab), Nasonex (mometasone furoate monohydrate), Cozaar (losartan potassium) and Hyzaar (losartan potassium and hydrochlorothiazide), Follistim AQ (follitropin beta injection), Isentress (raltegravir), PegIntron (peginterferon alpha-2b), and Gardasil (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant)/Gardasil 9 (Human Papillomavirus 9-valent Vaccine, Recombinant). Sales performance in the second quarter of 2016 reflects a decline of approximately \$210 million due to reduced operations in Venezuela.

Worldwide sales were \$19.2 billion for the first six months of 2016, essentially flat as compared with the first six months of 2015. Foreign exchange unfavorably affected global sales performance by 3% in the first six months of 2016, which includes a lower benefit from revenue hedging activities as compared with the first six months of 2015. Excluding the unfavorable effect of foreign exchange, sales performance reflects higher sales of Keytruda, Zepatier, Zetia, Adempas, Simponi, Noxafil (posaconazole), Januvia and Janumet and Varivax, as well as higher sales of Animal Health products. Revenue in the first six months of 2016 benefited from approximately one month of additional sales for products acquired in connection with the January 2015 acquisition of Cubist Pharmaceuticals, Inc. (Cubist). In addition, the Company recognized revenue of \$75 million in the first six months of 2016 in connection with the sale of the U.S. marketing rights to certain products. Offsetting revenue growth in the first six months of 2016 were declines in Remicade, Nasonex, Cozaar and Hyzaar, Isentress, PegIntron, and Zostavax (Zoster Vaccine Live). Sales performance in the first six months of 2016 reflects a decline of approximately \$450 million due to reduced

operations in Venezuela.

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access worldwide. In the United States, health care reform is contributing to an increase in the number of patients in the Medicaid program under which sales of pharmaceutical products are subject to substantial rebates. In many 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 2016. The Company anticipates these pricing actions, including the biennial price reductions in Japan, and other austerity measures will continue to negatively affect revenue performance for the remainder of 2016.

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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,	
	2016	2015	2016	2015
Primary Care and Women's Health				
Cardiovascular				
Zetia	\$702	\$635	\$1,314	\$1,202
Vytorin	293	320	570	640
Diabetes				
Januvia	1,064	1,044	1,970	1,928
Janumet	569	554	1,075	1,063
General Medicine and Women's Health				
NuvaRing	200	182	376	348
Implanon/Nexplanon	164	124	298	261
Dulera	121	120	234	251
Follistim AQ	73	111	167	193
Hospital and Specialty				
Hepatitis				
Zepatier	112	—	161	—
HIV				
Isentress	338	375	678	760
Hospital Acute Care				
Cubicin	357	293	649	480
Noxafil	143	117	288	228
Cancidas	131	134	263	297
Invanz	143	139	257	271
Bridion	113	87	204	172
Primaxin	81	88	154	153
Immunology				
Remicade	339	455	688	956
Simponi	199	169	387	327
Oncology				
Keytruda	314	110	563	192
Emend	143	134	268	255
Temodar	73	80	139	155
Diversified Brands				
Respiratory				
Singulair	229	212	465	457
Nasonex	101	215	331	504
Other				
Cozaar/Hyzaar	132	189	258	374
Arcoxia	117	115	228	238
Fosamax	73	96	148	190
Zocor	50	63	96	112
Vaccines <sup>(1)</sup>				
Gardasil/Gardasil 9	393	427	770	785

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ProQuad/M-M-R II/Varivax	383	358	739	705
RotaTeq	130	89	318	281
Zostavax	149	149	274	324
Pneumovax 23	120	106	228	216
Other pharmaceutical <sup>(2)</sup>	1,151	1,274	2,246	2,512
Total Pharmaceutical segment sales	8,700	8,564	16,804	16,830
Other segment sales <sup>(3)</sup>	979	911	1,883	1,839
Total segment sales	9,679	9,475	18,687	18,669
Other <sup>(4)</sup>	165	310	469	541
	\$9,844	\$9,785	\$19,156	\$19,210

These amounts do not reflect sales of vaccines sold in most major European markets through the Company's joint venture, Sanofi Pasteur MSD (SPMSD), the results of which are reflected in equity income from affiliates which is

- (1) included in Other (income) expense, net. These amounts do, however, reflect supply sales to SPMSD. In March 2016, Merck and Sanofi announced their intent to end the SPMSD joint venture (see "Selected Joint Venture and Affiliate Information" below).
- (2) Other pharmaceutical primarily reflects sales of other human health pharmaceutical products, including products within the franchises not listed separately.
- (3) Represents the non-reportable segments of Animal Health, Healthcare Services and Alliances.

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

(4) third-party manufacturing sales. Other in the first six months of 2016 also includes \$75 million related to the sale of the U.S. marketing rights to certain products (see Note 2 to the condensed consolidated financial statements).

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 sales by \$2.3 billion and \$2.0 billion for the three months ended June 30, 2016 and 2015, respectively, and by \$4.5 billion and \$3.7 billion for the first six months of 2016 and 2015, 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) and Vytorin (ezetimibe and simvastatin) (marketed outside the United States as Inegy), medicines for lowering LDL cholesterol, were \$994 million in the second quarter of 2016, growth of 4% compared with the second quarter of 2015. Combined worldwide sales of Zetia and Vytorin were \$1.9 billion in the first six months of 2016, an increase of 2% compared with the same period in 2015 including a 2% unfavorable effect from foreign exchange. In addition, in the second quarter and first six months of 2016, the Company recorded \$33 million and \$56 million, respectively, of sales of Atozet (ezetimibe and atorvastatin), which the Company markets in certain countries outside of the United States. Sales of the ezetimibe family (including Atozet) were \$1.0 billion in the second quarter of 2016, growth of 7% compared with the second quarter of 2015, and were \$1.9 billion for the first six months of 2016, growth of 5% compared with the same period of 2015 including a 2% unfavorable effect from foreign exchange. Growth in both periods reflects higher pricing in the United States, as well as volume growth in Europe, partially offset by lower volumes in the United States and lower sales in Venezuela due to reduced operations in this country.

By agreement, a generic manufacturer may launch a generic version of Zetia in the United States in December 2016 and the Company anticipates a substantial decline in U.S. Zetia sales thereafter. Sales of Zetia in the United States were \$843 million for the first six months of 2016. The U.S. patent and exclusivity periods for Zetia and Vytorin otherwise expire in April 2017. The Company has market exclusivity for Ezetrol in major European markets until October 2017; however, the Company expects to apply for pediatric extensions to the term which would extend the date to April 2018. The Company has market exclusivity for Inegy in those markets until April 2019.

In October 2014, Merck and Bayer AG (Bayer) announced a collaboration to market and develop novel therapies for cardiovascular disease. Pursuant to that collaboration, in January 2016, Merck began promoting and distributing Adempas, a novel cardiovascular drug for the treatment of pulmonary hypertension, in Europe. Transition in other Merck territories will occur later in 2016 and 2017. Under the terms of the agreement with Bayer, Merck has lead commercial rights in countries outside the Americas while Bayer continues to have lead rights in the Americas, including the United States. Merck recorded sales of \$40 million and \$72 million for Adempas in the second quarter and first six months of 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.

