Merck & Co., Inc.
Form 10-Q
May 09, 2016

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

FORM 10-Q

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

For the quarterly period ended March 31, 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 April 30, 2016: 2,768,025,348
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 x 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 x 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 x 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 x

Part I - Financial Information
Item 1. Financial Statements
MERCK & CO., INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENT OF INCOME
(Unaudited, $ in millions except per share amounts)

	Three Months Ended March 31,	
	2016	2015
Sales	$9,312	$9,425
Costs, Expenses and Other		
Materials and production	3,572	3,569
Marketing and administrative	2,318	2,601
Research and development	1,659	1,737
Restructuring costs	91	82
Other (income) expense, net	48	55
	7,688	8,044
Income Before Taxes	1,624	1,381
Taxes on Income	494	423
Net Income	1,130	958
Less: Net Income Attributable to Noncontrolling Interests	5	5
Net Income Attributable to Merck & Co., Inc.	$1,125	$953
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	$0.41	$0.34
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	$0.40	$0.33
Dividends Declared per Common Share	$0.46	$0.45

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

	Three Months Ended March 31,	
	2016	2015
Net Income Attributable to Merck & Co., Inc.	$1,125	$953
Other Comprehensive Income (Loss) Net of Taxes:		
Net unrealized (loss) gain on derivatives, net of reclassifications	(202)	252
Net unrealized gain on investments, net of reclassifications	63	46
Benefit plan net (loss) gain and prior service (credit) cost, net of amortization	(28)	35
Cumulative translation adjustment	121	(177)
	(46)	156
Comprehensive Income Attributable to Merck & Co., Inc.	$1,079	$1,109

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)

	March 31, 2016	December 31, 2015
Assets		
Current Assets		
Cash and cash equivalents	$9,716	$8,524
Short-term investments	3,227	4,903
Accounts receivable (net of allowance for doubtful accounts of $186 in 2016 and $165 in 2015) (excludes accounts receivable of $10 in 2016 and 2015 classified in Other assets - see Note 4)	6,850	6,484
Inventories (excludes inventories of $1,258 in 2016 and $1,569 in 2015 classified in Other assets - see Note 5)	5,102	4,700
Other current assets	3,877	5,140
Total current assets	28,772	29,751
Investments	12,554	13,039
Property, Plant and Equipment, at cost, net of accumulated depreciation of $16,052 in 2016 and $15,923 in 2015	12,360	12,507
Goodwill	17,784	17,723
Other Intangibles, Net	21,364	22,602
Other Assets	5,921	6,055
	$98,755	$101,677
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	$2,113	$2,583
Trade accounts payable	2,241	2,533
Accrued and other current liabilities	10,043	11,216
Income taxes payable	1,864	1,560
Dividends payable	1,307	1,309
Total current liabilities	17,568	19,201
Long-Term Debt	23,656	23,829
Deferred Income Taxes	6,256	6,535
Other Noncurrent Liabilities	7,374	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	40,145	40,222
Retained earnings	45,192	45,348
Accumulated other comprehensive loss	(4,194)	(4,148)
	82,931	83,210
Less treasury stock, at cost: 807,550,812 shares in 2016 and 795,975,449 shares in 2015	39,125	38,534
Total Merck & Co., Inc. stockholders' equity	43,806	44,676
Noncontrolling Interests	95	91
Total equity	43,901	44,767

	$98,755	$101,677

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

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

	Three Months Ended March 31,	
	2016	2015
Cash Flows from Operating Activities		
Net income	$1,130	$958
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	1,561	1,637
Intangible asset impairment charges	277	14
Equity income from affiliates	(34)	(145)
Dividends and distributions from equity affiliates	4	3
Deferred income taxes	(70)	(179)
Share-based compensation	68	63
Other	97	551
Net changes in assets and liabilities	(875)	(618)
Net Cash Provided by Operating Activities	2,158	2,284
Cash Flows from Investing Activities		
Capital expenditures	(279)	(203)
Purchases of securities and other investments	(2,367)	(5,039)
Proceeds from sales of securities and other investments	4,620	6,287
Acquisition of Cubist Pharmaceuticals, Inc., net of cash acquired	—	(7,598)
Acquisitions of other businesses, net of cash acquired	(147)	—
Other	(86)	(52)
Net Cash Provided by (Used in) Investing Activities	1,741	(6,605)
Cash Flows from Financing Activities		
Net change in short-term borrowings	—	2,177
Proceeds from issuance of debt	—	7,941
Payments on debt	(851)	(2,902)
Purchases of treasury stock	(913)	(1,015)
Dividends paid to stockholders	(1,279)	(1,280)
Proceeds from exercise of stock options	202	242
Other	(10)	(8)
Net Cash (Used in) Provided by Financing Activities	(2,851)	5,155
Effect of Exchange Rate Changes on Cash and Cash Equivalents	144	(295)
Net Increase in Cash and Cash Equivalents	1,192	539
Cash and Cash Equivalents at Beginning of Year	8,524	7,441
Cash and Cash Equivalents at End of Period	$9,716	$7,980

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.

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 March 2016, the FASB issued new guidance intended to simplify the accounting and reporting for employee share-based payment transactions, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification of taxes paid in the statement of cash flows. Among other provisions, the new guidance will require all income tax effects of awards to be recognized in the income statement when the awards vest or are settled (as opposed to existing guidance under which tax effects are recorded to other paid-in-capital in certain instances). The guidance is effective for interim and annual periods beginning in 2018. Early adoption is permitted. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

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.

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

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 an upfront 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 an upfront payment of $75 million, which was recorded in Sales in the first quarter 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. The acquisition complements Merck's existing hospital

acute care business. 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.

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:

($ in millions, except per share amounts)	Three Months Ended March 31, 2015
Sales	$ 9,511
Net income attributable to Merck & Co., Inc.	1,035
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	0.37
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	0.36

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, subsequent to the Merck and Schering-Plough Corporation (Schering-Plough) merger, the Company commenced actions under a global restructuring program (the Merger Restructuring Program) designed to streamline the cost structure of the combined company. In 2013, the Company initiated actions under a global restructuring program (the 2013 Restructuring Program) as part of a global initiative to sharpen its commercial and research and development focus. 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 is also reducing its global real estate footprint and continues to improve the efficiency of its manufacturing and supply network. The non-facility related restructuring actions under the Merger Restructuring Program are substantially complete. The actions under the 2013 Restructuring Program were substantially completed by the end of 2015. Accordingly, as of January 1, 2016, the remaining accrued liability for future separations under these programs were combined and remaining activities, which primarily relate to ongoing facility rationalizations, are being accounted for in the aggregate.

The Company recorded total pretax costs of $196 million and $225 million in the first quarter of 2016 and 2015, respectively, related to restructuring program activities. Since inception of the programs through March 31, 2016, Merck has recorded total pretax accumulated costs of approximately $11.7 billion and eliminated approximately 38,745 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 $1.3 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:

	Three Months Ended March 31, 2016			
($ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
Materials and production	$—	$ 22	$ 25	$47

Marketing and administrative	—	3	—	3
Research and development	—	55	—	55
Restructuring costs	26	—	65	91
	$26	$ 80	$ 90	$196

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

	Three Months Ended March 31, 2015			
($ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
Materials and production	$—	$ 13	$92	$105
Marketing and administrative	—	34	2	36
Research and development	—	—	2	2
Restructuring costs	29	—	53	82
	$29	$ 47	$149	$225

Separation costs are associated with actual headcount reductions, as well as those headcount reductions which were probable and could be reasonably estimated. In the first quarter of 2016 and 2015, approximately 470 positions and 1,085 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 three months ended March 31, 2016:

($ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
Restructuring reserves January 1, 2016	$ 592	$ —	$53	$645
Expense	26	80	90	196
(Payments) receipts, net	(108)	—	(66)	(174)
Non-cash activity	—	(80)	(26)	(106)
Restructuring reserves March 31, 2016 [1]	$ 510	$ —	$51	$561

[1] 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

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

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 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

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

the subsidiary. The cash flows from these contracts are reported as investing activities in the Condensed Consolidated Statement of Cash Flows.

Foreign exchange risk is also managed through the use of foreign currency debt. The Company's senior unsecured euro-denominated notes have been designated as, and are effective as, economic hedges of the net investment in a foreign operation. Accordingly, foreign currency transaction gains or losses due to spot rate fluctuations on the euro-denominated debt instruments are included in foreign currency translation adjustment within OCI. Included in the cumulative translation adjustment are pretax losses of $58 million and pretax gains $334 million for the first three 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.

