Merck & Co., Inc.
Form 10-Q
November 07, 2016

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

FORM 10-Q

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

For the quarterly period ended September 30, 2016
OR
TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____
Commission File No. 1-6571
Merck & Co., Inc.
2000 Galloping Hill Road
Kenilworth, N.J. 07033
(908) 740-4000
Incorporated in New Jersey I.R.S. Employer
Identification No. 22-1918501
The number of shares of common stock outstanding as of the close of business on October 31, 2016: 2,757,137,517
Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):
Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company
(Do not check if a smaller reporting company)
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Sales	$10,536	$10,073	$29,692	$29,283
Costs, Expenses and Other				
Materials and production	3,409	3,761	10,559	11,084
Marketing and administrative	2,393	2,472	7,169	7,698
Research and development	1,664	1,500	5,475	4,906
Restructuring costs	161	113	386	386
Other (income) expense, net	22	(170)	88	624
	7,649	7,676	23,677	24,698
Income Before Taxes	2,887	2,397	6,015	4,585
Taxes on Income	699	566	1,487	1,108
Net Income	2,188	1,831	4,528	3,477
Less: Net Income Attributable to Noncontrolling Interests	4	5	13	12
Net Income Attributable to Merck & Co., Inc.	$2,184	$1,826	$4,515	$3,465
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	$0.79	$0.65	$1.63	$1.23
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	$0.78	$0.64	$1.62	$1.22
Dividends Declared per Common Share	$0.46	$0.45	$1.38	$1.35

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net Income Attributable to Merck & Co., Inc.	$2,184	$1,826	$4,515	$3,465
Other Comprehensive Income (Loss) Net of Taxes:				
Net unrealized loss on derivatives, net of reclassifications	(74)	(118)	(367)	(42)
Net unrealized (loss) gain on investments, net of reclassifications	(30)	(67)	96	(35)
Benefit plan net (loss) gain and prior service (cost) credit, net of amortization	(144)	29	(280)	106
Cumulative translation adjustment	82	(85)	447	(279)
	(166)	(241)	(104)	(250)
Comprehensive Income Attributable to Merck & Co., Inc.	$2,018	$1,585	$4,411	$3,215

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

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

	September 30, 2016	December 31, 2015
Assets		
Current Assets		
Cash and cash equivalents	$7,907	$8,524
Short-term investments	5,160	4,903
Accounts receivable (net of allowance for doubtful accounts of $173 in 2016 and $165 in 2015) (excludes accounts receivable of $10 in 2016 and 2015 classified in Other assets)	7,364	6,484
Inventories (excludes inventories of $1,104 in 2016 and $1,569 in 2015 classified in Other assets - see Note 5)	5,244	4,700
Other current assets	3,765	5,140
Total current assets	29,440	29,751
Investments	11,657	13,039
Property, Plant and Equipment, at cost, net of accumulated depreciation of $16,022 in 2016 and $15,923 in 2015	12,029	12,507
Goodwill	18,260	17,723
Other Intangibles, Net	20,506	22,602
Other Assets	6,443	6,055
	$98,335	$101,677
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	$1,487	$2,583
Trade accounts payable	2,481	2,533
Accrued and other current liabilities	9,087	11,216
Income taxes payable	1,208	1,560
Dividends payable	1,292	1,309
Total current liabilities	15,555	19,201
Long-Term Debt	23,656	23,829
Deferred Income Taxes	6,374	6,535
Other Noncurrent Liabilities	8,793	7,345
Merck & Co., Inc. Stockholders' Equity		
Common stock, $0.50 par value		
Authorized - 6,500,000,000 shares	1,788	1,788
Issued - 3,577,103,522 shares in 2016 and 2015		
Other paid-in capital	39,897	40,222
Retained earnings	46,028	45,348
Accumulated other comprehensive loss	(4,252)	(4,148)
	83,461	83,210
Less treasury stock, at cost: 815,442,334 shares in 2016 and 795,975,449 shares in 2015	39,717	38,534
Total Merck & Co., Inc. stockholders' equity	43,744	44,676
Noncontrolling Interests	213	91
Total equity	43,957	44,767

	$ 98,335	$ 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)

	Nine Months Ended September 30,	
	2016	2015
Cash Flows from Operating Activities		
Net income	$4,528	$3,477
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	4,286	4,815
Intangible asset impairment charges	572	80
Foreign currency devaluation related to Venezuela	—	715
Equity income from affiliates	(59)	(210)
Dividends and distributions from equity affiliates	12	12
Deferred income taxes	(65)	(846)
Share-based compensation	225	221
Other	247	815
Net changes in assets and liabilities	(3,002)	(787)
Net Cash Provided by Operating Activities	6,744	8,292
Cash Flows from Investing Activities		
Capital expenditures	(1,063)	(790)
Purchases of securities and other investments	(10,084)	(12,425)
Proceeds from sales of securities and other investments	11,300	16,531
Acquisition of Cubist Pharmaceuticals, Inc., net of cash acquired	—	(7,598)
Acquisitions of other businesses, net of cash acquired	(778)	(110)
Dispositions of businesses, net of cash divested	—	151
Other	(22)	100
Net Cash Used in Investing Activities	(647)	(4,141)
Cash Flows from Financing Activities		
Net change in short-term borrowings	909	(1,526)
Proceeds from issuance of debt	8	7,938
Payments on debt	(2,386)	(2,905)
Purchases of treasury stock	(2,418)	(3,005)
Dividends paid to stockholders	(3,853)	(3,854)
Proceeds from exercise of stock options	790	434
Other	(117)	(63)
Net Cash Used in Financing Activities	(7,067)	(2,981)
Effect of Exchange Rate Changes on Cash and Cash Equivalents	353	(1,063)
Net (Decrease) Increase in Cash and Cash Equivalents	(617)	107
Cash and Cash Equivalents at Beginning of Year	8,524	7,441
Cash and Cash Equivalents at End of Period	$7,907	$7,548

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

Notes to Condensed Consolidated Financial Statements (unaudited)

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of Merck & Co., Inc. (Merck or the Company) have been prepared pursuant to the rules and regulations for reporting on Form 10-Q. Accordingly, certain information and disclosures required by accounting principles generally accepted in the United States for complete consolidated financial statements are not included herein. These interim statements should be read in conjunction with the audited financial statements and notes thereto included in Merck's Form 10-K filed on February 26, 2016.

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

Recently Adopted Accounting Standards

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

In the second quarter of 2016, the Company elected to early adopt an accounting standards update issued by the FASB in March of 2016 intended to simplify the accounting and reporting for employee share-based payment transactions. Among other provisions, the new standard requires that excess tax benefits and deficiencies that arise upon vesting or exercise of share-based payments be recognized in the income statement (as opposed to previous guidance under which tax effects were recorded to Other paid-in-capital in certain instances). This aspect of the new guidance, which was required to be adopted prospectively, resulted in the recognition of $35 million and $64 million of excess tax benefits in Taxes on income for the third quarter and first nine months of 2016, respectively, arising from share-based payments. The new guidance also amended the presentation of certain share-based payment items in the statement of cash flows. Cash flows related to excess income tax benefits are now classified as an operating activity (formerly included as a financing activity). The Company elected to adopt this aspect of the new guidance prospectively. The standard also clarified that cash payments made to taxing authorities on the employees' behalf for shares withheld should be presented as a financing activity. This aspect of the guidance was adopted retrospectively; accordingly, the Company reclassified $118 million of such payments from operating activities to financing activities in the Condensed Consolidated Statement of Cash Flows for the nine months ended September 30, 2015 to conform to the current presentation. The Company has elected to continue to estimate the impact of forfeitures when determining the amount of compensation cost to be recognized each period rather than account for them as they occur.

Recently Issued Accounting Standards

In May 2014, the FASB issued amended accounting guidance on revenue recognition that will be applied to all contracts with customers. The objective of the new guidance is to improve comparability of revenue recognition practices across entities and to provide more useful information to users of financial statements through improved disclosure requirements. In August 2015, the FASB approved a one-year deferral of the effective date making this guidance effective for interim and annual periods beginning in 2018. Reporting entities may choose to adopt the standard as of the original effective date. The Company is currently assessing the impact of adoption on its consolidated financial statements.

In January 2016, the FASB issued revised guidance for the accounting and reporting of financial instruments. The new guidance requires that equity investments with readily determinable fair values currently classified as available-for-sale be measured at fair value with changes in fair value recognized in net income. The new guidance also simplifies the impairment testing of equity investments without readily determinable fair values and changes certain disclosure requirements. This guidance is effective for interim and annual periods beginning in 2018. Early adoption is not permitted. The Company is currently assessing the impact of adoption on its consolidated financial statements.