In March 2016, following several business decisions that reduced sales expectations for Zontivity (vorapaxar) in the United States and Europe, the Company lowered its cash flow projections for Zontivity. Zontivity is approved in the United States for the reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction or with peripheral arterial disease. The Company has determined it will no longer promote Zontivity in the United States. Zontivity was approved by the European Commission (EC) in January 2015 for coadministration with acetylsalicylic acid and, where appropriate, clopidogrel, to reduce atherothrombotic events in adult patients with a history of myocardial infarction. 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 an impairment charge of \$252 million recorded in Materials and production costs in the first six months of 2016. The remaining intangible asset value for Zontivity was \$32 million at June 30, 2016.

##### Diabetes

Worldwide combined sales of Januvia and Janumet, medicines that help lower blood sugar levels in adults with type 2 diabetes, were \$1.6 billion in the second quarter of 2016 and \$3.0 billion for the first six months of 2016, increases of 2% compared with the same periods of 2015. Foreign exchange unfavorably affected global sales performance by 1% in the first six months of 2016. Sales growth was driven primarily by higher volumes in the United States and Europe, partially offset by lower pricing in the United States and lower sales in Venezuela due to the Company's reduced operations in that country.

**General Medicine and Women's Health**

Worldwide sales of NuvaRing (etonogestrel/ethinyl estradiol vaginal ring), a vaginal contraceptive product, increased 10% in the second quarter of 2016 to \$200 million and grew 8% in the first six months of 2016 to \$376 million compared with

the same periods of 2015, primarily reflecting higher pricing in the United States. Foreign exchange unfavorably affected global sales performance by 2% in the first six months of 2016.

Worldwide sales of Implanon/Nexplanon, single-rod subdermal contraceptive implants, grew 32% to \$164 million in the second quarter of 2016 and increased 14% to \$298 million in the first six months of 2016 compared with the same periods of 2015 driven primarily by higher demand and higher pricing in the United States. Foreign exchange unfavorably affected global sales performance by 3% for both the second quarter and first six months of 2016.

Global sales of Dulera Inhalation Aerosol (mometasone furoate/formoterol fumarate dihydrate), a combination medicine for the treatment of asthma, increased 1% to \$121 million in the second quarter of 2016. Worldwide sales of Dulera Inhalation Aerosol declined 7% to \$234 million in the first six months of 2016 compared with the same period of 2015 driven by lower sales in the United States reflecting competitive pricing pressures that were partially offset by higher demand.

Global sales of Follistim AQ (marketed in most countries outside the United States as Puregon), a fertility treatment, were \$73 million in the second quarter of 2016, a decline of 35% compared with the second quarter of 2015 and were \$167 million in the first six months of 2016, a decrease of 13% compared with the same period of 2015. The sales decline in both periods primarily reflects lower volumes in the United States due to a supply issue. Foreign exchange unfavorably affected global sales performance by 2% in both the second quarter and first six months of 2016.

In the second quarter of 2016, the Company determined that, for business reasons, it would terminate the North America partnership agreement with ALK-Abelló (ALK) that included both Grastek (Timothy Grass Pollen Allergen Extract) and Ragwitek (Short Ragweed Pollen Allergen Extract) allergy immunotherapy tablets for sublingual use. This decision was not due to efficacy or safety concerns for the tablets. Merck has provided ALK with six months' notice that it is terminating the agreement and therefore these compounds will be returned to ALK. In connection with this decision, the Company wrote-off amounts capitalized in connection with the assets (see Note 6 to the condensed consolidated financial statements).

#### Hospital and Specialty

##### Hepatitis

In January 2016, the Food and Drug Administration (FDA) approved Zepatier for the treatment of adult patients with chronic hepatitis C virus (HCV) genotype (GT) 1 or GT4 infection, with or without ribavirin. Zepatier is a once-daily, fixed-dose combination tablet containing the NS5A inhibitor elbasvir (50 mg) and the NS3/4A protease inhibitor grazoprevir (100 mg). Zepatier became available in the United States in February 2016. Sales of Zepatier were \$112 million and \$161 million in the second quarter and first six months of 2016, respectively.

In July 2016, the EC approved Zepatier for the treatment of chronic HCV in adult patients, allowing marketing of Zepatier in all 28 European Union (EU) member states. The Company is working to supply the EU market, with product launches estimated to begin between the fourth quarter of 2016 and the first quarter of 2017. In the course of the European review for Zepatier, the European Medicines Agency (EMA) cited Merck's third-party manufacturer for issues largely related to inadequate record-keeping and the need for improvement in their quality management systems. The Company is working with regulators and the manufacturer to resolve these issues as quickly as possible. The Company does not believe that the problems identified at its third-party manufacturer affect the safety, efficacy, or quality specifications of the product. The Company does not believe that these problems will affect the supply to the U.S. market.

##### HIV

Global sales of Isentress, an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection, were \$338 million in the second quarter of 2016 and \$678 million for the first six months of 2016, declines of 10% and 11%, respectively, compared with the same periods of 2015. Foreign exchange unfavorably affected global sales performance by 1% and 2% in the second quarter and first six months of 2016, respectively. The sales declines were driven primarily by lower volumes in the United States, as well as lower demand and pricing in Europe due to competitive pressures, partially offset by higher volumes in certain emerging markets.

##### Hospital Acute Care

Sales of Cubicin, an I.V. antibiotic for complicated skin and skin structure infections or bacteremia when caused by designated susceptible organisms, were \$357 million in the second quarter of 2016, an increase of 22% compared with the second quarter of 2015 driven primarily by higher sales in the United States due to pricing. Additionally, sales growth reflects sales of Cubicin in certain international markets for which the Company acquired marketing rights in the fourth quarter of 2015 (including Europe, Latin America, Australia, New Zealand, China, South Africa and certain other Asia Pacific countries). Sales of Cubicin were \$649 million in the first six months of 2016 compared with \$480 million in the first six months of 2015. Cubicin was acquired with the purchase of Cubist on January 21, 2015. Accordingly, the increase in sales in the first six months of 2016 compared with the first six months of 2015 is largely attributable to nearly one month of additional sales in 2016. The U.S. composition patent



for Cubicin expired in June 2016 and the Company anticipates a significant decline in U.S. Cubicin sales. U.S. sales of Cubicin were \$559 million for the first six months of 2016.

Worldwide sales of Noxafil, for the prevention of invasive fungal infections, grew 22% in the second quarter of 2016 to \$143 million and increased 26% in the first six months of 2016 to \$288 million compared with the same periods of 2015. Sales growth in both periods was driven primarily by pricing in the United States, as well as volume growth in Europe reflecting an ongoing positive impact from the approval of new formulations and higher demand in emerging markets. Foreign exchange unfavorably affected global sales performance by 1% and 3% in the second quarter and first six months of 2016, respectively.

Global sales of Cancidas (caspofungin acetate), an anti-fungal product, were \$131 million in the second quarter of 2016, a 2% decline compared with the second quarter of 2015 including a 1% unfavorable effect from foreign exchange. Worldwide sales of Cancidas were \$263 million for the first six months of 2016, a decline of 11% compared with the same prior year period, including a 4% unfavorable effect from foreign exchange. The sales decline in the year-to-date period was driven primarily by lower volumes in certain emerging markets, as well as lower volumes and pricing in Europe.