At March 31, 2016, the Company was a party to 30 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)	March 31, 2016		
Debt Instrument	Par Value of Debt	Number of Interest Rate Swaps Held	Total Swap Notional Amount
0.70% notes due 2016	$1,000	4	$ 1,000
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:

		March 31, 2016			December 31, 2015		
		Fair Value of Derivatives		U.S. Dollar Equivalent Notional	Fair Value of Derivatives		U.S. Dollar Equivalent Notional
($ in millions)	Balance Sheet Caption	Asset	Liability		Asset	Liability	
Derivatives Designated as Hedging Instruments							
Interest rate swap contracts (noncurrent)	Other assets	$ 169	$ —	$ 6,200	$ 42	$ —	$ 2,700
Interest rate swap contracts (current)	Accrued and other current liabilities	—	1	1,000	—	1	1,000
Interest rate swap contracts (noncurrent)	Other noncurrent liabilities	—	—	—	—	23	3,500
Foreign exchange contracts (current)	Other current assets	436	—	4,871	579	—	4,171

Foreign exchange contracts (noncurrent)	Other assets	252	—	3,552	386	—	4,136
Foreign exchange contracts (current)	Accrued and other current liabilities	—	11	236	—	1	77
		$ 857	$ 12	$ 15,859	$ 1,007	$ 25	$ 15,584
Derivatives Not Designated as Hedging Instruments							
Foreign exchange contracts (current)	Other current assets	$ 104	$ —	$ 2,829	$ 212	$ —	$ 8,783
Foreign exchange contracts (noncurrent)	Other assets	18	—	260	18	—	179
Foreign exchange contracts (current)	Accrued and other current liabilities	—	151	7,178	—	37	2,508
Foreign exchange contracts (noncurrent)	Other noncurrent liabilities	—	1	6	—	1	6
		$ 122	$ 152	$ 10,273	$ 230	$ 38	$ 11,476
		$ 979	$ 164	$ 26,132	$ 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:

	March 31, 2016		December 31, 2015	
($ in millions)	Asset	Liability	Asset	Liability
Gross amounts recognized in the consolidated balance sheet	$979	$ 164	$1,237	$ 63
Gross amount subject to offset in master netting arrangements not offset in the consolidated balance sheet	(112)	(113)	(59)	(59)
Cash collateral (received) posted	(495)	—	(862)	—
Net amounts	$372	$ 51	$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:

	Three Months Ended March 31,	
($ in millions)	2016	2015
Derivatives designated in a fair value hedging relationship		
Interest rate swap contracts		
Amount of gain recognized in Other (income) expense, net on derivatives [1]	$(150)	$(25)
Amount of loss recognized in Other (income) expense, net on hedged item [1]	147	22
Derivatives designated in foreign currency cash flow hedging relationships		
Foreign exchange contracts		
Amount of gain reclassified from AOCI to Sales	(143)	(167)
Amount of loss (gain) recognized in OCI on derivatives	167	(565)
Derivatives designated in foreign currency net investment hedging relationships		
Foreign exchange contracts		
Amount of gain recognized in Other (income) expense, net on derivatives [2]	—	(1)
Amount of loss recognized in OCI on derivatives	—	8
Derivatives not designated in a hedging relationship		
Foreign exchange contracts		
Amount of loss (gain) recognized in Other (income) expense, net on derivatives [3]	24	(248)
Amount of gain recognized in Sales	—	(1)

[1] There was $3 million of ineffectiveness on the hedge during both the first quarter of 2016 and 2015.

[2] There was no ineffectiveness on the hedge. Represents the amount excluded from hedge effectiveness testing.

[3] 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 March 31, 2016, the Company estimates $221 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 available-for-sale investments is as follows:

	March 31, 2016				December 31, 2015			
($ in millions)	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses
Corporate notes and bonds	$10,419	$ 10,377	$ 55	$ (13)	$10,259	$ 10,299	$ 7	$ (47)
U.S. government and agency securities	1,813	1,806	7	—	1,761	1,767	—	(6)
Asset-backed securities	1,292	1,292	2	(2)	1,284	1,290	—	(6)
Commercial paper	798	798	—	—	2,977	2,977	—	—
Mortgage-backed securities	684	681	4	(1)	694	697	1	(4)
Foreign government bonds	468	467	1	—	607	586	22	(1)
Equity securities	475	395	83	(3)	534	409	125	—
	$15,949	$ 15,816	$ 152	$ (19)	$18,116	$ 18,025	$ 155	$ (64)

Available-for-sale debt securities included in Short-term investments totaled $3.2 billion at March 31, 2016. Of the remaining debt securities, $11.3 billion mature within five years. At March 31, 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 In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
($ in millions)	March 31, 2016				December 31, 2015			
Assets								
Investments								
Corporate notes and bonds	$—	$ 10,419	$ —	$10,419	$—	$ 10,259	$ —	$10,259
U.S. government and agency securities	—	1,813	—	1,813	—	1,761	—	1,761
Asset-backed securities [1]	—	1,292	—	1,292	—	1,284	—	1,284
Commercial paper	—	798	—	798	—	2,977	—	2,977
Mortgage-backed securities [1]	—	684	—	684	—	694	—	694
Foreign government bonds	—	468	—	468	—	607	—	607
Equity securities	307	—	—	307	360	—	—	360
	307	15,474	—	15,781	360	17,582	—	17,942
Other assets								
Securities held for employee compensation	154	14	—	168	155	19	—	174
Derivative assets [2]								
Purchased currency options	—	735	—	735	—	1,041	—	1,041
Interest rate swaps	—	169	—	169	—	42	—	42
Forward exchange contracts	—	75	—	75	—	154	—	154
	—	979	—	979	—	1,237	—	1,237
Total assets	$461	$ 16,467	$ —	$16,928	$515	$ 18,838	$ —	$19,353
Liabilities								
Other liabilities								
Contingent consideration	$—	$ —	$ 652	$652	$—	$ —	$ 590	$590
Derivative liabilities [2]								
Forward exchange contracts	—	162	—	162	—	38	—	38
Written currency options	—	1	—	1	—	1	—	1
Interest rate swaps	—	1	—	1	—	24	—	24
	—	164	—	164	—	63	—	63
Total liabilities	$—	$ 164	$ 652	$816	$—	$ 63	$ 590	$653

(1) Primarily all of the asset-backed securities are highly-rated (Standard & Poor's rating of AAA and Moody's Investors Service rating of Aaa), secured primarily by 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 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 three months of 2016. As of March 31, 2016, Cash and cash equivalents of $9.7 billion included $8.9 billion of cash equivalents (considered Level 2 in the fair

value hierarchy).

Contingent Consideration

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

	Three Months Ended March 31,	
($ in millions)	2016	2015
Fair value January 1	$590	$428
Changes in fair value [1]	10	61
Additions	77	123
Payments	(25)	(50)
Fair value March 31	$652	$562

[1] Recorded in Research and development expenses and Materials and production costs.

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

In the first quarter of 2016 and 2015, the Company recognized liabilities for contingent consideration related to the acquisitions of IOmet and Cubist, respectively, 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 March 31, 2016, was $27.2 billion compared with a carrying value of $25.8 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 March 31, 2016 and December 31, 2015, Other assets included $10 million of accounts receivable not expected to be collected within one year. At March 31, 2016, the Company's total net accounts receivable outstanding for more than one year were approximately $130 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 March 31, 2016 and December 31, 2015, the Company had received cash collateral of $495 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 March 31, 2016 or December 31, 2015.

5. Inventories

Inventories consisted of:

($ in millions)	March 31, 2016	December 31, 2015
Finished goods	$1,417	$ 1,343
Raw materials and work in process	4,399	4,374
Supplies	169	168
Total (approximates current cost)	5,985	5,885
Increase to LIFO costs	375	384
	$6,360	$ 6,269
Recognized as:		
Inventories	$5,102	$ 4,700
Other assets	1,258	1,569

Amounts recognized as Other assets are comprised almost entirely of raw materials and work in process inventories. At March 31, 2016 and December 31, 2015, these amounts included $1.2 billion and $1.5 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included $100 million and $63 million at March 31, 2016 and December 31, 2015, respectively, of inventories produced in preparation for product launches.