In February 2016, the FASB issued new accounting guidance for the accounting and reporting of leases. The new guidance requires that lessees recognize a right-of-use asset and a lease liability recorded on the balance sheet for each

of its leases (other than leases that meet the definition of a short-term lease). Leases will be classified as either operating or finance. Operating leases will result in straight-line expense in the income statement (similar to current operating leases) while finance leases will result in more expense being recognized in the earlier years of the lease term (similar to current capital leases). The new guidance will be effective for interim and annual periods beginning in 2019. Early adoption is permitted. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

In June 2016, the FASB issued amended guidance on the accounting for credit losses on financial instruments within its scope. The guidance introduces an expected loss model for estimating credit losses, replacing the incurred loss model. The new guidance also changes the impairment model for available-for-sale debt securities, requiring the use of an allowance to record estimated credit losses (and subsequent recoveries). The new guidance is effective for interim and annual periods beginning in

Notes to Condensed Consolidated Financial Statements (unaudited)

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

In August 2016, the FASB issued guidance on the classification of certain cash receipts and payments in the statement of cash flows intended to reduce diversity in practice. The guidance is effective for interim and annual periods beginning in 2018. Early adoption is permitted. The guidance is to be applied retrospectively to all periods presented but may be applied prospectively if retrospective application would be impracticable. The Company is currently evaluating the effect of the standard on its Consolidated Statement of Cash Flows.

In October 2016, the FASB issued guidance on the accounting for the income tax consequences of intra-entity transfers of assets other than inventory. Under existing guidance, the recognition of current and deferred income taxes for an intra-entity asset transfer is prohibited until the asset has been sold to a third party. The new guidance will require the recognition of the income tax consequences of an intra-entity transfer of an asset (with the exception of inventory) when the intra-entity transfer occurs. The guidance is effective for interim and annual periods beginning in 2018. Early adoption is permitted. The new guidance is to be applied on a modified retrospective basis through a cumulative-effect adjustment directly to retained earnings in the beginning of the period of adoption. The Company does not anticipate the adoption of the new guidance will have a material effect on its financial statements.

2. Acquisitions, Divestitures, Research Collaborations and License Agreements

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

In July 2016, Merck acquired Afferent Pharmaceuticals (Afferent), a privately held pharmaceutical company focused on the development of therapeutic candidates targeting the P2X3 receptor for the treatment of common, poorly-managed, neurogenic conditions. Afferent's lead investigational candidate, MK-7264 (formerly AF-219), is a selective, non-narcotic, orally-administered P2X3 antagonist currently being evaluated in a Phase 2b clinical trial for the treatment of refractory, chronic cough as well as in a Phase 2 clinical trial in idiopathic pulmonary fibrosis with cough. Total consideration transferred of $510 million included cash paid for outstanding Afferent shares of $487 million, as well as share-based compensation payments to settle equity awards attributable to precombination service and cash paid for transaction costs on behalf of Afferent. In addition, former Afferent shareholders are eligible to receive a total of up to an additional $750 million contingent upon the attainment of certain clinical development and commercial milestones for multiple indications and candidates, including MK-7264. This transaction was accounted for as an acquisition of a business; accordingly, the assets acquired and liabilities assumed were recorded at their respective fair values as of the acquisition date. The Company determined the fair value of the contingent consideration was $223 million at the acquisition date utilizing a probability-weighted estimated cash flow stream adjusted for the expected timing of each payment using an appropriate discount rate dependent on the nature and timing of the milestone payment. Merck recognized an intangible asset for in-process research and development (IPR&D) of $779 million, net deferred tax liabilities of $258 million, and other net assets of $29 million (primarily consisting of cash acquired). The excess of the consideration transferred over the fair value of net assets acquired of $183 million was recorded as goodwill that was allocated to the Pharmaceutical segment and is not deductible for tax purposes. The fair value of the identifiable intangible asset related to IPR&D was determined using an income approach, 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 12.0%. Actual cash flows are likely to be different than those assumed. Pro forma financial information has not been included because Afferent's historical financial results are not significant when compared with the Company's financial results.

In July 2016, Merck, through its wholly owned subsidiary Healthcare Services & Solutions, LLC, acquired a majority ownership interest in The StayWell Company LLC (StayWell), a portfolio company of Vestar Capital Partners (Vestar). StayWell is a health engagement company that helps its clients engage and educate people to improve health and business results. Under the terms of the transaction, Merck paid $150 million for a majority ownership interest. Additionally, Merck provided StayWell with a $150 million intercompany loan to pay down preexisting third-party debt. Merck has an option to buy, and Vestar has an option to require Merck to buy, some or all of Vestar's remaining ownership interest beginning three years from the acquisition date at fair value. This transaction was accounted for as an acquisition of a business. Merck recognized intangible assets of $238 million, deferred tax liabilities of $84 million, other net liabilities of $5 million and noncontrolling interest of $124 million. The excess of the consideration transferred over the fair value of net assets acquired of $275 million was recorded as goodwill and is

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

largely attributable to anticipated synergies expected to arise after the acquisition. The goodwill was allocated to the Healthcare Services segment and is not deductible for tax purposes. The intangible assets recognized primarily relate to customer relationships, which are being amortized over a 10-year useful life, and medical information and solutions content, which are being amortized over a five-year useful life. Pro forma financial information has not been included because StayWell's historical financial results are not significant when compared with the Company's financial results.

Also in July 2016, Merck announced it had executed an agreement to acquire a controlling interest in Vallée S.A. (Vallée), a leading privately held producer of animal health products in Brazil. Vallée has an extensive portfolio of products spanning parasiticides, anti-infectives and vaccines that include products for livestock, horses, and companion animals. Under the terms of the agreement, Merck will acquire approximately 93% of the shares of Vallée for approximately $400 million, based on exchange rates at the time of the announcement. This agreement is subject to regulatory review and certain closing conditions.

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

As previously disclosed, in 2014, the Company entered into a worldwide clinical development collaboration with Bayer AG (Bayer) to market and develop soluble guanylate cyclase (sGC) modulators, including Bayer's Adempas. The arrangement provided for potential future milestone payments of up to $1.1 billion based upon the achievement of agreed-upon sales goals. During the second quarter of 2016, the Company determined it was probable that, in 2017, sales of Adempas would exceed the threshold triggering a $350 million milestone payment from Merck to Bayer. Accordingly, in the second quarter of 2016, the Company recorded a $350 million liability and a corresponding intangible asset and also recognized $50 million of cumulative amortization expense within Materials and production costs. The remaining intangible asset at June 30, 2016 of $300 million is being amortized over the then-remaining estimated useful life of the asset of 10.5 years as supported by projected future cash flows, subject to impairment testing. Additional potential future milestone payments of $775 million have not yet been accrued as they are not deemed by the Company to be probable at this time.

In January 2016, Merck acquired IOmet Pharma Ltd (IOmet), a privately held UK-based drug discovery company focused on the development of innovative medicines for the treatment of cancer, with a particular emphasis on the fields of cancer immunotherapy and cancer metabolism. The acquisition provides Merck with IOmet's preclinical pipeline of IDO (indoleamine-2,3-dioxygenase 1), TDO (tryptophan-2,3-dioxygenase), and dual-acting IDO/TDO inhibitors. Total purchase consideration in the transaction of $227 million included a cash payment of $150 million and future additional milestone payments of up to $250 million that are contingent upon certain clinical and regulatory milestones being achieved. The transaction was accounted for as an acquisition of a business. The Company determined the fair value of the contingent consideration was $77 million at the acquisition date utilizing a probability-weighted estimated cash flow stream adjusted for the expected timing of each payment utilizing a discount rate of 10.5%. Merck recognized intangible assets for IPR&D of $155 million and net deferred tax assets of $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 values of the identifiable intangible assets related to IPR&D were determined using an income approach. The assets' probability-adjusted future net cash flows were then discounted to present value also using a discount rate of 10.5%. Actual cash flows are likely to be different than those assumed. Pro forma financial information has not been included because IOmet's historical financial results are not significant when compared with the Company's financial results.