Worldwide sales of Bridion (sugammadex) Injection, for the reversal of two types of neuromuscular blocking agents used during surgery, were \$113 million in the second quarter of 2016, an increase of 30% compared with the second quarter of 2015 including a 1% favorable effect from foreign exchange. Global sales of Bridion were \$204 million for the first six months of 2016, an increase of 18% compared with the same period of 2015 including a 3% unfavorable effect from foreign exchange. Sales performance in both periods reflects volume growth in most markets, including in the United States where it was approved by the FDA in December 2015 for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery.

#### Immunology

Sales of Remicade, a treatment for inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were \$339 million in the second quarter of 2016 and \$688 million for the first six months of 2016, declines of 26% and 28%, respectively, compared with the same periods of 2015. Foreign exchange unfavorably affected sales performance by 2% in the first six months of 2016. In February 2015, the Company lost market exclusivity for Remicade in major European markets 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. The Company expects the Remicade sales decline to accelerate throughout 2016.

Sales of Simponi, 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 2016 and \$387 million for the first six months of 2016, growth of 18% and 19%, respectively, compared with the same periods in 2015. Foreign exchange favorably affected sales performance by 2% in the second quarter and unfavorably affected sales performance by 3% for first six months of 2016. Sales growth in both periods was driven primarily by higher volumes in Europe reflecting in part an ongoing positive impact from the ulcerative colitis indication.

#### Other

Other products contained in Hospital and Specialty include among others, Invanz (ertapenem sodium) for the treatment of certain infections; and Primaxin (imipenem and cilastatin sodium), an anti-bacterial product.

#### Oncology

Sales of Keytruda, an anti-PD-1 (programmed death receptor-1) therapy, were \$314 million in the second quarter of 2016 compared with \$110 million in the second quarter of 2015 and were \$563 million for the first six months of 2016 compared with \$192 million for the first six months of 2015. Sales growth in both periods primarily reflects higher sales in Europe, the United States and emerging markets as the Company continues to launch Keytruda. In September 2014, the FDA granted accelerated approval of Keytruda at a dose of 2 mg/kg every three weeks for the treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor. In December 2015, the Company announced that the FDA approved an expanded indication for Keytruda to include the first-line treatment of patients with unresectable or metastatic melanoma regardless of BRAF status. Additionally, the FDA approved an update to the product labeling for Keytruda

for the treatment of patients with ipilimumab-refractory advanced melanoma. In July 2015, Merck announced that the EC approved Keytruda for the treatment of advanced (unresectable or metastatic) melanoma in adults.

In addition, in October 2015, the FDA granted accelerated approval of Keytruda at a dose of 2 mg/kg every three weeks for the treatment of patients with metastatic non-small-cell lung cancer (NSCLC) whose tumors express PD-L1 as determined by an FDA-approved test and who have disease progression on or after platinum-containing chemotherapy across both squamous and non-squamous metastatic NSCLC. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Keytruda. In addition to approving Keytruda for NSCLC, the FDA approved the first companion diagnostic that will enable physicians to determine the level of PD-L1 expression in a patient's tumor.

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The Company has made additional regulatory filings in the United States and other countries and further filings are planned. The Keytruda clinical development program includes studies across a broad range of cancer types (see “Research and Development” below). See Note 8 to the condensed consolidated financial statements for a discussion of patent litigation related to Keytruda.

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 2016, an increase of 7% compared with the second quarter of 2015 including a 1% unfavorable effect from foreign exchange. Worldwide sales of Emend were \$268 million in the first six months of 2016, growth of 5% compared with the first six months of 2015 including a 3% unfavorable effect from foreign exchange. Sales growth in both periods reflects higher pricing in the United States, partially offset by volume declines in Japan reflecting timing of shipments. In February 2016, Merck announced that the FDA approved a supplemental new drug application for single-dose Emend for injection for the prevention of delayed nausea and vomiting in adults receiving initial and repeat courses of moderately emetogenic chemotherapy. With this approval, Emend for injection is the first intravenous single-dose NK1 receptor antagonist approved in the United States for both highly emetogenic chemotherapy as well as moderately emetogenic chemotherapy.

Other products contained in Oncology include among others, Temodar (temozolomide) (marketed as Temodal outside the United States), a treatment for certain types of brain tumors.

#### 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 (montelukast), a once-a-day oral medicine for the chronic treatment of asthma and for the relief of symptoms of allergic rhinitis, were \$229 million in the second quarter of 2016, an increase of 8% compared with the second quarter of 2015 and were \$465 million for the first six months of 2016, an increase of 2% compared with the first six months of 2016. The increase in both periods reflects higher sales in Japan. Foreign exchange favorably affected global sales performance by 1% in the second quarter of 2016. The Company has lost market exclusivity for Singulair in the United States and in most major international markets with the exception of Japan and expects generic competition in these markets to continue. The patent that provides market exclusivity for Singulair in Japan will expire in 2016 and the Company anticipates significant losses of Singulair sales in Japan thereafter. Singulair sales in Japan were \$229 million in the first six months of 2016.

Global sales of Nasonex, an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, declined 53% to \$101 million in the second quarter of 2016 and decreased 34% to \$331 million in the first six months of 2016 compared with the same periods of 2015. Foreign exchange unfavorably affected global sales performance by 1% in both the second quarter and first six months of 2016. The declines were driven primarily by lower volumes in the United States from generic competition. In March 2016, Apotex launched a generic version of Nasonex in the United States pursuant to a June 2012 U.S. District Court for the District of New Jersey ruling (upheld on appeal to the U.S. court of Appeals for the Federal Circuit) holding that Apotex’s generic version of Nasonex does not infringe on the Company’s formulation patent. Accordingly, the Company is experiencing a substantial decline in U.S. Nasonex sales and expects the decline to continue. The declines in global Nasonex sales in the second quarter and first six months of 2016 were also driven by lower volumes and pricing in Europe from ongoing generic erosion and lower sales in Venezuela due to reduced operations by the Company in this country.

#### Other

Global sales of Cozaar and its companion agent Hyzaar (a combination of Cozaar and hydrochlorothiazide), treatments for hypertension, were \$132 million in the second quarter of 2016 and \$258 million for the first six months of 2016, declines of 30% and 31%, respectively, compared with the same periods of 2015. Foreign exchange unfavorably affected global sales performance by 1% and 6% in the second quarter and first six months of 2016, respectively. The sales declines primarily reflect lower sales in emerging markets, particularly Venezuela due to reduced operations by the Company in this country, as well as lower volumes in Japan. The patents that provided

market exclusivity for Cozaar and Hyzaar in the United States and in most major international markets have expired. Accordingly, the Company is experiencing declines in Cozaar and Hyzaar sales and expects the declines to continue. Other products contained in Diversified Brands include among others, Arcoxia (etoricoxib) for the treatment of arthritis and pain; Fosamax (alendronate sodium) (marketed as Fosamac in Japan) and Fosamax Plus D (alendronate sodium/cholecalciferol) (marketed as Fosavance throughout the EU) for the treatment and, in the case of Fosamax, prevention of osteoporosis; and Zocor (simvastatin), a statin for modifying cholesterol.