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

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 first quarter of 2016, the Company recorded an intangible asset impairment charge of $252 million within Materials and production costs related 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. During the first quarter of 2015, the Company recorded an intangible asset impairment charge of $12 million related to Rebetol, a product marketed by the Company for the treatment of chronic hepatitis C virus infection. Sales of Rebetol were adversely affected by loss of market share as a result of the availability of newer therapeutic options, which led to changes in the cash flow assumptions for Rebetol that indicated that the Rebetol intangible asset value was not recoverable on an undiscounted cash flows basis. The Company utilized market participant assumptions to determine the fair value of the intangible asset related to Rebetol that, when compared with its related carrying value, resulted in the impairment charge noted above.

Also during the first quarter of 2016, the Company recorded $25 million of IPR&D impairment charges within Research and development expenses primarily related to deprioritized pipeline programs that were deemed to have no alternative use during the period.

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

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 $34 million and $145 million for the first quarter 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 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 $182 million and $162 million for the first quarter 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 $21 million of

such income in the first quarter 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.

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

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 five active federal and state lawsuits (Vioxx Product Liability Lawsuits) alleging personal injury as a result of the use of Vioxx. Most of these 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.

As previously disclosed, Merck is also 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 in the Vioxx MDL. Merck has reached a resolution, approved by Judge Fallon, of these class actions in the Vioxx MDL. 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 brought by state Attorneys General of three states — Alaska, Montana and Utah. The lawsuits are pending in state courts. These 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, and have been consolidated for all purposes. In August 2011, Judge Chesler granted in part and denied in part defendants' motions to dismiss in the consolidated securities class action (the Class Action). In June 2013, plaintiffs filed their Sixth Amended Class Action Complaint, which defendants answered in July 2013. Following the completion of discovery, defendants moved for summary judgment, which the court granted in part and denied in part in May 2015. On January 15, 2016, the Company announced that it had reached an agreement with plaintiffs to settle the Class Action for $830 million, plus an additional amount for attorneys' fees and expenses, in exchange for, among other things, a dismissal with prejudice of the Class Action and full releases of all claims against defendants. 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 proposed 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. The proposed settlement, including any award of attorneys' fees and expenses, is subject to final court approval. On February 8, 2016, the parties filed the stipulation of settlement, which the court preliminarily approved on February 11, 2016. The court has set a final approval hearing for June 28, 2016. The proposed settlement does not resolve the individual securities lawsuits discussed below.

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

As previously disclosed, 13 individual securities lawsuits filed by foreign and domestic institutional investors also are consolidated with the Vioxx Securities Lawsuits. The allegations in the individual securities lawsuits are substantially similar to the allegations in the Vioxx Securities Lawsuits. Discovery has been completed in those actions and the court has issued a final pre-trial schedule; no trial date has been set. The proposed settlement in the Class Action, discussed above, does not resolve the individual securities lawsuits, although each individual plaintiff has the right, at its option, to join the settlement class at no additional cost to Merck on or before June 23, 2016.

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. There are disputes with the insurers about the availability of some or all 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

In connection with the settlement of the Class Action, which remains subject to final court approval, the Company established a net reserve of $680 million in the fourth quarter of 2015. The Company also has a reserve with respect to certain Vioxx Product Liability Lawsuits and an immaterial remaining reserve relating to the previously disclosed Vioxx investigation 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, Vioxx Securities Lawsuits and Vioxx International Lawsuits (collectively, the Remaining Vioxx Litigation) and will vigorously defend against them. In view of the inherent difficulty of predicting the outcome of litigation, particularly where there are many claimants and the claimants seek indeterminate damages, the Company is unable to predict the outcome of these matters and, at this time, cannot reasonably estimate the possible loss or range of loss with respect to the Remaining Vioxx Litigation.

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 March 31, 2016, approximately 4,435 cases had been filed and were 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 30 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 4,405 of these actions generally allege that they sustained femur fractures and/or other bone injuries (Femur Fractures) in association with the use of Fosamax.

Cases Alleging ONJ and/or Other Jaw Related Injuries

In August 2006, the Judicial Panel on Multidistrict Litigation (JPML) ordered that certain Fosamax product liability cases pending in federal courts nationwide should be transferred and consolidated into one multidistrict litigation (Fosamax ONJ MDL) for coordinated pre-trial proceedings.

In December 2013, Merck reached an agreement in principle with the Plaintiffs' Steering Committee (PSC) in the Fosamax ONJ MDL to resolve pending ONJ cases not on appeal in the Fosamax ONJ MDL and in the state courts for an aggregate amount of $27.7 million. Merck and the PSC subsequently formalized the terms of this agreement in a Master Settlement Agreement (ONJ Master Settlement Agreement) that was executed in April 2014 and included over 1,200 plaintiffs. As a condition to the settlement, 100% of the state and federal ONJ plaintiffs had to agree to participate in the settlement plan or Merck could either terminate the ONJ Master Settlement Agreement, or waive the

100% participation requirement and agree to a lesser funding amount for the settlement fund. On July 14, 2014, Merck elected to proceed with the ONJ Master Settlement Agreement at a reduced funding level 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 35 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.

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

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 10, 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, on June 27, 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, on March 26, 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 17, 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 March 31, 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 March 31, 2016, approximately 3,040 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.

As of March 31, 2016, approximately 300 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 on February 17, 2015 and the jury returned a verdict in Merck's favor on April 3, 2015, and plaintiff has appealed that verdict to the California appellate court. The next Femur Fracture trial in California that was scheduled to begin on April 25, 2016, was stayed at plaintiffs' request and a new trial date has not been set.

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

Discovery is ongoing in the Femur Fracture MDL and in state courts where Femur Fracture cases are pending and the Company intends to defend against these lawsuits.

Januvia/Janumet

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving Januvia and/or Janumet. As of March 31, 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). There are 12 cases pending against Merck in state courts other than the California State Court.

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

On November 9, 2015, the MDL granted summary judgment on the grounds of preemption as to all claims alleging injury due to pancreatic cancer. Based on that ruling, on November 30, 2015, the MDL entered final judgment resulting in the dismissal of the pancreatic cancer claims against Merck relating to approximately 715 product users. On November 16, 2015, the California State Court likewise granted summary judgment on preemption grounds as to claims alleging injury due to pancreatic cancer. Based on that ruling, on April 5, 2016, the California State Court entered final judgment resulting in the dismissal of the pancreatic cancer claims against Merck relating to approximately 350 product users.

Plaintiffs are appealing the MDL preemption ruling, and are expected to do likewise with respect to the California State Court ruling.

In addition to the claims noted above, the Company has agreed, as of December 31, 2015, to toll the statute of limitations for approximately 20 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 March 31, 2016, approximately 1,385 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 55 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

The Company has received a civil investigative demand from the U.S. Attorney’s Office for the Southern District of New York that requests information relating to the Company’s contracts with, services from and payments to pharmacy benefit managers with respect to Maxalt and Levitra from January 1, 2006 to the present. The Company is cooperating with the investigation.

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.

Commercial and Other Litigation

Sales Force Litigation

As previously disclosed, in May 2013, Ms. Kelli Smith filed a complaint against the Company in the United States District Court for the District of New Jersey on behalf of herself and a putative class of female sales representatives and a putative sub-class of female sales representatives with children, claiming (a) discriminatory policies and practices in selection, promotion and advancement, (b) disparate pay, (c) differential treatment, (d) hostile work environment and (e) retaliation under federal and state discrimination laws. In January 2014, plaintiffs filed an amended complaint adding four additional named plaintiffs. On October 8, 2014, the court denied the Company’s motion to dismiss or strike the class claims as premature. In September 2015, plaintiffs filed additional motions, including a motion for conditional certification under the Equal Pay Act; a motion to amend the pleadings seeking to add ERISA and constructive discharge claims and a Company subsidiary as a named defendant; and a motion for equitable relief. Merck filed papers in opposition to the motions. On April 27, 2016, the court granted plaintiff’s motion for conditional certification but denied plaintiffs’ motions to extend the liability period for their Equal Pay Act claims back to June 2009. As a result, the liability period will date back to April 2012, at the earliest. On April 29, 2016, the Magistrate Judge granted plaintiffs’ request to amend the complaint to add the following: (i) a Company subsidiary as a corporate defendant; (ii) an ERISA claim and (iii) an individual constructive discharge claim for one of the named plaintiffs.