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

In July 2015, Merck acquired cCAM, a privately held biopharmaceutical company focused on the discovery and development of novel cancer immunotherapies. Total purchase consideration in the transaction of $201 million included an upfront payment of $96 million in cash and future additional payments of up to $510 million associated with the attainment of certain clinical development, regulatory and commercial milestones. The transaction was accounted for as an acquisition of a business. The Company determined the fair value of the contingent consideration was $105 million at the acquisition date utilizing a probability-weighted estimated cash flow stream adjusted for the expected timing of each payment utilizing a discount rate of 10.5%. Merck recognized an intangible asset for IPR&D of $180 million and other net assets of $7 million. The excess of the

consideration transferred over the fair value of net assets acquired of $14 million was recorded as goodwill that was allocated to the Pharmaceutical segment and is not deductible for tax purposes. The fair value of the identifiable intangible asset related to IPR&D was determined using an income approach. The asset's probability-adjusted future net cash flows were discounted to present value also using a discount rate of 10.5%. Actual cash flows are likely to be different than those assumed. Pro forma financial information has not been included because cCAM's historical financial results are not significant when compared with the Company's financial results.

Also in July 2015, Merck and Allergan plc (Allergan) entered into an agreement pursuant to which Allergan acquired the exclusive worldwide rights to MK-1602 and MK-8031, Merck's investigational small molecule oral calcitonin gene-related peptide (CGRP) receptor antagonists, which are being developed for the treatment and prevention of migraine. Under the terms of the agreement, Allergan acquired these rights for upfront payments of $250 million, of which $125 million was paid in August 2015 upon closing of the transaction and the remaining $125 million was paid in April of 2016. The Company recorded a gain of $250 million within Other (income) expense, net in the third quarter of 2015 related to the transaction. Allergan is fully responsible for development of the CGRP programs, as well as manufacturing and commercialization upon approval and launch of the products. Under the agreement, Merck is eligible for the receipt of potential development and commercial milestone payments and royalties at tiered double-digit rates based on commercialization of the programs. During the third quarter of 2016, Merck recognized a gain of $40 million within Other (income) expense, net for the achievement of a research and development milestone, which was paid by Allergan.

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. 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 was 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 has the option to extend the research agreement for two additional two-year terms.

Acquisition of Cubist Pharmaceuticals, Inc.

In January 2015, Merck acquired Cubist Pharmaceuticals, Inc. (Cubist), a leader in the development of therapies to treat serious infections caused by a broad range of bacteria. This transaction, which was accounted for as an acquisition of a business, 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. Total consideration transferred of $8.3 billion included cash paid for outstanding Cubist shares of $7.8 billion, as well as share-based compensation payments to settle equity awards attributable to precombination service and cash paid for transaction costs on behalf of Cubist. In addition, the Company assumed all of the outstanding convertible debt of Cubist, which had a fair value of approximately $1.9 billion at the acquisition date. Merck redeemed this debt in February 2015.

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

The estimated fair value of assets acquired and liabilities assumed from Cubist is as follows:

($ in millions)	
Cash and cash equivalents	$733
Accounts receivable	123
Inventories	216
Other current assets	55
Property, plant and equipment	151
Identifiable intangible assets:	
Products and product rights (11 year weighted-average useful life)	6,923
IPR&D	50
Other noncurrent assets	184
Current liabilities [1]	(233)
Deferred income tax liabilities	(2,519)
Long-term debt	(1,900)
Other noncurrent liabilities [1]	(122)
Total identifiable net assets	3,661
Goodwill [2]	4,670
Consideration transferred	$8,331

(1) Included in current liabilities and other noncurrent liabilities is contingent consideration of $73 million and $50 million, respectively.

(2) The goodwill recognized is largely attributable to anticipated synergies expected to arise after the acquisition and was allocated to the Pharmaceutical segment. The goodwill is not deductible for tax purposes.

The estimated fair values of identifiable intangible assets related to currently marketed products were determined using an income approach through which fair value is estimated based on market participant expectations of each asset's discounted projected net cash flows. The probability-adjusted future net cash flows of each product were then discounted to present value utilizing a discount rate of 8%. Actual cash flows are likely to be different than those assumed. In connection with the Cubist acquisition, liabilities were recorded for potential future consideration that is contingent upon the achievement of future sales-based milestones. The fair value of contingent consideration liabilities was determined at the acquisition date using unobservable inputs. These inputs include the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and a risk-adjusted discount rate of 8% used to present value the probability-weighted cash flows. Changes in the inputs could result in a different fair value measurement.

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 September 30, 2015	Nine Months Ended September 30, 2015
Sales	$ 10,073	$ 29,369
Net income attributable to Merck & Co., Inc.	1,833	3,645
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	0.65	1.29
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	0.65	1.28

The unaudited supplemental pro forma data reflects the historical information of Merck and Cubist adjusted to include additional amortization expense based on the fair value of assets acquired, additional interest expense that would have been incurred on borrowings used to fund the acquisition, transaction costs associated with the acquisition, and the related tax effects of these adjustments. The pro forma data should not be considered indicative of the results that

would have occurred if the acquisition had been consummated on January 1, 2014, nor are they indicative of future results.

3. Restructuring

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

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

restructuring actions under these programs are substantially complete; the remaining activities primarily relate to ongoing facility rationalizations.

The Company recorded total pretax costs of $212 million and $217 million in the third quarter of 2016 and 2015, respectively, and $759 million and $770 million for the first nine months of 2016 and 2015, respectively, related to restructuring program activities. Since inception of the programs through September 30, 2016, Merck has recorded total pretax accumulated costs of approximately $12.2 billion and eliminated approximately 39,630 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 $800 million of additional pretax costs. The Company estimates that approximately two-thirds of the cumulative pretax costs will result in cash outlays, primarily related to employee separation expense. Approximately one-third of the cumulative pretax costs are non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested.

For segment reporting, restructuring charges are unallocated expenses.

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

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

	Three Months Ended September 30, 2015				Nine Months Ended September 30, 2015			
($ in millions)	Separation Costs	Accelerated Depreciation	Other	Total	Separation Costs	Accelerated Depreciation	Other	Total
Materials and production	$—	$ 17	$ 53	$ 70	$—	$ 47	$ 233	$ 280
Marketing and administrative	—	5	12	17	—	53	17	70
Research and development	—	9	8	17	—	25	9	34
Restructuring costs	12	—	101	113	100	—	286	386
	$ 12	$ 31	$ 174	$ 217	$ 100	$ 125	$ 545	$ 770

Separation costs are associated with actual headcount reductions, as well as those headcount reductions which were probable and could be reasonably estimated. In the third quarter of 2016 and 2015, approximately 300 positions and 685 positions, respectively, and for the first nine months of 2016 and 2015, approximately 1,355 positions and 2,635 positions, respectively, were eliminated under 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 asset, based upon the anticipated date the site will be closed or divested or the equipment disposed of, and depreciation expense as determined utilizing the useful life prior to the restructuring actions. All of the sites have and will continue to operate up through the respective closure dates and, since future undiscounted cash flows were sufficient to recover the respective book values, Merck 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 12) and share-based

compensation.

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

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

($ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
Restructuring reserves January 1, 2016	$ 592	$ —	$ 53	$ 645
Expense	172	210	377	759
(Payments) receipts, net	(251)	—	(200)	(451)
Non-cash activity	—	(210)	(164)	(374)
Restructuring reserves September 30, 2016 [1]	$ 513	$ —	$ 66	$ 579

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

Purchased put options 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.

Forward contracts obligate the Company 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, 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.

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 fair values of these derivative contracts are recorded as either assets (gain positions) or liabilities (loss positions) in the Condensed Consolidated Balance Sheet. Changes in the fair value of derivative contracts are recorded each period in either current earnings or Other comprehensive income (OCI), depending on whether the derivative is designated as part of a hedge transaction and, if so, the type of hedge transaction. For derivatives that are designated as cash flow hedges, the effective portion of the unrealized gains or losses on these contracts is recorded in Accumulated other comprehensive income (AOCI) and reclassified into Sales when the hedged anticipated revenue is recognized. The hedge relationship is highly effective and hedge ineffectiveness has been de minimis. For those derivatives which are not designated as cash flow hedges, but serve as economic hedges of forecasted sales, unrealized gains or losses are recorded in Sales each period. The cash flows from both designated and non-designated contracts are reported as operating activities in the Condensed Consolidated Statement of Cash Flows. The Company does not enter into derivatives for trading or speculative purposes.