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## Vaccines

The following discussion of vaccines does not include sales of vaccines sold in most major European markets through Sanofi Pasteur MSD (SPMSD), the Company's joint venture with Sanofi Pasteur, the results of which are reflected in equity income from affiliates included in Other (income) expense, net (see "Selected Joint Venture and Affiliate Information" below). Supply sales to SPMSD, however, are included. In March 2016, Merck and Sanofi Pasteur announced their intention to terminate SPMSD and end their joint vaccines operations in Europe (see Note 7 to the condensed consolidated financial statements).

Merck's sales of Gardasil/Gardasil 9, vaccines to help prevent certain diseases caused by certain types of human papillomavirus (HPV), declined 8% in the second quarter of 2016 to \$393 million and decreased 2% in the first six months of 2016 to \$770 million compared with the prior year periods driven by the timing of public sector purchases in the United States and government tenders in Brazil, partially offset by higher pricing in the United States. Foreign exchange unfavorably affected global sales performance by 1% in both the second quarter and first six months of 2016.

Merck's sales of ProQuad, a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, were \$117 million in the second quarter of 2016 compared with \$136 million in the second quarter of 2015 and were \$239 million in the first six months of 2016 compared with \$221 million in the first six months of 2015 driven primarily by the effects of public sector purchasing in the United States. In addition, sales in the first six months of 2016 benefited from \$29 million of sales to the U.S. Centers for Disease Control and Prevention Pediatric Vaccine Stockpile. Merck's sales of M M R II, a vaccine to help protect against measles, mumps and rubella, were \$78 million for the second quarter of 2016 compared with \$75 million for the second quarter of 2015 and were \$154 million for the first six months of 2016 compared with \$182 million for the first six months of 2015. The sales decline in the year-to-date period largely reflects higher demand in the prior year due to measles outbreaks in the United States. Merck's sales of Varivax, a vaccine to help prevent chickenpox (varicella), were \$188 million for the second quarter of 2016 compared with \$147 million for the second quarter of 2015 and were \$346 million for the first six months of 2016 compared with \$302 million in the first six months of 2015. Sales performance reflects the effects of public sector purchasing in the United States.

Merck's sales of RotaTeq, a vaccine to help protect against rotavirus gastroenteritis in infants and children, were \$130 million in the second quarter of 2016, an increase of 46% compared with the second quarter of 2015 including a 2% unfavorable effect from foreign exchange. Merck's sales of RotaTeq were \$318 million in the first six months of 2016, growth of 13% compared with the same period of 2015 including a 1% unfavorable effect from foreign exchange. The higher sales in both periods were primarily driven by the effects of public sector purchasing in the United States.

Merck's sales of Zostavax, a vaccine to help prevent shingles (herpes zoster) in adults 50 years of age and older, were \$149 million in the second quarter of 2016, essentially flat as compared with the first quarter of 2015. Merck's sales of Zostavax were \$274 million for the first six months of 2016, a decline of 15% compared with the first six months of 2015 including a 1% unfavorable effect from foreign exchange. The sales decline in the year-to-date period was driven by lower volumes in the United States, as well as in Canada. The Company is continuing to educate U.S. customers on the broad managed care coverage for Zostavax and the process for obtaining reimbursement. Merck is continuing to launch Zostavax outside of the United States.

Merck's sales of Pneumovax 23 (pneumococcal vaccine polyvalent), a vaccine to help prevent pneumococcal disease, grew 14% in the second quarter of 2016 to \$120 million reflecting higher sales in the United States, Japan and certain emerging markets. Foreign exchange favorably affected global sales performance by 1% in the second quarter of 2016. Merck's sales of Pneumovax 23 increased 5% in the first six months of 2016 to \$228 million. Sales growth primarily reflects higher volumes in certain emerging markets.

## 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 \$898 million for the second quarter of 2016, an increase of 7% compared with the second quarter of 2015 including a 3% unfavorable effect from foreign exchange. Sales of Animal Health products were \$1.7 billion in the first six months of 2016, an increase of 4% compared with the same period of 2015 including a 6% unfavorable effect from foreign exchange. Sales performance in both periods reflects volume growth across most species areas, particularly in products for companion animal, driven primarily by higher sales of Bravecto (fluralaner) chewable tablets for dogs to treat fleas and ticks.

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In May 2016, the Company received marketing approval from the EMA for Bravecto Spot-On Solution for cats and dogs, and in July 2016, the Company received approval in the United States to market the product under the tradename Bravecto Topical (fluralaner topical solution).

In July 2016, Merck announced it had executed an agreement to acquire a controlling interest in Vallée, a leading privately held producer of animal health products in Brazil (see Note 2 to the condensed consolidated financial statements).

#### Costs, Expenses and Other

##### Materials and Production

Materials and production costs were \$3.6 billion for the second quarter of 2016 and \$7.2 billion for the first six months of 2016, declines of 5% and 2%, respectively, compared with the same periods of 2015. Costs in the second quarter of 2016 and 2015 include \$1.0 billion and \$1.2 billion, respectively, and for the first six months of 2016 and 2015 include \$2.1 billion and \$2.4 billion, respectively, of expenses for the amortization of intangible assets recognized in connection with business acquisitions. Costs also include intangible asset impairment charges of \$95 million and \$347 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 on intangible assets related to marketed products that were measured at fair value and capitalized in connection with business acquisitions and such charges could be material. Additionally, in the second quarter of 2016, the Company recorded \$50 million of cumulative amortization related to amounts capitalized in connection with the recognition of a liability for potential future milestone payments (see Note 2 to the condensed consolidated financial statements). In addition, expenses for the second quarter and first six months of 2015 include \$44 million and \$65 million, respectively, of amortization of purchase accounting adjustments to Cubist's inventories. Included in materials and production costs are costs associated with restructuring activities which amounted to \$66 million and \$105 million in the second quarter of 2016 and 2015, respectively, and \$113 million and \$210 million for the first six months of 2016 and 2015, 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 63.7% in the second quarter of 2016 compared with 61.6% in the second quarter of 2015 and was 62.7% in the first six months of 2016 compared with 61.9% in the first six months of 2015. The amortization of intangible assets and purchase accounting adjustments to inventories, as well as the restructuring and impairment charges noted above reduced gross margin by 12.0 and 13.8 percentage points for the second quarter of 2016 and 2015, respectively, and by 13.6 and 14.0 percentage points for the first six months of 2016 and 2015, respectively. Excluding the impact of these items, the increases in gross margin in the second quarter and first six months of 2016 compared with the corresponding prior year periods were driven primarily by the favorable effects of foreign exchange and product mix, partially offset by the cumulative amortization recorded in the second quarter related to potential future milestone payments. Additionally, the increase in the year-to-date period reflects lower inventory write-offs.

##### Marketing and Administrative

Marketing and administrative expenses decreased 6% to \$2.5 billion in the second quarter of 2016 and declined 9% to \$4.8 billion in the first six months of 2016 compared with the same periods of 2015. The declines largely reflect lower acquisition and divestiture-related costs, the favorable effects of foreign exchange, lower administrative costs, such as legal defense costs, as well as lower selling costs. These declines were partially offset by higher restructuring costs and, for the year-to-date period, higher promotional spending largely related to product launches. Marketing and administrative expenses include acquisition and divestiture-related costs of \$18 million and \$136 million in the second quarter of 2016 and 2015, respectively, and \$20 million and \$363 million in the first six months of 2016 and 2015, respectively, consisting of integration, transaction, and certain other costs related to business acquisitions, including severance costs which are not part of the Company's formal restructuring programs, as well as transaction and certain other costs related to divestitures of businesses. Acquisition and divestiture-related costs in the first six months of 2015 include costs related to the acquisition of Cubist (see Note 2 to the condensed consolidated financial statements.)