Merck KGaA Litigation

In January 2016, to protect its long-established brand rights in the United States, the Company filed a lawsuit against Merck KGaA, Darmstadt, Germany (KGaA), operating as the EMD Group in the United States, alleging it improperly uses the name “Merck” in the United States. KGaA has filed suit against the Company in France, the United Kingdom (UK), Germany, Switzerland and Mexico alleging breach of the parties’ co-existence agreement, unfair competition and/or trademark infringement. In December 2015, the Paris Court of First Instance issued a judgment finding that certain activities by the Company directed towards France did not constitute trademark infringement and unfair competition while other activities were found to infringe. The Company and KGaA have both appealed the decision. In January 2016, the UK High Court issued a judgment finding that the Company had breached the co-existence agreement and infringed KGaA’s trademark rights as a result of certain activities

directed towards the UK based on use of the word MERCK on promotional and information activity. As noted in the UK decision, this finding was not based on the Company's use of the sign MERCK in connection with the sale of products or any material pharmaceutical business transacted in the UK. The Company and KGaA have both appealed this decision.

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 has appealed this decision, and the appeal was heard in March 2016. 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.

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 expires 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. The Company has asked the United States Supreme Court to review this decision. Hospira's application will not be approved until at least June 2016.

In October 2013, a patent infringement lawsuit was filed in the United States against Strides, Inc. and Agila Specialties Private Limited (Strides/Agila), with respect to Strides/Agila's application to the FDA seeking pre-patent expiry approval to market a generic version of Cubicin. As a result of the Hospira decision, Strides/Agila's application will not be approved until at least June 2016.

In July 2014, a patent infringement lawsuit was filed in the United States against Fresenius, with respect to Fresenius's application to the FDA seeking pre-patent expiry approval to market a generic version of Cubicin. As a result of the Hospira decision, Fresenius's application will not be approved until at least June 2016.

In December 2015, a patent infringement lawsuit was filed in the United States against Sagent Pharmaceuticals, Inc. (Sagent), with respect to Sagent's application to the FDA seeking pre-patent expiry approval to market a generic version of Cubicin. As a result of the Hospira decision, Sagent's application will not be approved until at least June 2016.

In December 2015, a patent infringement lawsuit was filed in the United States against Actavis LLC (Actavis), with respect to Actavis's application to the FDA seeking pre-patent expiry approval to market a generic version of Cubicin. As a result of the Hospira decision, Actavis's application will not be approved until at least June 2016.

In January 2016, a patent infringement lawsuit was filed in the United States against Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. (Dr. Reddy's), with respect to Dr. Reddy's application to the FDA seeking pre-patent

expiry approval to market a generic version of Cubicin. As a result of the Hospira decision, Dr. Reddy's application will not be approved until at least June 2016.

In February 2016, a patent infringement lawsuit was filed in the United States against Crane Pharmaceuticals LLC (Crane), with respect to Crane's application to the FDA seeking pre-patent expiry approval to market a generic version of Cubicin. As a result of the Hospira decision, Crane's application will not be approved until at least June 2016.

An earlier district court action against Teva Parenteral Medicines Inc., Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, Teva) resulted in a settlement whereby Teva can launch a generic version of Cubicin at the latest in December 2017, or earlier under certain conditions, but in no event before June 2016.

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

In October 2014, Agila Specialties Inc. and Mylan Pharmaceuticals Inc. (Agila/Mylan) filed petitions for Inter Partes Review (IPR) at the United States Patent and Trademark Office (USPTO) seeking the invalidity of the September 2019 and November 2020 patents. In April 2015, Agila/Mylan withdrew its petitions for IPR in exchange for the Company agreeing to narrow the issues in the Strides/Agila lawsuit referenced above. In November 2014, Fresenius filed petitions for IPR at the USPTO seeking the invalidity of the September 2019 patents. In May 2015, the USPTO granted Fresenius's petition for an IPR on the September 2019 patents. The IPR hearing was held in February 2016. In July 2015, Fresenius filed petitions for IPR seeking invalidity of the November 2020 patents. In January 2016, the USPTO granted Fresenius's petition for an IPR on the November 2020 patents.

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 is scheduled to begin in May 2016. 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 is scheduled to begin in June 2016.

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 the Actavis and Crane 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 has 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, subject, in one case involving lovastatin, to Apotex's right to file a motion for reconsideration to the Supreme Court of Canada. As a consequence of the conclusion of all of this litigation, in the second quarter of 2016, if Apotex does not move for reconsideration or such motion is denied, the Company will record a net gain of approximately $100 million.

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, if valid, broadly claims anti-PD-1 antibodies that could include Keytruda. BMS and Ono recently submitted a request to amend the claims of the '336 patent. If the EPO allows this amendment, the claims of the '336 patent would 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.

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 and the Company is anticipating a decision in May 2016.

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 have 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 '336 and '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 or '336 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 USPTO granted US Patent Nos. 8,728,474 to Ono and 8,779,105 to Ono and BMS. 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. Recently, 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.

On April 15, 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.
In September 2014, the Company filed a lawsuit in Australia seeking the revocation of Australian Patent No. 2011203119, which is equivalent to the ’336 patent. 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.

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

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.

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 judge held a bench trial on the equitable defenses raised by Gilead. The parties have completed their briefing and argument on these defenses and are awaiting the judge's decision. The parties have agreed to sever the issue of a reasonable royalty for sales after March 2016. The Company will pay 20%, net of legal fees, of any damages or royalties 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, 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. The Australian patent was recently found to be invalid. The Company is currently analyzing the decision and considering its options.

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 March 31, 2016 and December 31, 2015 of approximately $250 million and $245 million, respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

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

9. Equity

($ and shares in millions)	Common Stock Shares	Common Stock Par Value	Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock Shares	Treasury Stock Cost	Non-Controlling Interests	Total
Balance at January 1, 2015	3,577	$ 1,788	$40,423	$46,021	$ (4,323)	739	$(35,262)	$ 144	$48,791
Net income attributable to Merck & Co., Inc.	—	—	—	953	—	—	—	—	953
Cash dividends declared on common stock	—	—	—	(1,282)	—	—	—	—	(1,282)
Treasury stock shares purchased	—	—	—	—	—	17	(1,015)	—	(1,015)
Share-based compensation plans and other	—	—	(68)	—	—	(7)	374	—	306
Other comprehensive income	—	—	—	—	156	—	—	—	156
Changes in noncontrolling ownership interests	—	—	—	—	—	—	—	5	5
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	5	5
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(2)	(2)
Balance at March 31, 2015	3,577	$ 1,788	$40,355	$45,692	$ (4,167)	749	$(35,903)	$ 152	$47,917
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.	—	—	—	1,125	—	—	—	—	1,125
Cash dividends declared on common stock	—	—	—	(1,281)	—	—	—	—	(1,281)
Treasury stock shares purchased	—	—	—	—	—	18	(913)	—	(913)
Share-based compensation plans and other	—	—	(77)	—	—	(6)	322	—	245
Other comprehensive loss	—	—	—	—	(46)	—	—	—	(46)
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	5	5
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(1)	(1)
Balance at March 31, 2016	3,577	$ 1,788	$40,145	$45,192	$ (4,194)	808	$(39,125)	$ 95	$43,901

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:

	Three Months Ended March 31,	
($ in millions)	2016	2015
Pretax share-based compensation expense	$68	$63
Income tax benefit	(20)	(19)

Total share-based compensation expense, net of taxes	$48	$44

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 three months of 2016 and 2015, the Company granted 133 thousand RSUs with a weighted-average grant date fair value of $48.83 per RSU and 87 thousand RSUs with a weighted-average grant date fair value of $58.33 per RSU, respectively. During the first three months of 2016 and 2015, the Company granted 74 thousand stock options with a weighted-average exercise price of $48.83 per option and 95 thousand stock options with a weighted-average exercise price of $58.33 per option, respectively. The weighted-average fair value of options granted for the first three months of 2016 and 2015 was $5.76 and $6.98 per option, respectively, and was determined using the following assumptions:

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

	Three Months Ended March 31,	
	2016	2015
Expected dividend yield	3.8 %	4.2 %
Risk-free interest rate	1.3 %	1.7 %
Expected volatility	21.0%	21.7%
Expected life (years)	6.2	6.3

At March 31, 2016, there was $689 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 2.4 years.