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

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

The Company also uses forward exchange contracts to hedge its net investment in foreign operations against movements in exchange rates. The forward contracts are designated as hedges of the net investment in a foreign operation. The Company hedges a portion of the net investment in certain of its foreign operations and measures ineffectiveness based upon changes in spot foreign exchange rates. The effective portion of the unrealized gains or losses on these contracts is recorded in foreign currency translation adjustment within OCI, and remains in AOCI until either the sale or complete or substantially complete liquidation of the subsidiary. The cash flows from these contracts are reported as investing activities in the Condensed Consolidated Statement of Cash Flows.

Foreign exchange risk is also managed through the use of foreign currency debt. The Company's senior unsecured euro-denominated notes have been designated as, and are effective as, economic hedges of the net investment in a foreign operation. Accordingly, foreign currency transaction gains or losses due to spot rate fluctuations on the euro-denominated debt instruments are included in foreign currency translation adjustment within OCI. Included in the cumulative translation adjustment are pretax losses of $60 million and pretax gains $255 million for the first nine months of 2016 and 2015, respectively, from the euro-denominated notes.

Interest Rate Risk Management

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

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

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

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

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

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

		September 30, 2016 Fair Value of Derivative			December 31, 2015 Fair Value of Derivative		
($ in millions)	Balance Sheet Caption	Asset	Liability	U.S. Dollar Notional	Asset	Liability	U.S. Dollar Notional
Derivatives Designated as Hedging Instruments							
Interest rate swap contracts (noncurrent)	Other assets	$ 158	$ —	$ 5,200	$ 42	$ —	$ 2,700
Interest rate swap contracts (current)	Accrued and other current liabilities	—	—	—	—	1	1,000
Interest rate swap contracts (noncurrent)	Other noncurrent liabilities	—	1	1,000	—	23	3,500
Foreign exchange contracts (current)	Other current assets	274	—	4,265	579	—	4,171
Foreign exchange contracts (noncurrent)	Other assets	96	—	2,162	386	—	4,136
Foreign exchange contracts (current)	Accrued and other current liabilities	—	20	845	—	1	77
		$ 528	$ 21	$ 13,472	$ 1,007	$ 25	$ 15,584
Derivatives Not Designated as Hedging Instruments							
Foreign exchange contracts (current)		$ 92	$ —	$ 6,157	$ 212	$ —	$ 8,783

Foreign exchange contracts (noncurrent)	Other current assets	—	—	—	18	—	179
	Other assets						
Foreign exchange contracts (current)	Accrued and other current liabilities	—	35	4,062	—	37	2,508
Foreign exchange contracts (noncurrent)	Other noncurrent liabilities	—	1	7	—	1	6
		$ 92	$ 36	$ 10,226	$ 230	$ 38	$ 11,476
		$ 620	$ 57	$ 23,698	$ 1,237	$ 63	$ 27,060

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:

	September 30, 2016		December 31, 2015	
($ in millions)	Asset	Liability	Asset	Liability
Gross amounts recognized in the consolidated balance sheet	$620	$ 57	$1,237	$ 63
Gross amount subject to offset in master netting arrangements not offset in the consolidated balance sheet	(50)	(50)	(59)	(59)
Cash collateral (received) posted	(299)	—	(862)	—
Net amounts	$271	$ 7	$316	$ 4

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

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 September 30,		Nine Months Ended September 30,	
($ in millions)	2016	2015	2016	2015
Derivatives designated in a fair value hedging relationship				
Interest rate swap contracts				
Amount of loss (gain) recognized in Other (income) expense, net on derivatives [1]	$59	$(130)	$(139)	$(97)
Amount of (gain) loss recognized in Other (income) expense, net on hedged item [1]	(60)	125	135	91
Derivatives designated in foreign currency cash flow hedging relationships				
Foreign exchange contracts				
Amount of gain reclassified from AOCI to Sales	(44)	(170)	(251)	(528)
Amount of loss (gain) recognized in OCI on derivatives	69	17	311	(464)
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)	—	(4)
Amount of loss (gain) recognized in OCI on derivatives	—	13	—	(5)
Derivatives not designated in a hedging relationship				
Foreign exchange contracts				
Amount of loss (gain) recognized in Other (income) expense, net on derivatives [3]	29	(155)	(87)	(360)
Amount of gain recognized in Sales	—	—	—	(1)

[1] There was $1 million and $5 million of ineffectiveness on the hedge during the third quarter of 2016 and 2015, respectively, and $4 million and $6 million of ineffectiveness on the hedge for the first nine months of 2016 and 2015, respectively.

[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 September 30, 2016, the Company estimates $52 million of pretax net unrealized gains on derivatives maturing within the next 12 months that hedge foreign currency denominated sales over that same period will be reclassified from AOCI to Sales. The amount ultimately reclassified to Sales may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity.

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

Investments in Debt and Equity Securities

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

	September 30, 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	$10,857	$ 10,791	$ 71	$ (5)	$10,259	$ 10,299	$ 7	$ (47)
U.S. government and agency securities	2,293	2,288	6	(1)	1,761	1,767	—	(6)
Commercial paper	1,516	1,516	—	—	2,977	2,977	—	—
Asset-backed securities	1,397	1,394	4	(1)	1,284	1,290	—	(6)
Mortgage-backed securities	895	892	4	(1)	694	697	1	(4)
Foreign government bonds	494	493	1	—	607	586	22	(1)
Equity securities	410	316	102	(8)	534	409	125	—
	$17,862	$ 17,690	$ 188	$ (16)	$18,116	$ 18,025	$ 155	$ (64)

Available-for-sale debt securities included in Short-term investments totaled $5.2 billion at September 30, 2016. Of the remaining debt securities, $10.4 billion mature within five years. At September 30, 2016 and December 31, 2015, there were no debt securities pledged as collateral.

Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The Company uses a fair value hierarchy which maximizes the use of observable inputs and minimizes the use of unobservable inputs when measuring fair value. There are three levels of inputs used to measure fair value with Level 1 having the highest priority and Level 3 having the lowest:

Level 1 - Quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2 - Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 - Unobservable inputs that are supported by little or no market activity. Level 3 assets or liabilities are those whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques with significant unobservable inputs, as well as assets or liabilities for which the determination of fair value requires significant judgment or estimation.

If the inputs used to measure the financial assets and liabilities fall within more than one level described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

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

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

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

	Fair Value Measurements Using				Fair Value Measurements Using			
	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
($ in millions)	September 30, 2016				December 31, 2015			
Assets								
Investments								
Corporate notes and bonds	$—	$ 10,651	$ —	$10,651	$—	$ 10,259	$ —	$10,259
U.S. government and agency securities	30	1,950	—	1,980	—	1,761	—	1,761
Commercial paper	—	1,516	—	1,516	—	2,977	—	2,977
Asset-backed securities [1]	—	1,265	—	1,265	—	1,284	—	1,284
Mortgage-backed securities [1]	—	663	—	663	—	694	—	694
Foreign government bonds	—	493	—	493	—	607	—	607
Equity securities	249	—	—	249	360	—	—	360
	279	16,538	—	16,817	360	17,582	—	17,942
Other assets [2]								
U.S. government and agency securities	—	313	—	313	—	—	—	—
Mortgage-backed securities [1]	—	232	—	232	—	—	—	—
Corporate notes and bonds	—	206	—	206	—	—	—	—
Asset-backed securities [1]	—	132	—	132	—	—	—	—
Foreign government bonds	—	1	—	1	—	—	—	—
Equity securities	161	—	—	161	155	19	—	174
	161	884	—	1,045	155	19	—	174
Derivative assets [3]								
Purchased currency options	—	399	—	399	—	1,041	—	1,041
Interest rate swaps	—	158	—	158	—	42	—	42
Forward exchange contracts	—	63	—	63	—	154	—	154
	—	620	—	620	—	1,237	—	1,237
Total assets	$440	$ 18,042	$ —	$18,482	$515	$ 18,838	$ —	$19,353
Liabilities								
Other liabilities								
Contingent consideration	$—	$ —	$ 894	$894	$—	$ —	$ 590	$590
Derivative liabilities [3]								
Forward exchange contracts	—	55	—	55	—	38	—	38
Written currency options	—	1	—	1	—	1	—	1
Interest rate swaps	—	1	—	1	—	24	—	24
	—	57	—	57	—	63	—	63
Total liabilities	$—	$ 57	$ 894	$951	$—	$ 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 increase in investments included in Other assets reflects certain assets previously restricted for retiree benefits that became available to fund certain other health and welfare benefits during the second quarter of 2016 (see Note 12).

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

There were no transfers between Level 1 and Level 2 during the first nine months of 2016. As of September 30, 2016, Cash and cash equivalents of $7.9 billion included $7.2 billion of cash equivalents (considered Level 2 in the fair value hierarchy).