Expenses for the second quarter of 2016 and 2015 also include \$87 million and \$17 million, respectively, and for the first six months of 2016 and 2015 include \$90 million and \$53 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 expenses were \$2.2 billion for the second quarter of 2016, an increase of 29% compared with the second quarter of 2015. The increase primarily reflects higher licensing costs, higher in-process research and development (IPR&D) impairment charges, increased clinical development spending and higher restructuring costs, partially offset by the favorable effects of foreign exchange. Research and development expenses were \$3.8 billion for the first six months of 2016, an increase of 12% compared with the same period of 2015 reflecting increased clinical development spending, higher IPR&D



impairment charges, higher restructuring costs and increased licensing costs, partially offset by lower expenses recorded in connection with liabilities for contingent consideration and the favorable effects of foreign exchange. Research and development 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 approximately \$1.1 billion and \$980 million in the second quarter of 2016 and 2015, respectively, and were \$2.1 billion and \$1.9 billion for the first six months of 2016 and 2015, respectively. Also included in research and development expenses are costs incurred by other divisions in support of research and development 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 \$770 million and \$600 million for the second quarter of 2016 and 2015, respectively, and were \$1.4 billion for both the first six months of 2016 and 2015. The increase in the second quarter of 2016 was driven primarily by higher licensing costs reflecting in part expenses incurred in 2016 related to a collaboration with Moderna (see Note 2 to the condensed consolidated financial statements). In addition, research and development expenses include IPR&D impairment charges of \$195 million and \$59 million for the second quarter of 2016 and 2015, respectively, and \$220 million and \$61 million for the first six months of 2016 and 2015, 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. Research and development expenses also include expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration recorded in connection with acquisitions. During both the second quarter of 2016 and 2015, the Company recorded charges of \$12 million, and for the first six months of 2016 and 2015 recognized charges of \$21 million and \$73 million, respectively, resulting from increases in the estimated fair value of liabilities for contingent consideration (see Note 4 to the condensed consolidated financial statements). Research and development expenses also reflect accelerated depreciation and asset abandonment costs associated with restructuring activities of \$64 million and \$15 million in the second quarter of 2016 and 2015, respectively, and \$119 million and \$17 million for the first six months of 2016 and 2015, respectively (see Note 3 to the condensed consolidated financial statements).

#### Restructuring Costs

The Company incurs substantial costs for restructuring program activities related to Merck's productivity and cost reduction initiatives, as well as in connection with the integration of certain acquired businesses. In 2010 and 2013, the Company commenced actions under global restructuring programs designed to streamline its cost structure. The actions under these programs include the elimination of positions in sales, administrative and headquarters organizations, as well as the sale or closure of certain manufacturing and research and development sites and the consolidation of office facilities. The Company also continues to reduce its global real estate footprint and improve the efficiency of its manufacturing and supply network.

Restructuring costs, primarily representing separation and other related costs associated with these restructuring activities, were \$134 million and \$191 million for the second quarter of 2016 and 2015, respectively, and were \$225 million and \$273 million for the first six months of 2016 and 2015, 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 585 positions and 860 positions in the second quarter of 2016 and 2015, respectively, and approximately 1,055 positions and 1,950 positions in the first six months of 2016 and 2015, respectively, related to these restructuring activities. These position eliminations are comprised of actual headcount reductions, and the elimination of contractors and vacant positions. 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 (see Note 3 to the condensed

consolidated financial statements). The Company recorded aggregate pretax costs of \$351 million and \$328 million in the second quarter of 2016 and 2015, respectively, and \$547 million and \$553 million for the first six months of 2016 and 2015, respectively, related to restructuring program activities. The Company expects to substantially complete the remaining actions under the programs by the end of 2017 and incur approximately \$1.0 billion of additional pretax costs. The Company anticipates that total costs associated with restructuring program activities in 2016 will be approximately \$900 million.

**Other (Income) Expense, Net**

Other (income) expense, net was \$19 million of expense in the second quarter of 2016 compared with \$739 million of expense in the second quarter of 2015. The favorability was driven primarily by lower foreign exchange losses in 2016 related to Venezuela, as well as a gain of \$115 million in 2016 related to the settlement of certain patent litigation (see Note 8 to the condensed consolidated financial statements). Other (income) expense, net was \$67 million of expense in the first six months of 2016 compared with \$793 million of expense in the first six months of 2015. The favorability was driven primarily by lower exchange losses

related to Venezuela, the 2016 gain related to the settlement of certain patent litigation, as well as an expense of \$78 million in 2015 for a contribution of investments in equity securities to the Merck Foundation, partially offset by lower equity income in 2016 from certain research investment funds.

Since January 2010, Venezuela has been designated hyperinflationary and, as a result, local foreign operations are remeasured in U.S. dollars with the impact recorded in results of operations. In the second quarter of 2015, the Venezuelan government identified multiple exchange rates, which included the CENCOEX rate (6.3 VEF per U.S. dollar at June 30, 2015) and the SIMADI rate (197.30 VEF per U.S. dollar at June 30, 2015). While the Venezuelan government had indicated that essential goods, including food and medicine, would remain at the CENCOEX rate, during the second quarter of 2015, upon evaluation of evolving economic conditions in Venezuela and volatility in the country, combined with a decline in transactions that were being settled at the CENCOEX rate, the Company determined it was unlikely that all outstanding net monetary assets would be settled at the CENCOEX rate. Accordingly, during the second quarter of 2015, the Company recorded a charge of \$715 million within Other (income) expense, net to devalue its net monetary assets in Venezuela to an amount that represented the Company's estimate of the U.S. dollar amount that would ultimately be collected. As a result of the further deterioration of economic conditions in Venezuela and continued declines in transactions which were settled at the CENCOEX rate (subsequently replaced by the DIPRO rate), in the fourth quarter of 2015, the Company began using the SIMADI rate (subsequently replaced with the DICOM rate) to report its Venezuelan operations. At June 30, 2016, the DICOM rate was 628.34 VEF per U.S. dollar.

#### Segment Profits

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
(\$ in millions)	2016	2015	2016	2015
Pharmaceutical segment profits	\$5,420	\$5,282	\$10,537	\$10,447
Other non-reportable segment profits	424	407	809	847
Other	(4,340 )	(4,882 )	(8,218 )	(9,106 )
Income before income taxes	\$1,504	\$807	\$3,128	\$2,188

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 and intangible asset impairment charges, restructuring costs, taxes paid at the joint venture level 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 3% in the second quarter of 2016 compared with the second quarter of 2015, reflecting higher sales, and grew 1% in the first six months of 2016 as compared with the corresponding prior year period primarily reflecting manufacturing efficiencies and cost reduction efforts.

#### Taxes on Income

The effective income tax rates of 19.6% and 14.7% for the second quarter of 2016 and 2015, respectively, and 25.2% and 24.8% for the first six months of 2016 and 2015, 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 2016 also reflect the beneficial impact of

orphan drug federal income tax credits, primarily for Keytruda, recorded in the quarter. The effective income tax rates for the second quarter and first six months of 2015 reflect the favorable impact of a net benefit of \$370 million related to the settlement of certain federal income tax issues, as well as the unfavorable effect of non-tax deductible foreign exchange losses related to Venezuela (see Note 12 to the condensed consolidated financial statements) and a \$75 million out of period discrete adjustment related to deferred taxes associated with prior year restructuring activities. Management considered the discrete adjustment to be immaterial to current and prior period financial statements as reported.