The Company typically communicates the value of annual share-based compensation awards to employees during the first quarter, but the related share amounts are not established and communicated until early May. Therefore, while the number of RSU and stock option grants disclosed above do not reflect any amounts relating to the annual grants, share-based compensation costs for the first quarter of 2016 and 2015 and unrecognized compensation expense at March 31, 2016 reflect an impact relating to the awards communicated to employees. 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:

	Three Months Ended March 31,			
	2016		2015	
($ in millions)	U.S.	International	U.S.	International
Service cost	$73	$ 58	$83	$ 66
Interest cost	113	52	109	53
Expected return on plan assets	(210)	(95)	(206)	(97)
Net amortization	15	19	43	27
Termination benefits	4	—	16	1
Curtailments	—	1	(7)	—
Settlements	—	—	—	2
	$(5)	$ 35	$38	$ 52

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:

	Three Months Ended March 31,	
($ in millions)	2016	2015
Service cost	$13	$20
Interest cost	21	27
Expected return on plan assets	(35)	(36)
Net amortization	(26)	(15)
Termination benefits	1	4
Curtailments	(1)	(6)
	$(27)	$(6)

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.

The Company currently expects that, following certain allowable administrative actions expected to occur later in 2016, approximately $1.0 billion of other postretirement benefit plan assets will no longer be restricted for retiree benefits and will be 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 March 31,	
($ in millions)	2016	2015
Interest income	$(79)	$(74)
Interest expense	172	164
Exchange losses	38	95
Equity income from affiliates	(34)	(145)
Other, net	(49)	15
	$48	$55

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

Other, net (as reflected in the table above) in the first quarter of 2015 includes an expense of $78 million for a contribution of investments in equity securities to the Merck Foundation.

Interest paid for the three months ended March 31, 2016 and 2015 was $160 million and $138 million, respectively.

13. Taxes on Income

The effective income tax rates of 30.4% and 30.6% for the first quarter 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 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.

14. Earnings Per Share

The calculations of earnings per share are as follows:

	Three Months Ended March 31,	
($ and shares in millions except per share amounts)	2016	2015
Net income attributable to Merck & Co., Inc.	$1,125	$953
Average common shares outstanding	2,774	2,835
Common shares issuable [(1)]	21	30
Average common shares outstanding assuming dilution	2,795	2,865
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	$0.41	$0.34
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	$0.40	$0.33

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

For the three months ended March 31, 2016 and 2015, 10 million and 3 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.

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

15. Other Comprehensive Income (Loss)

Changes in AOCI by component are as follows:

	Three Months Ended March 31,				
($ in millions)	Derivatives	Investments	Employee Benefit Plans	Cumulative Translation Adjustment	Accumulated 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	565	93	6	(53)	611
Tax	(198)	(10)	(3)	(124)	(335)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	367	83	3	(177)	276
Reclassification adjustments, pretax	(171)[1]	(56)[2]	54[3]	—	(173)
Tax	56	19	(22)	—	53
Reclassification adjustments, net of taxes	(115)	(37)	32	—	(120)
Other comprehensive income (loss), net of taxes	252	46	35	(177)	156
Balance March 31, 2015, net of taxes	$782	$ 157	$ (2,951)	$ (2,155)	$ (4,167)
Balance January 1, 2016, net of taxes	$404	$ 41	$ (2,407)	$ (2,186)	$ (4,148)
Other comprehensive income (loss) before reclassification adjustments, pretax	(167)	54	(35)	99	(49)
Tax	58	16	(1)	22	95
Other comprehensive income (loss) before reclassification adjustments, net of taxes	(109)	70	(36)	121	46
Reclassification adjustments, pretax	(143)[1]	(11)[2]	7[3]	—	(147)
Tax	50	4	1	—	55
Reclassification adjustments, net of taxes	(93)	(7)	8	—	(92)
Other comprehensive income (loss), net of taxes	(202)	63	(28)	121	(46)
Balance March 31, 2016, net of taxes	$202	$ 104	$ (2,435)	$ (2,065)	$ (4,194)

(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.

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

Sales of the Company's products were as follows:

	Three Months Ended March 31,	
($ in millions)	2016	2015
Primary Care and Women's Health		
Cardiovascular		
Zetia	$612	$568
Vytorin	277	320
Diabetes		
Januvia	906	884
Janumet	506	509
General Medicine and Women's Health		
NuvaRing	175	166
Implanon/Nexplanon	134	137
Dulera	113	130
Follistim AQ	94	82
Hospital and Specialty		
Hepatitis		
Zepatier	50	—
HIV		
Isentress	340	385
Hospital Acute Care		
Cubicin	292	187
Noxafil	145	111
Cancidas	133	163
Invanz	114	132
Bridion	90	85
Primaxin	73	65
Immunology		
Remicade	349	501
Simponi	188	158
Oncology		
Keytruda	249	83
Emend	126	122
Temodar	66	74
Diversified Brands		
Respiratory		
Singulair	237	245
Nasonex	229	289
Other		
Cozaar/Hyzaar	126	185
Arcoxia	111	123
Fosamax	75	94
Zocor	46	49
Vaccines [1]		
Gardasil/Gardasil 9	378	359
ProQuad/M-M-R II/Varivax	357	348
RotaTeq	188	192

Zostavax	125	175
Pneumovax 23	107	110
Other pharmaceutical [2]	1,093	1,235
Total Pharmaceutical segment sales	8,104	8,266
Other segment sales [3]	905	929
Total segment sales	9,009	9,195
Other [4]	303	230
	$9,312	$9,425

(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 quarter of 2016 also includes $75 million related to the sale of certain U.S. marketing rights (see Note 2).

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

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

	Three Months Ended March 31,	
($ in millions)	2016	2015
Segment profits:		
Pharmaceutical segment	$5,117	$5,165
Other segments	386	438
Total segment profits	5,503	5,603
Other profits	227	152
Unallocated:		
Interest income	79	74
Interest expense	(172)	(164)
Equity income from affiliates	20	143
Depreciation and amortization	(430)	(396)
Research and development	(1,373)	(1,561)
Amortization of purchase accounting adjustments	(1,134)	(1,238)
Restructuring costs	(91)	(82)
Other unallocated, net	(1,005)	(1,150)
	$1,624	$1,381

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.

Operating Results

Sales

Worldwide sales were $9.3 billion for the first quarter of 2016, a decline of 1% compared with the first quarter of 2015. Foreign exchange unfavorably affected global sales performance by 4% in the first quarter of 2016. Excluding the unfavorable effect of foreign exchange, sales growth reflects higher sales of Keytruda (pembrolizumab), Januvia (sitagliptin) and Janumet (sitagliptin and metformin HCl), Zetia (ezetimibe), Zepatier (elbasvir and grazoprevir), Simponi (golimumab), Noxafil (posaconazole), ProQuad (Measles, Mumps, Rubella and Varicella Virus Vaccine Live) and Adempas (riociguat). Revenue in the first quarter of 2016 benefited from approximately one month of additional sales related to 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 quarter of 2016 in connection with the sale of the U.S. marketing right to certain products. Partially offsetting revenue growth in the quarter were declines in Remicade (infliximab), Nasonex (mometasone furoate monohydrate), Zostavax (Zoster Vaccine Live), Cozaar (losartan potassium) and Hyzaar (losartan potassium and hydrochlorothiazide), Isentress (raltegravir) and M-M-R II (Measles, Mumps and Rubella Virus Vaccine Live). Sales performance in the first quarter of 2016 reflects a decline of approximately $240 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 quarter 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.

Sales of the Company's products were as follows:

	Three Months Ended March 31,	
($ in millions)	2016	2015
Primary Care and Women's Health		
Cardiovascular		
Zetia	$612	$568
Vytorin	277	320
Diabetes		
Januvia	906	884
Janumet	506	509
General Medicine and Women's Health		
NuvaRing	175	166
Implanon/Nexplanon	134	137
Dulera	113	130
Follistim AQ	94	82
Hospital and Specialty		
Hepatitis		
Zepatier	50	—
HIV		
Isentress	340	385
Hospital Acute Care		
Cubicin	292	187
Noxafil	145	111
Cancidas	133	163
Invanz	114	132
Bridion	90	85
Primaxin	73	65
Immunology		
Remicade	349	501
Simponi	188	158
Oncology		
Keytruda	249	83
Emend	126	122
Temodar	66	74
Diversified Brands		
Respiratory		
Singulair	237	245
Nasonex	229	289
Other		
Cozaar/Hyzaar	126	185
Arcoxia	111	123
Fosamax	75	94
Zocor	46	49
Vaccines [1]		
Gardasil/Gardasil 9	378	359
ProQuad/M-M-R II/Varivax	357	348

RotaTeq	188	192
Zostavax	125	175
Pneumovax 23	107	110
Other pharmaceutical [2]	1,093	1,235
Total Pharmaceutical segment sales	8,104	8,266
Other segment sales [3]	905	929
Total segment sales	9,009	9,195
Other [4]	303	230
	$9,312	$9,425

(1) 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 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.