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

Contingent Consideration

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

	Nine Months Ended September 30,	
($ in millions)	2016	2015
Fair value January 1	$590	$428
Changes in fair value [1]	29	8
Additions	300	228
Payments	(25)	(50)
Fair value September 30	$894	$614

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

The Company recognized liabilities for contingent consideration in 2016 related to the acquisitions of IOmet and Afferent and in 2015 related to the acquisitions of Cubist and cCAM (see Note 2), reflected as "Additions" in the table above. 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 September 30, 2016, was $27.0 billion compared with a carrying value of $25.1 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 September 30, 2016, the Company's total net accounts receivable outstanding for more than one year were approximately $125 million. The Company does not expect to have write-offs or adjustments to accounts receivable which would have a material adverse effect on its financial position, liquidity or results of operations.

Derivative financial instruments are executed under International Swaps and Derivatives Association master agreements. The master agreements with several of the Company's financial institution counterparties also include credit support annexes. These annexes contain provisions that require collateral to be exchanged depending on the value of the derivative assets and liabilities, the Company's credit rating, and the credit rating of the counterparty. As of September 30, 2016 and December 31, 2015, the Company had received cash collateral of $299 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 September 30, 2016 or December 31, 2015.

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

5. Inventories

Inventories consisted of:

($ in millions)	September 30, 2016	December 31, 2015
Finished goods	$ 1,421	$ 1,343
Raw materials and work in process	4,432	4,374
Supplies	175	168
Total (approximates current cost)	6,028	5,885
Increase to LIFO costs	320	384
	$ 6,348	$ 6,269
Recognized as:		
Inventories	$ 5,244	$ 4,700
Other assets	1,104	1,569

Amounts recognized as Other assets are comprised almost entirely of raw materials and work in process inventories. At September 30, 2016 and December 31, 2015, these amounts included $1.0 billion and $1.5 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included $56 million and $63 million at September 30, 2016 and December 31, 2015, respectively, of inventories produced in preparation for product launches.

6. Other Intangibles

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

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

Also, during the first nine months of 2016, the Company recorded $225 million of IPR&D impairment charges within Research and development expenses. Of this amount, $112 million relates to a charge for an in-licensed program for house dust mite allergies that, for business reasons, will be returned to the licensor. The remaining IPR&D impairment charges primarily relate to deprioritized pipeline programs that were deemed to have no alternative use during the period, including a $79 million impairment charge for MK-8342B, an investigational candidate for contraception.

During the first nine months of 2015, the Company recorded $62 million of IPR&D impairment charges. Of this amount, $50 million relates to the surotomycin clinical development program. During the second quarter of 2015, the Company received unfavorable efficacy data from a clinical trial for surotomycin. The evaluation of this data, combined with an assessment of the commercial opportunity of surotomycin, resulted in the IPR&D impairment charge noted above.

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

7. Joint Ventures and Other Equity Method Affiliates

Equity income from affiliates reflects the performance of the Company’s joint ventures and other equity method affiliates including Sanofi Pasteur MSD (SPMSD) and certain investment funds. Equity income from affiliates was $21 million and $63 million for the third quarter of 2016 and 2015, respectively, and $59 million and $210 million for the first nine months of 2016 and 2015, respectively, and is included in Other (income) expense, net (see Note 13).

Sanofi Pasteur MSD

In March 2016, Merck and Sanofi Pasteur announced their intention to end their joint vaccines operations in Europe. The joint venture Sanofi Pasteur MSD (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. SPMSD vaccine sales were $351 million and $318 million for the third quarter of 2016 and 2015, respectively, and were $725 million and $655 million for the first nine months of 2016 and 2015, respectively.

AstraZeneca LP

In 1998, Merck and Astra completed the restructuring of the ownership and operations of their existing joint venture whereby Merck acquired Astra's interest in KBI Inc. (KBI) and contributed KBI's operating assets to a new U.S. limited partnership, Astra Pharmaceuticals L.P. (the Partnership). Astra contributed the net assets of its wholly owned subsidiary, Astra USA, Inc., to the Partnership. The Partnership, renamed AstraZeneca LP (AZLP) upon Astra's 1999 merger with Zeneca Group Plc, became the exclusive distributor of the products for which KBI retained rights.

In connection with AstraZeneca's 2014 exercise of its option to purchase Merck's interest in KBI, the Company deferred $327 million of the exercise price, which reflected an estimate of the fair value of Merck's interest in Nexium and Prilosec. This amount, which is subject to a true-up in 2018 based on actual sales from closing in 2014 to June 2018, was deferred and recognized over time in Other (income) expense, net as the contingency was eliminated as sales occurred. The deferred income amount has been fully amortized based on the sales performance of Nexium and Prilosec subsequent to the 2014 option exercise. Beginning in the first quarter of 2016, the Company is recognizing income and a corresponding receivable for amounts that will be due to Merck from AstraZeneca based on the sales performance of Nexium and Prilosec subject to the true-up in June 2018. The Company recognized $76 million of such income in the first nine months of 2016.

8. Long-Term Debt

In November 2016, the Company issued €1.0 billion principal amount of senior unsecured notes consisting of €500 million principal amount of 0.50% notes due 2024 and €500 million principal amount of 1.375% notes due 2036. The Company intends to use the net proceeds of the offering of $1.1 billion for general corporate purposes, including without limitation the repayment of outstanding commercial paper borrowings and other indebtedness with upcoming maturities.

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

9. Contingencies

The Company is involved in various claims and legal proceedings of a nature considered normal to its business, including product liability, intellectual property, and commercial litigation, as well as certain additional matters including environmental matters. In the opinion of the Company, it is unlikely that the resolution of these matters will be material to the Company's financial position, results of operations or cash flows.

Given the nature of the litigation discussed below and the complexities involved in these matters, the Company is unable to reasonably estimate a possible loss or range of possible loss for such matters until the Company knows, among other factors, (i) what claims, if any, will survive dispositive motion practice, (ii) the extent of the claims, including the size of any potential class, particularly when damages are not specified or are indeterminate, (iii) how the discovery process will affect the litigation, (iv) the settlement posture of the other parties to the litigation and (v) any other factors that may have a material effect on the litigation.

The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available. For product liability claims, a portion of the overall accrual is actuarially determined and considers such factors as past experience, number of claims reported and estimates of claims incurred but not yet reported. Individually significant contingent losses are accrued when probable and reasonably estimable. Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable.

The Company's decision to obtain insurance coverage is dependent on market conditions, including cost and availability, existing at the time such decisions are made. The Company has evaluated its risks and has determined

that the cost of obtaining product liability insurance outweighs the likely benefits of the coverage that is available and, as such, has no insurance for most product liabilities effective August 1, 2004.

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Vioxx Litigation

Product Liability Lawsuits

As previously disclosed, Merck was a defendant in a number of putative class action lawsuits alleging economic injury as a result of the purchase of Vioxx, all but one of which have been settled. Under the settlement, Merck agreed to 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 claims review process has been completed with the Company paying approximately $700,000. The amount of attorneys' fees to be paid is yet to be determined.

Merck is also a defendant in a lawsuit (together with the above-referenced lawsuits, the Vioxx Product Liability Lawsuits) brought by the Attorney General of Utah. The lawsuit is pending in Utah state court. Utah alleges that Merck misrepresented the safety of Vioxx and seeks damages and penalties under the Utah False Claims Act. No trial date has been set. Merck recently reached agreements with the Attorneys General in Alaska and Montana to settle their state consumer protection act cases against the Company for $15.25 million and $16.7 million, respectively. As a result, Alaska's action was dismissed with prejudice on September 30, 2016, and Montana's action was dismissed with prejudice on October 6, 2016.

Shareholder Lawsuits

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

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

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

Insurance

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

International Lawsuits

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

Reserves

The Company has an immaterial reserve with respect to certain Vioxx Product Liability Lawsuits. The Company has established no other liability reserves for, and believes that it has meritorious defenses to, the remaining Vioxx Product Liability Lawsuits and Vioxx International Lawsuits and will vigorously defend against them.

Other Product Liability Litigation

Fosamax

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving Fosamax (Fosamax Litigation). As of September 30, 2016, approximately 4,310 cases are filed and pending against Merck in either federal or state court. In approximately 20 of these actions, plaintiffs allege, among other things, that they have suffered osteonecrosis of the jaw (ONJ), generally subsequent to invasive dental procedures, such as tooth extraction or dental implants and/or delayed

healing, in association with the use of Fosamax. In addition, plaintiffs in approximately 4,290 of these actions generally allege that they sustained femur fractures and/or other bone injuries (Femur Fractures) in association with the use of Fosamax.