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 \$1.2 billion for the second quarter of 2016 compared with \$687 million for the second quarter of 2015 and was \$2.3 billion for the first six months of 2016 compared with \$1.6 billion for the first six months of 2015. Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders (EPS) for the second quarter of 2016 were \$0.43 compared with \$0.24 in the second quarter of 2015 and were \$0.83 for the first six months of 2016 compared with \$0.57 for the first six months of 2015.

#### 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 and permits investors to more fully understand how management assesses performance. Non-GAAP income and non-GAAP EPS exclude certain items because of the nature of these items and the impact that they have on the analysis of underlying business performance and trends. The excluded items (which should not be considered non-recurring) consist of acquisition and divestiture-related costs, restructuring costs and certain other items. These excluded items are significant components in understanding and assessing financial performance. Non-GAAP income and non-GAAP EPS are important internal measures for the Company. Senior management receives a monthly analysis of operating results that includes non-GAAP EPS. Management uses these measures internally for planning and forecasting purposes and to measure the performance of the Company along with other metrics. Senior management's annual compensation is derived in part using non-GAAP income and non-GAAP EPS. Since non-GAAP income and non-GAAP EPS are not measures determined in accordance with GAAP, they have no standardized meaning prescribed by GAAP and, therefore, may not be comparable to the calculation of similar measures of other companies. The information on non-GAAP income and non-GAAP EPS should be considered in addition to, but not as a substitute for or superior to, net income and EPS prepared in accordance with generally accepted accounting principles in the United States (GAAP).

A reconciliation between GAAP financial measures and non-GAAP financial measures is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(\$ in millions except per share amounts)	2016	2015	2016	2015
Pretax income as reported under GAAP	\$ 1,504	\$ 807	\$ 3,128	\$ 2,188
Increase (decrease) for excluded items:				
Acquisition and divestiture-related costs	1,345	1,448	2,768	2,988
Restructuring costs	351	328	547	553
Other items:				
Foreign currency devaluation related to Venezuela	—	715	—	715
Other	—	—	—	(14 )
	3,200	3,298	6,443	6,430
Taxes on income as reported under GAAP	295	119	789	542
Estimated tax benefit on excluded items	314	367	566	645
Net tax benefit from settlement of certain federal income tax issues	—	370	—	370
	609	856	1,355	1,557
Non-GAAP net income	2,591	2,442	5,088	4,873
Less: Net income attributable to noncontrolling interests	4	1	9	7
Non-GAAP net income attributable to Merck & Co., Inc.	\$ 2,587	\$ 2,441	\$ 5,079	\$ 4,866
EPS assuming dilution as reported under GAAP	\$ 0.43	\$ 0.24	\$ 0.83	\$ 0.57

EPS difference <sup>(1)</sup>	0.50	0.62	0.99	1.13
Non-GAAP EPS assuming dilution	\$0.93	\$0.86	\$1.82	\$1.70

Represents the difference between calculated GAAP EPS and calculated non-GAAP EPS, which may be different <sup>(1)</sup> 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 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

acquisitions, including severance costs which are not part of the Company's formal restructuring programs, as well as transaction and certain other costs associated with divestitures of businesses.

#### 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 site, based upon the anticipated date the site will be closed or divested, 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 difficult to project, 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 2015 are foreign exchange losses related to the devaluation of the Company's net monetary assets in Venezuela (see Note 12 to the condensed consolidated financial statements), as well as a net tax benefit related to the settlement of certain federal income tax issues (see Note 13 to the condensed consolidated financial statements).

#### Research and Development Update

In August 2016, Merck announced that the FDA approved Keytruda, at a fixed dose of 200 mg every three weeks, 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. Under the FDA's accelerated approval regulations, this indication for Keytruda is approved based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. For HNSCC patients, PD-L1 testing is not needed prior to use of Keytruda.

Also in August 2016, Merck announced that the EC approved Keytruda, at a dose of 2 mg/kg every three weeks, for patients with locally advanced or metastatic NSCLC in patients whose tumors express PD-L1 and who have received at least one prior chemotherapy regimen. Patients with EGFR or ALK positive tumor mutations should also have received approved therapy for these mutations prior to receiving Keytruda. The EC approval allows marketing of Keytruda in all 28 EU member states. The approval is based on findings from KEYNOTE-010, a pivotal study which showed Keytruda significantly improved overall survival compared to standard of care chemotherapy.

In April 2016, Merck announced that the FDA accepted for review a supplemental Biologics License Application (sBLA) for Keytruda for the treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma with disease progression on or after platinum-containing chemotherapy. The application is seeking approval for Keytruda as a single agent at a dose of 200 mg administered intravenously every three weeks. The FDA granted Priority Review with a Prescription Drug User Fee Act (PDUFA), or target action, date of August 9, 2016. The sBLA will be reviewed under the FDA's Accelerated Approval program.

Also in April 2016, Merck announced that the FDA granted Breakthrough Therapy designation to Keytruda for the treatment of patients with relapsed or refractory classical Hodgkin lymphoma (cHL). This is the fourth Breakthrough Therapy designation granted for Keytruda. 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. Keytruda was previously granted breakthrough status for specific patients with advanced melanoma, advanced NSCLC, and advanced colorectal cancer. The Breakthrough Therapy designation in cHL is based on data from the ongoing Phase 1b KEYNOTE-013 and Phase 2 KEYNOTE-087 studies evaluating single agent Keytruda in patients with cHL.

In March 2016, Merck announced that the FDA accepted for review an sBLA for Keytruda to include data from the KEYNOTE-010 clinical trial. The trial was a pivotal Phase 2/3 study designed to evaluate Keytruda compared to chemotherapy based on prospective measurement of PD-L1 expression in previously treated patients with advanced NSCLC. Keytruda is currently indicated in the United States for the treatment of patients with metastatic NSCLC whose tumors express PD-L1 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. The NSCLC indication, approved under accelerated approval, was based on tumor response rate and durability of response in patients with PD-L1 expression on 50% or more of the cancer cells. Under accelerated approval, improvement in survival or disease-related symptoms has not yet been established. Continued approval for this indication may be contingent upon

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verification and description of clinical benefit in the confirmatory trials. In accordance with the accelerated approval process, the data from KEYNOTE-010 was intended to serve as the confirmatory trial for receiving full approval, establishing the clinical benefit by demonstrating improved survival over standard chemotherapy.

In June 2016, Merck announced that the KEYNOTE-024 trial investigating the use of Keytruda, in patients with previously untreated advanced NSCLC whose tumors expressed high levels of PD-L1 (tumor proportion score of 50% or more), met its primary endpoint. In this trial, Keytruda was superior compared to chemotherapy for both the primary endpoint of progression-free survival, and the secondary endpoint of overall survival. Based on these results, an independent Data Monitoring Committee has recommended that the trial be stopped, and that patients receiving chemotherapy in KEYNOTE-024 be offered the opportunity to receive Keytruda. The safety profile of Keytruda in this trial was consistent with that observed in previously reported studies in patients with advanced NSCLC. Results from KEYNOTE-024 will be presented at an upcoming medical meeting.