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

The provision for discounts 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 $2.1 billion and $1.7 billion for the three months ended March 31, 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 $889 million in the first quarter of 2016, essentially flat as compared with the first quarter of 2015 including a 4% unfavorable effect from foreign exchange. Sales performance reflects higher pricing in the United States, as well as higher volumes in Europe, partially offset by lower volumes in the United States.

By agreement, a generic manufacturer may launch a generic version of Zetia in the United States in December 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 $33 million for Adempas in the first quarter of 2016.

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. 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 quarter of 2016. The remaining intangible asset value for Zontivity was $32 million at March 31, 2016.

Diabetes

Worldwide combined sales of Januvia and Janumet, medicines that help lower blood sugar levels in adults with type 2 diabetes, were $1.4 billion in the first quarter of 2016, an increase of 1% compared with the same period of 2015. Foreign exchange unfavorably affected global sales performance by 3% in the first quarter of 2016. Sales growth was driven primarily by higher volumes in the United States and Europe, partially offset by volume declines in certain emerging markets, particularly Venezuela due to the Company's reduced operations in that country.

In September 2015, Merck announced that the Japanese Pharmaceuticals and Medical Devices Agency approved Marizev (omarigliptin) 25 mg and 12.5 mg tablets, an oral, once-weekly dipeptidyl peptidase-4 (DPP-4) inhibitor indicated for the treatment of adults with type 2 diabetes. In April 2016, Merck announced that it will not proceed with submitting marketing applications for omarigliptin in the United States or Europe for business reasons. This decision did not result from concerns about the efficacy or safety of omarigliptin. Merck remains committed to Marizev in Japan.

General Medicine and Women's Health

Worldwide sales of NuvaRing (etonogestrel/ethinyl estradiol vaginal ring), a vaginal contraceptive product, increased 6% in the first quarter of 2016 to $175 million, primarily reflecting higher pricing in the United States. Foreign exchange unfavorably affected global sales performance by 3% in the first quarter of 2016.

Worldwide sales of Implanon/Nexplanon (etonogestrel implant), single-rod subdermal contraceptive implants, declined 2% to $134 million in the first quarter of 2016 compared with the same period of 2015 including a 2% unfavorable effect from foreign exchange. Sales performance reflects higher demand in the United States that was offset by lower volumes in certain emerging markets.

Global sales of Dulera Inhalation Aerosol (mometasone furoate/formoterol fumarate dihydrate), a combination medicine for the treatment of asthma, declined 13% to $113 million in the first quarter of 2016 compared with the same period of 2015 driven by lower sales in the United States reflecting customer buying patterns and competitive pricing pressures that were partially offset by higher demand.

Global sales of Follistim AQ (follitropin beta injection) (marketed in most countries outside the United States as Puregon), a fertility treatment, were $94 million in the first quarter of 2016, an increase of 16% compared with the first quarter of 2015 including a 4% unfavorable effect from foreign exchange. Sales performance in the first quarter primarily reflects higher sales in the United States from both price and volume.

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 $50 million in the first quarter of 2016.

In the course of the European review for Zepatier, the European Medicines Agency 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. The Company continues to believe that European Union (EU) approval can be achieved according to the midyear timeline that was previously disclosed. However, the European launch will be delayed until the fourth quarter of 2016 or possibly until the end of the first quarter of 2017, dependent upon how quickly these matters can be resolved.

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 $340 million in the first quarter of 2016, a decline of 12% compared with the first quarter of 2015 including a 4% unfavorable effect from foreign exchange. The sales decline was 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 pricing in the United States.

Hospital Acute Care

Sales of Cubicin (daptomycin for injection), an I.V. antibiotic for complicated skin and skin structure infections or bacteremia when caused by designated susceptible organisms, were $292 million in the first quarter of 2016 and $187 million in the first quarter of 2015. Cubicin was acquired with the purchase of Cubist on January 21, 2015. Accordingly, the increase in sales in the first quarter of 2016 compared with the first quarter of 2015 is largely attributable to nearly one month of additional sales in 2016. The U.S. composition patent for Cubicin expires in June 2016 and significant losses of Cubicin sales are expected to occur thereafter.

In many markets outside of the United States, Cubicin was commercialized by other companies in accordance with distribution agreements established prior to Merck's acquisition of Cubist. In the fourth quarter of 2015, Merck entered into agreements to reacquire the marketing rights to Cubicin in certain international markets (including Europe, Latin America, Australia, New Zealand, China, South Africa and certain other Asia Pacific countries).

Worldwide sales of Noxafil, for the prevention of invasive fungal infections, grew 31% in the first quarter of 2016 to $145 million compared with the same period of 2015 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 5% in the first quarter of 2016.

Global sales of Cancidas (caspofungin acetate), an anti-fungal product, decreased 19% in the first quarter of 2016 to $133 million compared with the same prior year period. Foreign exchange unfavorably affected sales performance by

7% in the first quarter of 2016. The sales decline was driven primarily by lower volumes in certain emerging markets reflecting in part timing of shipments.

Sales of Bridion (sugammadex) Injection, for the reversal of two types of neuromuscular blocking agents used during surgery, were $90 million in the first quarter of 2016, an increase of 6% compared with the first quarter of 2015 including a 7% unfavorable effect from foreign exchange. Sales performance 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 $349 million in the first quarter of 2016, a decline of 30% compared with the first quarter of 2015. Foreign exchange unfavorably affected sales performance by 4% in the first quarter 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 $188 million in the first quarter of 2016, growth of 19% compared with the same period in 2015. Foreign exchange unfavorably affected global sales performance by 8% in the first quarter of 2016. The sales growth was driven primarily by higher volumes in Europe reflecting in part an ongoing positive impact from the ulcerative colitis indication, as well as timing of shipments.

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 $249 million in the first quarter of 2016 compared with $83 million in the first quarter of 2015. The increase 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.

The Company has made additional regulatory filings in 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).

Global sales of Emend (aprepitant), for the prevention of chemotherapy-induced and post-operative nausea and vomiting, were $126 million in the first quarter of 2016, an increase of 3% compared with the first quarter of 2015 including a 5% unfavorable effect from foreign exchange. Sales growth reflects higher pricing in the United States and volume growth in emerging markets. 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 $237 million in the first quarter of 2016, a decrease of 3% compared with the first quarter of 2015 including a 2% unfavorable effect from foreign exchange. 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 losses of Singulair sales in Japan thereafter. Singulair sales in Japan were $116 million in the first quarter of 2016.

Global sales of Nasonex, an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, declined 21% to $229 million in the first quarter of 2016. Foreign exchange unfavorably affected global sales performance by 2% in the first quarter of 2016. The decline was driven primarily by lower volumes in the United States reflecting competition from alternative generic treatment options, as well as lower volumes and pricing in Europe from ongoing generic erosion and lower sales in emerging markets, partially offset by higher pricing in the United States. 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 anticipates a substantial decline in U.S. Nasonex sales during 2016.

Other

Global sales of Cozaar and its companion agent Hyzaar (a combination of Cozaar and hydrochlorothiazide), treatments for hypertension, were $126 million in the first quarter of 2016, a decline of 32% compared with the first quarter of 2015 including an 11% unfavorable effect from foreign exchange. The sales decline primarily reflects lower sales in 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.

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 (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant)/Gardasil 9 (Human Papillomavirus 9-valent Vaccine, Recombinant), vaccines to help prevent certain diseases caused by certain types of human papillomavirus (HPV), grew 5% in the first quarter of 2016 to $378 million driven by increased sales in the United States reflecting higher pricing, partially offset by lower volumes reflecting the timing of public sector purchases. Foreign exchange unfavorably affected global sales performance by 2% in the first quarter of 2016.

Merck's sales of ProQuad, a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, were $122 million in the first quarter of 2016 compared with $86 million in the first quarter of 2015. The increase was driven primarily by $29 million of sales to the U.S. Centers for Disease Control and Prevention Pediatric Vaccine Stockpile in the first quarter of 2016. Merck's sales of M M R II, a vaccine to help protect against measles, mumps and rubella, were $76 million for the first quarter of 2016 compared with $107 million for the first quarter of 2015. The sales decline largely reflects higher demand in the prior year due to measles outbreaks in the United States.