Cases Alleging ONJ and/or Other Jaw Related Injuries

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

In December 2013, Merck reached an agreement in principle with the Plaintiffs' Steering Committee (PSC) in the Fosamax ONJ MDL to resolve pending ONJ cases not on appeal in the Fosamax ONJ MDL and in the state courts for an aggregate amount of $27.7 million. Merck and the PSC subsequently formalized the terms of this agreement in a Master Settlement Agreement (ONJ Master Settlement Agreement) that was executed in April 2014 and included over 1,200 plaintiffs. In July 2014, Merck elected to proceed with the ONJ Master Settlement Agreement at a reduced funding level of $27.3 million since the participation level was approximately 95%. Merck has fully funded the ONJ Master Settlement Agreement and the escrow agent under the agreement has been making settlement payments to qualifying plaintiffs. The ONJ Master Settlement Agreement has no effect on the cases alleging Femur Fractures discussed below.

Cases Alleging Femur Fractures

In March 2011, Merck submitted a Motion to Transfer to the JPML seeking to have all federal cases alleging Femur Fractures consolidated into one multidistrict litigation for coordinated pre-trial proceedings. The Motion to Transfer was granted in May 2011, and all federal cases involving allegations of Femur Fracture have been or will be transferred to a multidistrict litigation in the District of New Jersey (the Femur Fracture MDL). Judge Pisano presided over the Femur Fracture MDL until March 2015, at which time the Femur Fracture MDL was reassigned from Judge Pisano to Judge Freda L. Wolfson following Judge Pisano's retirement. In the only bellwether case tried to date in the Femur Fracture MDL, Glynn v. Merck, the jury returned a verdict in Merck's favor. In addition, in June 2013, the Femur Fracture MDL court granted Merck's motion for judgment as a matter of law in the Glynn case and held that the plaintiff's failure to warn claim was preempted by federal law.

In August 2013, the Femur Fracture MDL court entered an order requiring plaintiffs in the Femur Fracture MDL to show cause why those cases asserting claims for a femur fracture injury that took place prior to September 14, 2010, should not be dismissed based on the court's preemption decision in the Glynn case. Pursuant to the show cause order, in March 2014, the Femur Fracture MDL court dismissed with prejudice approximately 650 cases on preemption grounds. Plaintiffs in approximately 515 of those cases are appealing that decision to the U.S. Court of Appeals for the Third Circuit. The Femur Fracture MDL court has since dismissed without prejudice another approximately 540 cases pending plaintiffs' appeal of the preemption ruling to the Third Circuit. On June 30, 2016, the Third Circuit heard oral argument on plaintiffs' appeal of the preemption ruling and the parties await the decision.

In addition, in June 2014, Judge Pisano granted Merck summary judgment in the Gaynor v. Merck case and found that Merck's updates in January 2011 to the Fosamax label regarding atypical femur fractures were adequate as a matter of law and that Merck adequately communicated those changes. The plaintiffs in Gaynor have appealed Judge Pisano's decision to the Third Circuit. In August 2014, Merck filed a motion requesting that Judge Pisano enter a further order requiring all plaintiffs in the Femur Fracture MDL who claim that the 2011 Fosamax label is inadequate and the proximate cause of their alleged injuries to show cause why their cases should not be dismissed based on the court's preemption decision and its ruling in the Gaynor case. In November 2014, the court granted Merck's motion and entered the requested show cause order.

As of September 30, 2016, three cases were pending in the Femur Fracture MDL, excluding the 515 cases dismissed with prejudice on preemption grounds that are pending appeal and the 540 cases dismissed without prejudice that are also pending the aforementioned appeal.

As of September 30, 2016, approximately 2,940 cases alleging Femur Fractures have been filed in New Jersey state court and are pending before Judge Jessica Mayer in Middlesex County. The parties selected an initial group of 30 cases to be reviewed through fact discovery. Two additional groups of 50 cases each to be reviewed through fact discovery were selected in November 2013 and March 2014, respectively. A further group of 25 cases to be reviewed

through fact discovery was selected by Merck in July 2015, and Merck has recently begun selecting the next group of cases to be reviewed through fact discovery.

As of September 30, 2016, approximately 285 cases alleging Femur Fractures have been filed and are pending in California state court. A petition was filed seeking to coordinate all Femur Fracture cases filed in California state court before a single judge in Orange County, California. The petition was granted and Judge Thierry Colaw is currently presiding over the coordinated proceedings. In March 2014, the court directed that a group of 10 discovery pool cases be reviewed through fact discovery and subsequently scheduled the Galper v. Merck case, which plaintiffs selected, as the first trial. The Galper trial began in February 2015 and the jury returned a verdict in Merck's favor in April 2015, and plaintiff has appealed that verdict to the

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

California appellate court. The next Femur Fracture trial in California that was scheduled to begin in April 2016, was stayed at plaintiffs' request and a new trial date has not been set.

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

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

Januvia/Janumet

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving Januvia and/or Janumet. As of September 30, 2016, approximately 1,140 product user claims have been served on Merck alleging generally that use of Januvia and/or Janumet caused the development of pancreatic cancer and other injuries. These complaints were filed in several different state and federal courts.

Most of the claims were filed in a consolidated multidistrict litigation proceeding in the U.S. District Court for the Southern District of California called "In re Incretin-Based Therapies Products Liability Litigation" (MDL). The MDL includes federal lawsuits alleging pancreatic cancer due to use of the following medicines: Januvia, Janumet, Byetta and Victoza, the latter two of which are products manufactured by other pharmaceutical companies. The majority of claims not filed in the MDL were filed in the Superior Court of California, County of Los Angeles (California State Court). As of September 30, 2016, nine product users have claims pending against Merck in state courts other than the California State Court.

In November 2015, the MDL and California State Court – in separate opinions – granted summary judgment to defendants on grounds of preemption. Of the approximately 1,140 served product user claims, these rulings resulted in the dismissal of approximately 1,100 product user claims.

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

In addition to the claims noted above, the Company has agreed, as of September 30, 2016, to toll the statute of limitations for approximately 50 additional claims. The Company intends to continue defending against these lawsuits.

Propecia/Proscar

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving Propecia and/or Proscar. As of September 30, 2016, approximately 1,370 lawsuits have been filed by plaintiffs who allege that they have experienced persistent sexual side effects following cessation of treatment with Propecia and/or Proscar. Approximately 50 of the plaintiffs also allege that Propecia or Proscar has caused or can cause prostate cancer, testicular cancer or male breast cancer. The lawsuits have been filed in various federal courts and in state court in New Jersey. The federal lawsuits have been consolidated for pretrial purposes in a federal multidistrict litigation before Judge Brian Cogan of the Eastern District of New York. The matters pending in state court in New Jersey have been consolidated before Judge Mayer in Middlesex County. In addition, there is one matter pending in state court in Massachusetts and one matter pending in state court in New York. The Company intends to defend against these lawsuits.

Governmental Proceedings

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

Commercial and Other Litigation

K-DUR Antitrust Litigation

As previously disclosed, in June 1997 and January 1998, Schering-Plough Corporation (Schering-Plough) settled patent litigation with Upsher-Smith, Inc. (Upsher-Smith) and ESI Lederle, Inc. (Lederle), respectively, relating to generic versions of Schering-Plough's long-acting potassium chloride product supplement used by cardiac patients, for which Lederle and Upsher-Smith had filed Abbreviated New Drug Applications (ANDAs). Following the commencement of an administrative proceeding by the U.S. Federal Trade Commission (FTC) in 2001 alleging anti-competitive effects from those settlements (which was resolved in Schering-Plough's favor), putative class and non-class action suits were filed on behalf of direct and indirect purchasers of K-DUR against Schering-Plough,

Upsher-Smith and Lederle and were consolidated in a multidistrict litigation in the U.S. District Court for the District of New Jersey. These suits claimed violations of federal and state antitrust laws, as well as other state statutory and common law causes of action, and sought unspecified damages. In April 2008, the indirect purchasers voluntarily dismissed their case. In March 2010, the District Court granted summary judgment to the defendants on the remaining lawsuits and dismissed the matter in its entirety. In July 2012, the Third Circuit Court of Appeals reversed the District Court's grant of summary judgment and remanded the case for further proceedings. At the same time, the Third Circuit upheld a December 2008 decision by the District Court certifying certain direct purchaser plaintiffs' claims as a class action.