The Keytruda clinical development program includes patients with more than 30 tumor types in more than 300 clinical trials, including more than 100 trials that combine Keytruda with other cancer treatments. Registration-enabling trials of Keytruda are currently enrolling patients in melanoma, NSCLC, head and neck cancer, bladder cancer, gastric cancer, colorectal cancer, esophageal cancer, breast cancer, ovarian cancer, hepatocellular carcinoma, Hodgkin lymphoma, non-Hodgkin lymphoma, multiple myeloma, nasopharyngeal cancer, prostate cancer and other tumors, with further trials in planning for other cancers.

In January 2016, Merck announced that the FDA accepted for review the Biologics License Application (BLA) for Zinplava (bezlotoxumab) and granted Priority Review designation to the BLA with a PDUFA action date of July 23, 2016. Zinplava is an investigational antitoxin for the prevention of *Clostridium difficile* infection recurrence. In June 2016, the Antimicrobial Drugs Advisory Committee of the FDA voted 10-to-5, with one abstention, in support of bezlotoxumab as showing substantial evidence of efficacy and safety in preventing the recurrence of *C. difficile* infection. The FDA is not bound by the committee's guidance, but takes its advice into consideration when reviewing investigational medicines. Following the Advisory Committee meeting, the FDA requested the submission of new data and analyses from the MODIFY I and MODIFY II clinical trials previously submitted to the pending BLA for bezlotoxumab. The FDA noted that the additional data and analyses constitute a major amendment to the BLA, resulting in an extension of the PDUFA action date by three months. The new action date is October 23, 2016. Bezlotoxumab is also under review in the EU.

In August 2016, Merck announced that the FDA has accepted for review the New Drug Application for MK-1293, an investigational follow-on biologic insulin glargine candidate for the treatment of people with type 1 and type 2 diabetes, which is being developed in collaboration with Samsung Bioepis. Separately, the marketing authorization application for MK-1293, which Merck submitted to the EMA in December 2015, is also under review.

In July 2016, Merck announced two regulatory milestones for V920, an investigational rVSV-ZEBOV (Ebola) vaccine: the FDA has granted the vaccine candidate Breakthrough Therapy designation, and the EMA has granted PRIME (PRIority MEDicines) status. In November 2014, Merck and NewLink Genetics announced an exclusive licensing and collaboration agreement for the investigational Ebola vaccine.

Also in July 2016, Merck acquired Afferent, a privately held pharmaceutical company focused on the development of therapeutic candidates targeting the P2X3 receptor for the treatment of common, poorly-managed, neurogenic conditions. Afferent's lead investigational candidate, MK-7264 (formerly AF-219), is a selective, non-narcotic, orally-administered P2X3 antagonist currently being evaluated in a Phase 2b clinical trial for the treatment of refractory, chronic cough as well as in a Phase 2 clinical trial in idiopathic pulmonary fibrosis (IPF) with cough (see Note 2 to the condensed consolidated financial statements).

During the second quarter of 2016, the Company determined that, for business reasons, it would terminate the North America partnership agreement with ALK that included MK-8237, an investigational allergy immunotherapy tablet for house dust mite allergy. Merck has given ALK six months' notice that it is terminating the agreement and therefore this compound will be returned to ALK. This decision was not due to efficacy or safety concerns. In connection with the decision, the Company recorded an IPR&D impairment charge (see Note 6 to the condensed consolidated financial statements).

During the second quarter of 2016, the Company decided, for business reasons, to discontinue the clinical development of MK-8342B, referred to as the Next Generation Ring, an investigational combination (etonogestrel and 17 $\beta$ -estradiol) vaginal ring for contraception and the treatment of dysmenorrhea in women seeking contraception. This decision was not due to safety or efficacy concerns. As a result of this decision, the Company recorded an IPR&D impairment charge (see Note 6 to the condensed consolidated financial statements).

Also, in April 2016, Merck announced that, for business reasons, it will not proceed with submitting marketing applications for omarigliptin, an investigational, once-weekly DPP-4 inhibitor, in the United States or Europe. This decision did not result from concerns about the efficacy or safety of omarigliptin. Merck remains committed to omarigliptin in Japan, where it is approved and marketed as Marizev.

The chart below reflects the Company's research pipeline as of August 1, 2016. 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 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	Allergy
MK-1029	MK-8931 (verubecestat) (December 2013)	MK-8237, House Dust Mite (U.S.) <sup>(2)</sup>
Cancer	Atherosclerosis	Cancer
MK-3475 Keytruda	MK-0859 (anacetrapib) (May 2008)	MK-3475 Keytruda
Advanced Solid Tumors	Bacterial Infection	Head and Neck (U.S.) <sup>(3)</sup>
Hepatocellular	MK-7655A	Clostridium difficile Infection
Hodgkin Lymphoma	(relebactam+imipenem/cilastatin)	MK-6072 Zinplava (U.S./EU)
PMBCL (Primary Mediastinal Large B-Cell Lymphoma)	(October 2015)	Diabetes Mellitus
Nasopharyngeal	Cancer	MK-1293 (U.S./EU) <sup>(1)</sup>
Ovarian	MK-3475 Keytruda	Pediatric Hexavalent Combination Vaccine V419 (U.S.) <sup>(4)</sup>
Prostate	Bladder (October 2014)	
MK-2206	Breast (October 2015)	Footnotes:
MK-8628	Colorectal (November 2015)	<sup>(1)</sup> Being developed in a collaboration.
Cough, including cough with IPF	Esophageal (December 2015)	<sup>(2)</sup> MK-8237 was being developed as part of a North America partnership with ALK. Merck has given ALK six months' notice that it is terminating the agreement and therefore this compound will be returned to ALK.
MK-7264	Gastric (May 2015)	<sup>(3)</sup> Approved by the FDA on August 5, 2016.
Diabetes Mellitus	Head and Neck (November 2014) (EU)	<sup>(4)</sup> V419 is being developed and, if approved, will be commercialized through a partnership of Merck and Sanofi Pasteur. On November 2, 2015, the FDA issued a Complete Response Letter (CRL) with respect to V419. Both companies are reviewing the CRL and plan to have further communication with the FDA.
MK-8521	Multiple Myeloma (December 2015)	
Heart Failure	CMV Prophylaxis in Transplant Patients	
MK-1242 (vericiguat) <sup>(1)</sup>	MK-8228 (letermovir) (June 2014)	
Hepatitis C	Diabetes Mellitus	
MK-3682B	MK-8835 (ertugliflozin) (November 2013) <sup>(1)</sup>	
(MK-3682/MK-5172 (grazoprevir)/MK-8408 (ruzasvir))	MK-8835A	
Pneumoconjugate Vaccine V114	(ertugliflozin+sitagliptin) (September 2015) <sup>(1)</sup>	
	MK-8835B	
	(ertugliflozin+metformin) (August 2015) <sup>(1)</sup>	
	MK-0431J (sitagliptin+ipragliflozin) (October 2015) (Japan) <sup>(1)</sup>	
	Ebola Vaccine	
	V920 (March 2015)	
	Herpes Zoster	
	V212 (inactivated VZV vaccine) (December 2010)	
	HIV	