Merck's sales of Varivax (Varicella Virus Vaccine Live), a vaccine to help prevent chickenpox (varicella), were $158 million for the first quarter of 2016, comparable to sales of $155 million for the first quarter of 2015.

Merck's sales of RotaTeq (Rotavirus Vaccine, Live Oral, Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and children, were $188 million in the first quarter of 2016, a decline of 2% compared with the first quarter of 2015 including a 1% unfavorable effect from foreign exchange. The sales decline was primarily

driven by lower public sector purchasing in the United States, partially offset by higher volumes in certain emerging markets.

Merck's sales of Zostavax, a vaccine to help prevent shingles (herpes zoster) in adults 50 years of age and older, were $125 million in the first quarter of 2016, a decline of 28% compared with the first quarter of 2015 including a 1% unfavorable effect from foreign exchange. The sales decline was driven by lower volumes in the United States. 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, declined 3% in the first quarter of 2016 to $107 million. Foreign exchange unfavorably affected global sales performance by 1% in the first quarter of 2016. The sales decline primarily reflects lower demand in the United States, as well as lower volumes in Japan, partially offset by 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 $829 million for the first quarter of 2016, essentially flat compared with the first quarter of 2015 including a 9% unfavorable effect from foreign exchange. Sales performance reflects volume growth in companion animal products, driven primarily by higher sales of Bravecto (fluralaner) chewable tablets for dogs to treat fleas and ticks.

Costs, Expenses and Other

Materials and Production

Materials and production costs were $3.6 billion for the first quarter of 2016, essentially flat as compared with the first quarter of 2015. Costs in the first quarter of 2016 and 2015 include $1.1 billion and $1.2 billion, respectively, of expenses for the amortization of intangible assets recognized in connection with business acquisitions. In addition, expenses for the first quarter of 2016 and 2015 include $24 million and $20 million, respectively, of amortization of purchase accounting adjustments to Cubist's inventories. Costs also include intangible asset impairment charges of $252 million and $12 million for the first quarter 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 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. Included in materials and production costs are costs associated with restructuring activities which amounted to $47 million and $105 million in the first quarter 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 61.6% in the first quarter of 2016 compared with 62.1% in the first quarter 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 15.4 and 14.4 percentage points for the first quarter of 2016 and 2015, respectively. Excluding the impact of these items, the gross margin increase in the first quarter of 2016 compared with the corresponding prior year period was driven primarily by lower inventory write-offs.

Marketing and Administrative

Marketing and administrative expenses decreased 11% to $2.3 billion in the first quarter of 2016 compared with the first quarter of 2015. The decline largely reflects lower acquisition and divestiture-related costs, the favorable effects of foreign exchange, lower restructuring costs, as well as lower selling costs, partially offset by higher promotional spending largely related to product launches. Marketing and administrative expenses include acquisition and divestiture-related costs of $2 million and $227 million in the first quarter 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 quarter of 2015 include costs related to the acquisition of Cubist (see Note 2 to the condensed consolidated financial statements.) Expenses for the first quarter of 2016 and 2015 also include $3 million and $36 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 $1.7 billion for the first quarter of 2016, a decline of 4% compared with the first quarter of 2015, reflecting lower licensing costs, lower expenses recorded in connection with liabilities for contingent consideration, as well as the favorable effects of foreign exchange, partially offset by higher clinical

development spending, increased restructuring costs and higher IPR&D impairment charges.

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 $980 million and $920 million in the first quarter 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 $590 million and $750 million for the first quarter of 2016 and 2015, respectively. The decline primarily reflects higher licensing costs in the prior year period reflecting in part the collaboration with NGM Biopharmaceuticals, Inc. (see Note 2 to the condensed consolidated financial statements). 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 the first quarter of 2016 and 2015, the Company recorded charges of $9 million and $61 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 $55 million and $2 million in the first quarter of 2016 and 2015, respectively (see Note 3 to the condensed consolidated financial statements). In addition, research and development expenses include IPR&D impairment charges of $25 million for the first quarter of 2016 (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.

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, subsequent to the Merck and Schering-Plough Corporation (Schering-Plough) merger, the Company commenced actions under a global restructuring program (the Merger Restructuring Program) designed to streamline the cost structure of the combined company. In 2013, the Company initiated actions under a global restructuring program (the 2013 Restructuring Program) as part of a global initiative to sharpen its commercial and research and development focus. 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 is also reducing its global real estate footprint and continues to improve the efficiency of its manufacturing and supply network.

Restructuring costs, primarily representing separation and other related costs associated with these restructuring activities, were $91 million and $82 million for the first quarter of 2016 and 2015, respectively. Separation costs were incurred that were associated with actual headcount reductions, as well as estimated expenses under existing severance programs for headcount reductions that were probable and could be reasonably estimated. Merck eliminated approximately 470 positions in the first quarter of 2016 compared with approximately 1,085 positions in the first quarter of 2015 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 pretax costs of $196 million and $225 million in the aggregate in the first quarter 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 $1.3 billion of additional pretax costs. The Company anticipates that total costs associated with restructuring program activities in 2016 will be in the range of $700 million to $900 million.

Other (Income) Expense, Net

Other (income) expense, net was $48 million of expense in the first quarter of 2016 compared with $55 million of expense in the first quarter of 2015. The favorability was driven primarily by an expense of $78 million in 2015 for a contribution of investments in equity securities to the Merck Foundation, as well as lower foreign exchange losses in 2016, partially offset by lower equity income in 2016 from certain research investment funds.

Segment Profits

	Three Months Ended March 31,	
($ in millions)	2016	2015
Pharmaceutical segment profits	$5,117	$5,165
Other non-reportable segment profits	386	438
Other	(3,879)	(4,222)
Income before income taxes	$1,624	$1,381

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 declined 1% in the first quarter of 2016 as compared with the corresponding prior year period primarily reflecting the unfavorable effect of foreign exchange.

Taxes on Income

The effective income tax rates of 30.4% and 30.6% for the first quarter 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 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 $1.1 billion for the first quarter of 2016 compared with $953 million for the first quarter of 2015. Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders (EPS) for the first quarter of 2016 were $0.40 compared with $0.33 in the first quarter of 2015.

Non-GAAP Income and Non-GAAP EPS

Non-GAAP income and non-GAAP EPS are alternative views of the Company's performance used by management that Merck is providing because management believes this information enhances investors' understanding of the Company's results. 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 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. Therefore, the information on non-GAAP income and non-GAAP EPS should be considered in addition to, but not in lieu of, net income and EPS prepared in accordance with generally accepted accounting principles in the United States (GAAP). Additionally, 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.

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 income and non-GAAP EPS and the performance of the Company is measured on this basis along with other performance metrics. Senior management's annual compensation is derived in part using non-GAAP income and non-GAAP EPS.

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

	Three Months Ended March 31,	
($ in millions except per share amounts)	2016	2015
Pretax income as reported under GAAP	$1,624	$1,381
Increase (decrease) for excluded items:		
Acquisition and divestiture-related costs	1,423	1,526
Restructuring costs	196	225
	3,243	3,132
Taxes on income as reported under GAAP	494	423
Estimated tax benefit on excluded items	252	278
	746	701
Non-GAAP net income	2,497	2,431
Less: Net income attributable to noncontrolling interests	5	5
Non-GAAP net income attributable to Merck & Co., Inc.	$2,492	$2,426
EPS assuming dilution as reported under GAAP	$0.40	$0.33
EPS difference [(1)]	0.49	0.52
Non-GAAP EPS assuming dilution	$0.89	$0.85

(1) Represents the difference between calculated GAAP EPS and calculated non-GAAP EPS, which may be different than the amount calculated by dividing the impact of the excluded items by the weighted-average shares for the applicable period.

Acquisition and Divestiture-Related Costs

Non-GAAP income and non-GAAP EPS exclude the impact of certain amounts recorded in connection with 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. These costs should not be considered non-recurring; however, management excludes these amounts from non-GAAP income and non-GAAP EPS because it believes it is helpful for understanding the performance of the continuing business.

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. The Company has undertaken restructurings of different types during the covered periods and, therefore, these charges should not be considered non-recurring; however, management excludes these amounts from non-GAAP income and non-GAAP EPS because it believes it is helpful for understanding the performance of the continuing business.