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In August 2012, the Company filed a petition for certiorari with the U.S. Supreme Court seeking review of the Third Circuit's decision. In June 2013, the Supreme Court granted that petition, vacated the judgment of the Third Circuit, and remanded the case for further consideration in light of its decision in FTC v. Actavis, Inc. That decision held that whether a so-called "reverse payment" - i.e., a payment from the holder of a pharmaceutical patent to a party challenging the patent made in connection with a settlement of their dispute - violates the antitrust laws should be determined on the basis of a "rule of reason" analysis. In September 2013, the Third Circuit returned the case to the District Court for further proceedings in accordance with the Actavis standard. In April 2015, the Company filed motions for summary judgment. On February 25, 2016, the District Court denied the Company's motion for summary judgment relating to all of the direct purchasers' claims concerning the settlement with Upsher-Smith and granted the Company's motion for summary judgment relating to all of the direct purchasers' claims concerning the settlement with Lederle. In anticipation of trial, which is expected to occur in the spring of 2017, the parties on October 31, 2016, filed motions to exclude certain expert opinions and defendants filed a motion for summary judgment.

Patent Litigation

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

Cancidas — In February 2014, a patent infringement lawsuit was filed in the United States against Xellia Pharmaceuticals ApS (Xellia) with respect to Xellia's application to the FDA seeking pre-patent expiry approval to market a generic version of Cancidas. In June 2015, the district court found that Xellia infringed the Company's patent and ordered that Xellia's application not be approved until the patent expires in September 2017 (including pediatric exclusivity). Xellia appealed this decision, and the appeal was heard in March 2016. In May 2016, the parties reached a settlement whereby Xellia can launch its generic version in August 2017, or earlier under certain conditions. In August 2014, a patent infringement lawsuit was filed in the United States against Fresenius Kabi USA, LLC (Fresenius) in respect of Fresenius's application to the FDA seeking pre-patent expiry approval to market a generic version of Cancidas. The trial in this matter is currently scheduled to begin in November 2016. 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.

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, in October 2016, the district court ruled that the patent is valid and infringed. In August 2015, a patent infringement lawsuit was filed in the United States against Savior Lifetec Corporation (Savior) in respect of Savior's application to the FDA seeking pre-patent expiry approval to market a generic version of Invanz. The lawsuit automatically stays FDA approval of Savior's application until November 2017 or until an adverse court decision, if any, whichever may occur earlier.

Nasonex — In July 2014, a patent infringement lawsuit was filed in the United States against Teva Pharmaceuticals USA, Inc. (Teva Pharma) in respect of Teva Pharma's application to the FDA seeking pre-patent expiry approval to market a generic version of Nasonex. The lawsuit automatically stays FDA approval of Teva Pharma's application until November 2016 or until an adverse court decision, if any, whichever may occur earlier. The trial in this matter was held in June 2016 and the Company is currently awaiting the court's decision. In March 2015, a patent infringement lawsuit was filed in the United States against Amneal Pharmaceuticals LLC (Amneal) in respect of

Amneal’s application to the FDA seeking pre-patent expiry approval to market a generic version of Nasonex. The lawsuit automatically stays FDA approval of Amneal’s application until August 2017 or until an adverse court decision, if any, whichever may occur earlier. The trial in this matter was held in June 2016 and the Company is currently awaiting the court’s decision.

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.

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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. In October 2016, the parties reached a settlement whereby Par can launch its generic version in January 2023, or earlier under certain conditions.

NuvaRing — In December 2013, the Company filed a lawsuit against a subsidiary of Allergan plc in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of NuvaRing. The trial in this matter was held in January 2016. In August 2016, the district court ruled that the patent was invalid and the Company has appealed this decision. In September 2015, the Company filed a lawsuit against Teva Pharma in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of NuvaRing.

The Company had been involved in ongoing litigation in Canada with Apotex concerning the Company's patents related to lovastatin, alendronate, and norfloxacin. All of the litigation has now been either settled or concluded. As a consequence of the conclusion of all of this litigation, in the first nine months of 2016, the Company recorded a net gain of $117 million included in Other (income) expense, net (see Note 13).

Anti-PD-1 Antibody Patent Oppositions and Litigation

As previously disclosed, Ono Pharmaceutical Co. (Ono) has a European patent (EP 1 537 878) ('878) that broadly claims the use of an anti-PD-1 antibody, such as the Company's immunotherapy, Keytruda, for the treatment of cancer. Ono has previously licensed its commercial rights to an anti-PD-1 antibody to Bristol-Myers Squibb (BMS) in certain markets. The Company believes that the '878 patent is invalid and filed an opposition in the European Patent Office (EPO) seeking its revocation. In June 2014, the Opposition Division of the EPO found the claims in the '878 patent are valid. The Company received the Opposition Division's written opinion in September 2014 and the Company submitted its substantive appeal in February 2015. In April 2014, the Company, and three other companies, opposed another European patent (EP 2 161 336) ('336) owned by BMS and Ono that it believes is invalid. The '336 patent, as granted, broadly claimed anti-PD-1 antibodies that could include Keytruda. In February 2015 and May 2016, BMS and Ono submitted requests to amend the claims of the '336 patent. During a hearing in July 2016, the EPO allowed the May 2016 amendment and, as a result, the claims of the '336 patent no longer broadly claim anti-PD-1 antibodies such as Keytruda.

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

In February 2015, the Company filed lawsuits in the Netherlands seeking revocation of the Dutch national versions of both the '878 and '336 patents. BMS and Ono amended the claims of the '336 patent so that the claims of the '336 patent no longer broadly claim anti-PD-1 antibodies such as Keytruda. Trial regarding the validity and infringement of the

’878 patent was held in January 2016. In June 2016, the District Court in The Hague issued its judgment finding the Dutch ‘878 patent valid and infringed. The Company has appealed this judgment.

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

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

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

The Company can file lawsuits seeking revocation of the ’878 patents in other national courts in Europe at any time, and Ono and BMS can file patent infringement actions against the Company in other national courts in Europe at or around the time the Company launches Keytruda. If a national court determines that the Company infringed a valid claim in the ’878 patent, Ono and BMS may be entitled to monetary damages, including royalties on future sales of Keytruda, and potentially could seek an injunction to prevent the Company from marketing Keytruda in that country.

The United States Patent and Trademark Office (USPTO) granted US Patent Nos. 8,728,474 to Ono and 8,779,105 to Ono and BMS in May 2014. These patents are equivalent to the ’878 and ’336 patents, respectively. In September 2014, BMS and Ono filed a lawsuit in the United States alleging that, by marketing Keytruda, the Company will infringe US Patent No. 8,728,474. BMS and Ono are not seeking to prevent or stop the marketing of Keytruda in the United States. The trial in this matter is currently scheduled to begin in April 2017. The Company believes that the 8,728,474 patent and the 8,779,105 patent are both invalid. In June 2015 and July 2015, Ono filed lawsuits in the United States alleging that, by marketing Keytruda, the Company will infringe US Patent Nos. 9,067,999 and 9,073,994, which are patents related to the 8,728,474 patent. The Company believes the 9,067,999 and 9,073,994 patents are also invalid. In June 2016, the Company filed petitions for Inter Partes Review (IPR) in the USPTO alleging that the 9,067,999 and 9,073,994 patents are invalid. The USPTO has until December 2016 to decide these petitions.

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

In September 2014, the Company filed a lawsuit in Australia seeking revocation of Australian Patent No. 2011203119, which is equivalent to the ’336 patent as originally granted. In March 2015, BMS and Ono counterclaimed in this matter alleging that the Company’s manufacture and supply of Keytruda to the Australian market will infringe Australian Patent No. 2011203119. A trial on this patent is scheduled for September 2017.

Ono and BMS have similar and other patents and applications, which the Company is closely monitoring, pending in the United States, Japan and other countries.

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

In October 2015, PDL Biopharma (PDL) filed a lawsuit in the United States against the Company alleging that the manufacture of Keytruda infringed US Patent No. 5,693,761 (’761 patent), which expired in December 2014. This patent claims platform technology used in the creation and manufacture of recombinant antibodies and PDL is seeking damages for pre-expiry infringement of the ’761 patent.