MK-1439 (doravirine) (December  
2014)  
Osteoporosis  
MK-0822 (odanacatib)  
(September 2007)

#### Selected Joint Venture and Affiliate Information

##### AstraZeneca LP

In 1998, Merck and Astra completed the restructuring of the ownership and operations of their existing joint venture whereby Merck acquired Astra's interest in KBI Inc. (KBI) and contributed KBI's operating assets to a new U.S. limited partnership, Astra Pharmaceuticals L.P. (the Partnership). Astra contributed the net assets of its wholly owned subsidiary, Astra USA, Inc., to the Partnership. The Partnership, renamed AstraZeneca LP (AZLP) upon Astra's 1999 merger with Zeneca Group Plc, became the exclusive distributor of the products for which KBI retained rights. In connection with AstraZeneca's 2014 exercise of its option to purchase Merck's interest in KBI, the Company deferred \$327 million of the exercise price, which reflected an estimate of the fair value of Merck's interest in Nexium and Prilosec. This amount, which is subject to a true-up in 2018 based on actual sales from closing in 2014 to June 2018, was deferred and recognized over time in Other (income) expense, net as the contingency was eliminated as sales occurred. The deferred income amount has been fully amortized based on the sales performance of Nexium and Prilosec subsequent to the 2014 option exercise. Beginning in the first quarter of 2016, the Company is recognizing income and a corresponding receivable for amounts that will be due to Merck from AstraZeneca based on the sales performance of Nexium and Prilosec subject to the true-up in June 2018. The Company recognized \$54 million of such income in the first six months of 2016.

##### Sanofi Pasteur MSD

In 1994, Merck and Pasteur Mérieux Connaught (now Sanofi Pasteur S.A.) established an equally-owned joint venture to market vaccines in Europe and to collaborate in the development of combination vaccines for distribution in Europe. Total vaccine sales reported by SPMSD were \$202 million and \$175 million in the second quarter of 2016 and 2015, respectively, and were \$383 million and \$337 million for the first six months of 2016 and 2015, respectively. SPMSD sales of Gardasil/Gardasil 9

were \$60 million and \$41 million for the second quarter of 2016 and 2015, respectively, and were \$101 million and \$81 million for the first six months of 2016 and 2015, respectively. The Company records the results from its interest in SPMSD and other equity method affiliates in Other (income) expense, net.

In March 2016, Merck and Sanofi Pasteur announced their intention to terminate SPMSD and end their joint vaccines operations in Europe. Sanofi Pasteur and Merck expect the project to be completed by the end of 2016, subject to local labor laws and regulations and regulatory approvals. Upon concluding the joint venture, Merck plans to integrate its European vaccine business into its operations, manage its product portfolio and pursue its growth strategy in Europe.

#### Liquidity and Capital Resources

(\$ in millions)	June 30,	December
	2016	31, 2015
Cash and investments	\$23,713	\$26,466
Working capital	13,008	10,550
Total debt to total liabilities and equity	25.2 %	26.0 %

Cash provided by operating activities was \$3.8 billion in the first six months of 2016 compared with \$5.0 billion in the first six months of 2015. 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 operating activities in the first six months of 2016 reflects a net payment of approximately \$680 million to fund the Vioxx shareholder class action litigation settlement not covered by insurance proceeds (see Note 8 to the condensed consolidated financial statements).

Cash provided by investing activities was \$243 million in the first six months of 2016 compared with a use of cash of \$4.1 billion in the first six months of 2015. The change was driven primarily by cash used in 2015 for the acquisition of Cubist, as well as lower purchases of securities and other investments in 2016, partially offset by lower proceeds from the sales of securities and other investments in 2016.

Cash used in financing activities was \$6.2 billion in the first six months of 2016 compared with \$442 million in the first six months of 2015 driven primarily by lower proceeds from the issuance of debt, partially offset by lower payments on debt, including short-term borrowings.

At June 30, 2016, the total of worldwide cash and investments was \$23.7 billion, including \$11.8 billion of cash, cash equivalents and short-term investments and \$11.9 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.

Capital expenditures totaled \$654 million and \$474 million for the first six months of 2016 and 2015, respectively. Dividends paid to stockholders were \$2.6 billion for both the first six months of 2016 and 2015. In May 2016, the Board of Directors declared a quarterly dividend for the third quarter of \$0.46 per share on the Company's common stock that was paid in July 2016. In July 2016, the Board of Directors declared a quarterly dividend for the fourth quarter of \$0.46 per share on the Company's common stock that is payable in October 2016.

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 2016, the Company purchased \$1.6 billion (30 million shares) for its treasury. As of June 30, 2016, the Company's remaining share repurchase authorization was \$6.9 billion.

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.

In February 2015, Merck issued \$8.0 billion aggregate principal amount of senior unsecured notes. The Company used a portion of the net proceeds of the offering of \$7.9 billion to repay commercial paper issued to substantially finance the Company's acquisition of Cubist. The remaining net proceeds were used for general corporate purposes, including for repurchases of the Company's common stock, and the repayment of outstanding commercial paper borrowings and debt maturities.

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Also in February 2015, the Company redeemed \$1.9 billion of legacy Cubist debt acquired in the acquisition (see Note 2 to the condensed consolidated financial statements).

In June 2016, the Company terminated its existing credit facility and entered into a new \$6.0 billion, five-year credit facility that matures in July 2021. The facility provides backup liquidity for the Company's commercial paper borrowing facility and is to be used for general corporate purposes. The Company has not drawn funding from this facility.

#### Critical Accounting Policies

The Company's significant accounting policies, which include management's best estimates and judgments, are included in Note 2 to the consolidated financial statements for the year ended December 31, 2015 included in Merck's Form 10-K filed on February 26, 2016. 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, 2015.

#### 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. In August 2015, the FASB approved a one-year deferral of the effective date making this guidance effective for interim and annual periods beginning in 2018.

Reporting entities may choose to adopt the standard as of the original effective date. The Company is currently assessing the impact of adoption on its consolidated financial statements.

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 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 for each of its leases recorded on the balance sheet (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 within its scope. 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.

#### 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, 2016, the Company's disclosure controls and procedures are effective.

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

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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, 2015, as filed on February 26, 2016, the Company discusses in more detail various important risk factors that could cause actual results to differ from expected or historic results. The Company notes these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. One should understand that it is not possible to predict or identify all such factors. Consequently, the reader should not consider any such list to be a complete statement of all potential risks or uncertainties.

## PART II - Other Information

### Item 1. Legal Proceedings

The information called for by this Item is incorporated herein by reference to Note 8 included in Part I, Item 1, Financial Statements (unaudited) — Notes to Condensed Consolidated Financial Statements.

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

Issuer purchases of equity securities for the three months ended June 30, 2016 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	4,120,176	\$55.19	\$7,348
May 1 - May 31	3,819,143	\$54.80	\$7,139
June 1 - June 30	3,936,846	\$56.61	\$6,916
Total	11,876,165	\$55.53	\$6,916

<sup>(1)</sup> 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~~

101 ~~The following materials from Merck & Co., Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, 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, 2016 /s/ Michael J. Holston  
MICHAEL J. HOLSTON  
Executive Vice President and General Counsel

Date: August 8, 2016 /s/ Rita A. Karachun  
RITA A. KARACHUN  
Senior Vice President Finance - Global Controller

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EXHIBIT INDEX

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