Certain Other Items

Non-GAAP income and non-GAAP EPS exclude certain other items. These items represent substantive, unusual items that are evaluated on an individual basis. Such evaluation considers both the quantitative and the qualitative aspect of their unusual nature and generally represent items that, either as a result of their nature or magnitude, management

would not anticipate that they would occur as part of the Company's normal business on a regular basis.

Research and Development Update

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 non-small-cell lung cancer (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 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.

The Keytruda clinical development program includes patients with more than 30 tumor types in more than 250 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, Hodgkin lymphoma, non-Hodgkin lymphoma, multiple myeloma, nasopharyngeal 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 with a PDUFA action date of July 23, 2016. Zinplava is an investigational antitoxin for the prevention of Clostridium difficile infection recurrence. The Antimicrobial Drugs Advisory Committee of the FDA has scheduled a meeting on June 9, 2016 to discuss the BLA for Zinplava. Bezlotoxumab is also under review in the EU.

In addition, in April 2016, Merck announced that the FDA accepted for review the BLA for MK-8237, Merck's house dust mite sublingual allergy immunotherapy (SLIT) tablet. Merck's house dust mite SLIT-tablet is an investigational sublingual immunotherapy dissolvable tablet designed to help treat allergic rhinitis with or without conjunctivitis caused by house dust mite-specific allergens. Merck has partnered with ALK-Abelló to develop its house dust mite SLIT-tablet in North America.

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 May 6, 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
Asthma
MK-1029
Cancer
MK-3475 Keytruda
Hodgkin Lymphoma
PMBCL (Primary Mediastinal Large B-Cell Lymphoma)
Advanced Solid Tumors
Nasopharyngeal
Ovarian
MK-2206
MK-8628
Diabetes Mellitus
MK-8521
Heart Failure
MK-1242 (vericiguat)(1)
Hepatitis C
MK-3682B (MK-3682/MK-8408/MK-5172 (grazoprevir))
Pneumoconjugate Vaccine
V114

Phase 3 (Phase 3 entry date)
Alzheimer's Disease
MK-8931 (verubecestat) (December 2013)
Atherosclerosis
MK-0859 (anacetrapib) (May 2008)
Bacterial Infection
MK-7655A (relebactam+imipenem/cilastatin) (October 2015)
Cancer
MK-3475 Keytruda
Bladder (October 2014)
Breast (October 2015)
Colorectal (November 2015)
Esophageal (December 2015)
Gastric (May 2015)
Head and Neck (November 2014) (EU)
Multiple Myeloma (December 2015)
CMV Prophylaxis in Transplant Patients
MK-8228 (letermovir) (June 2014)
Contraception, Next Generation Ring
MK-8342B (September 2015)
Diabetes Mellitus
MK-8835 (ertugliflozin) (November 2013)(1)
MK-8835A (ertugliflozin+sitagliptin) (September 2015)(1)
MK-8835B (ertugliflozin+metformin) (August 2015)(1)
MK-1293 (February 2014) (U.S.)(1)
MK-0431J (sitagliptin+ipragliflozin) (October 2015) (Japan) (1)
Ebola Vaccine
V920 (March 2015)
Herpes Zoster
V212 (inactivated VZV vaccine) (December 2010)
HIV
MK-1439 (doravirine) (December 2014)
Osteoporosis

Under Review
Allergy
MK-8237, House Dust Mite (U.S.)(1,2)
Cancer
MK-3475 Keytruda
Head and Neck (U.S.)
Non-Small-Cell Lung (EU)
Clostridium difficile Infection
MK-6072 Zinplava (U.S./EU)
Diabetes Mellitus
MK-1293 (EU)(1)
Hepatitis C
MK-5172A Zepatier (EU)
Pediatric Hexavalent Combination Vaccine
V419 (U.S.)(3)

Footnotes:
(1) Being developed in a collaboration.
(2) North American rights only.
(3) 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-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 $21 million of such income in the first quarter 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 $182 million and $162 million in the first quarter of 2016 and 2015, respectively. SPMSD sales of Gardasil were $41 million and $39 million for the first quarter 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.

Simcere MSD Shanghai Pharmaceutical Co., Ltd.

In March 2015, Merck and Simcere Pharmaceutical Group (Simcere) executed a restructuring agreement in which Merck agreed to transfer its 51% ownership interest in the Simcere MSD Shanghai Pharmaceutical Co., Ltd. joint venture to Simcere. As a result, Merck deconsolidated the joint venture and recorded a net loss of $4 million in Other (income) expense, net in the first quarter of 2015.

Liquidity and Capital Resources

($ in millions)	March 31, 2016	December 31, 2015
Cash and investments	$25,497	$26,466
Working capital	11,204	10,550
Total debt to total liabilities and equity	26.1 %	26.0 %

Cash provided by operating activities was $2.2 billion in the first three months of 2016 compared with $2.3 billion in the first three 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 investing activities was $1.7 billion in the first three months of 2016 compared with a use of cash of $6.6 billion in the first three 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 $2.9 billion in the first three months of 2016 compared with cash provided by financing activities of $5.2 billion in the first three months of 2015 driven primarily by lower proceeds from the issuance of debt and a decrease in short-term borrowings, partially offset by lower payments on debt.

At March 31, 2016, the total of worldwide cash and investments was $25.5 billion, including $12.9 billion of cash, cash equivalents and short-term investments and $12.6 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.

In April 2016, the Company funded the portion of the Vioxx shareholder class action litigation settlement not covered by insurance proceeds (see Note 8 to the condensed consolidated financial statements).

Capital expenditures totaled $279 million and $203 million for the first three months of 2016 and 2015, respectively.

Dividends paid to stockholders were $1.3 billion for both the first three months of 2016 and 2015. In February 2016, the Board of Directors declared a quarterly dividend of $0.46 per share on the Company's common stock that was paid in April 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 three months of 2016, the Company purchased $913 million (18 million shares) for its treasury. As of March 31, 2016, the Company's remaining share repurchase authorization was $7.6 billion.

In January 2016, $850 million of 2.2% 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 consisting of $300 million principal amount of floating rate notes due 2017, $700 million principal amount of floating rate notes due 2020, $1.25 billion principal amount of 1.85% notes due 2020, $1.25 billion aggregate principal amount of 2.35% notes due 2022, $2.5 billion aggregate principal amount of 2.75% notes due 2025 and $2.0 billion aggregate principal

amount of 3.70% notes due 2045. 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.

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).

The Company has a $6.0 billion, five-year credit facility that matures in August 2019. 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 March 2016, the FASB issued new guidance intended to simplify the accounting and reporting for employee share-based payment transactions, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification of taxes paid in the statement of cash flows. Among other provisions, the new guidance will require all income tax effects of awards to be recognized in the income statement when the awards vest or are settled (as opposed to existing guidance under which tax effects are recorded to other paid-in-capital in certain instances). The guidance is effective for interim and annual periods beginning in 2018. Early adoption is permitted. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

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 March 31, 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 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 March 31, 2016 were as follows:

ISSUER PURCHASES OF EQUITY SECURITIES

			($ in millions)
Period	Total Number of Shares Purchased[1]	Average Price Paid Per Share	Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs[1]
January 1 - January 31	6,589,446	$51.75	$8,148
February 1 - February 29	6,626,155	$49.73	$7,818
March 1 - March 31	4,653,800	$52.12	$7,576
Total	17,869,401	$51.10	$7,576

(1) Shares purchased during the period were made as part of a plan approved by the Board of Directors in March 2015 to purchase up to $10 billion of Merck's common stock for its treasury.

Item 6. Exhibits

Number	Description
3.1	Restated Certificate of Incorporation of Merck & Co., Inc. (November 3, 2009) – Incorporated by reference to Current Report on Form 8-K filed on November 4, 2009 (No. 1-6571)
3.2	By-Laws of Merck & Co., Inc. (effective July 22, 2015) – Incorporated by reference to Current Report on Form 8-K filed on July 28, 2015 (No. 1-6571)
31.1	Rule 13a – 14(a)/15d – 14(a) Certification of Chief Executive Officer
31.2	Rule 13a – 14(a)/15d – 14(a) Certification of Chief Financial Officer
32.1	Section 1350 Certification of Chief Executive Officer
32.2	Section 1350 Certification of Chief Financial Officer
101	The following materials from Merck & Co., Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 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: May 9, 2016 /s/ Michael J. Holston
MICHAEL J. HOLSTON
Executive Vice President and General Counsel

Date: May 9, 2016 /s/ Rita A. Karachun
RITA A. KARACHUN
Senior Vice President Finance - Global Controller

EXHIBIT INDEX

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