In July 2016, the Company filed a declaratory judgment action in the United States against Genentech and City of Hope seeking a ruling that US Patent No. 7,923,221 (the Cabilly III patent), which claims platform technology used in the creation and manufacture of recombinant antibodies, is invalid and that Keytruda and bezlotoxumab do not infringe the Cabilly III patent. In July 2016, the Company also filed a petition in the USPTO for IPR of certain claims of US Patent No. 6,331,415 (the Cabilly II patent), which claims platform technology used in the creation and manufacture of recombinant antibodies and is also owned by Genentech and City of Hope, as being invalid. The USPTO has six months to decide this petition.

Gilead Patent Litigation and Opposition

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

unenforceable with respect to Gilead. The Company has appealed the court's decision. Gilead has also asked the court to overturn the jury's decision on validity. The court held a hearing on Gilead's motion on August 4, 2016, and the court subsequently rejected Gilead's request. The Company will pay 20%, net of legal fees, of damages or royalties, if any, that it is awarded to Ionis Pharmaceuticals, Inc.

The Company, through its Idenix Pharmaceuticals, Inc. subsidiary, has pending litigation against Gilead in the United States, the UK, Norway, Canada, Germany, France, and Australia based on different patent estates that would also be infringed by Gilead's sales of these two products. Gilead has opposed the European patent at the EPO. Trial in the United States is currently

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

scheduled for December 2016. In the UK, Norway, Australia and Canada, the Company was initially unsuccessful and those cases are currently under appeal. The EPO opposition division revoked the European patent, and the Company has appealed this decision. The cases in France and Germany have been stayed pending the final decision of the EPO.

Other Litigation

There are various other pending legal proceedings involving the Company, principally product liability and intellectual property lawsuits. While it is not feasible to predict the outcome of such proceedings, in the opinion of the Company, either the likelihood of loss is remote or any reasonably possible loss associated with the resolution of such proceedings is not expected to be material to the Company's financial position, results of operations or cash flows either individually or in the aggregate.

Legal Defense Reserves

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of September 30, 2016 and December 31, 2015 of approximately $200 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.

10. 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.	—	—	—	3,465	—	—	—	—	3,465
Other comprehensive loss, net of tax	—	—	—	—	(250)	—	—	—	(250)
Cash dividends declared on common stock	—	—	—	(3,826)	—	—	—	—	(3,826)
Treasury stock shares purchased	—	—	—	—	—	53	(3,005)	—	(3,005)
Share-based compensation plans and other	—	—	(263)	—	—	(17)	840	—	577
Changes in noncontrolling ownership interests	—	—	(21)	—	—	—	—	(55)	(76)
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	12	12
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(9)	(9)
Balance at September 30, 2015	3,577	$ 1,788	$40,139	$45,660	$ (4,573)	775	$(37,427)	$ 92	$45,679
Balance at January 1, 2016	3,577	$ 1,788	$40,222	$45,348	$ (4,148)	796	$(38,534)	$ 91	$44,767
Net income attributable to Merck & Co., Inc.	—	—	—	4,515	—	—	—	—	4,515
Other comprehensive loss, net of tax	—	—	—	—	(104)	—	—	—	(104)

Cash dividends declared on common stock	—	—	—	(3,835)	—	—	—	—	(3,835)
Treasury stock shares purchased	—	—	—	—	—	44	(2,418)	—	(2,418)
Share-based compensation plans and other	—	—	(325)	—	—	(25)	1,235	—	910
Changes in noncontrolling ownership interests	—	—	—	—	—	—	—	124	124
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	13	13
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(15)	(15)
Balance at September 30, 2016	3,577	$ 1,788	$39,897	$46,028	$ (4,252)	815	$(39,717)	$ 213	$43,957

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

11. Share-Based Compensation Plans

The Company has share-based compensation plans under which the Company grants restricted stock units (RSUs) and performance share units (PSUs) to certain management level employees. 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 September 30,		Nine Months Ended September 30,	
($ in millions)	2016	2015	2016	2015
Pretax share-based compensation expense	$77	$75	$225	$221
Income tax benefit	(24)	(23)	(69)	(69)
Total share-based compensation expense, net of taxes	$53	$52	$156	$152

Amounts in the table above do not reflect share-based compensation costs to settle non-vested Afferent and Cubist equity awards attributable to postcombination service that were recognized as transaction expense in 2016 and 2015, respectively (see Note 2).

During the first nine months of 2016 and 2015, the Company granted 6 million RSUs with a weighted-average grant date fair value of $54.61 per RSU and 4 million RSUs with a weighted-average grant date fair value of $59.79 per RSU, respectively. During the first nine months of 2016 and 2015, the Company granted 6 million stock options with a weighted-average exercise price of $54.62 per option and 5 million stock options with a weighted-average exercise price of $59.82 per option, respectively. The weighted-average fair value of options granted for the first nine months of 2016 and 2015 was $5.89 and $6.46 per option, respectively, and was determined using the following assumptions:

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

At September 30, 2016, there was $524 million of total pretax unrecognized compensation expense related to nonvested stock options, RSU and PSU awards which will be recognized over a weighted-average period of 2.1 years. For segment reporting, share-based compensation costs are unallocated expenses.

12. Pension and Other Postretirement Benefit Plans

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

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2016		2015		2016		2015	
($ in millions)	U.S.	International	U.S.	International	U.S.	International	U.S.	International
Service cost	$66	$ 59	$65	$ 61	$212	$ 179	$230	$ 190
Interest cost	116	51	108	52	342	155	326	156
Expected return on plan assets	(203)	(95)	(203)	(95)	(623)	(288)	(614)	(286)
Net amortization	18	18	33	26	48	55	119	79
Termination benefits	6	1	2	—	11	2	20	1
Curtailments	3	(2)	(1)	(2)	3	(1)	(10)	(3)

Settlements	—	—	—	1	—	—	—	4
	$6	$ 32	$4	$ 43	$(7)	$ 102	$71	$ 141

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

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 September 30,		Nine Months Ended September 30,	
($ in millions)	2016	2015	2016	2015
Service cost	$14	$22	$41	$61
Interest cost	19	28	62	83
Expected return on plan assets	(19)	(36)	(88)	(107)
Net amortization	(25)	(13)	(78)	(44)
Termination benefits	1	1	1	6
Curtailments	(5)	(1)	(7)	(8)
	$(15)	$1	$(69)	$(9)

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 now anticipates that contributions to its international pension plans will approximate $450 million during 2016.

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

13. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2016	2015	2016	2015
Interest income	$(87)	$(68)	$(244)	$(214)
Interest expense	170	165	513	503
Exchange losses	3	228	79	1,038
Equity income from affiliates	(21)	(63)	(59)	(210)
Other, net	(43)	(432)	(201)	(493)
	$22	$(170)	$88	$624

The higher exchange losses in 2015 compared with 2016 are primarily related to the Venezuelan Bolívar. During the second quarter of 2015, upon evaluation of evolving economic conditions in Venezuela and volatility in the country, the Company determined it was unlikely that all outstanding net monetary assets would be settled at the then official (CENCOEX) rate of 6.30 VEF (Bolívar Fuertes) per U.S. dollar. Accordingly, during the second quarter of 2015, the Company recorded a charge of $715 million to devalue its net monetary assets in Venezuela to an amount that represented the Company’s estimate of the U.S. dollar amount that would ultimately be collected. Since January 2010, Venezuela has been designated hyperinflationary and, as a result, local foreign operations are remeasured in U.S. dollars with the impact recorded in results of operations. During the third quarter of 2015, the Company recorded additional exchange losses of $138 million in the aggregate reflecting the ongoing effect of translating transactions and net monetary assets consistent with the second quarter of 2015.

The declines in equity income from affiliates in the third quarter and first nine months of 2016 as compared with the corresponding periods of 2015 were driven primarily by lower equity income from certain research investment funds. Other, net (as reflected in the table above) in the first nine months of 2016 includes a gain of $117 million related to the settlement of certain patent litigation (see Note 9). Other, net in the third quarter and first nine months of 2015 includes a $250 million gain on the sale of certain migraine clinical development programs (see Note 2). Other, net in the first nine months of 2015 also includes an expense of $78 million for a contribution of investments in equity securities to the Merck Foundation.

Interest paid for the nine months ended September 30, 2016 and 2015 was $470 million and $452 million, respectively.

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

14. Taxes on Income

The effective income tax rates of 24.2% and 23.6% for the third quarter of 2016 and 2015, respectively, and 24.7% and 24.2% for the first nine months of 2016 and 2015, respectively, reflect the impacts of acquisition and divestiture-related costs and restructuring costs, partially offset by the beneficial impact of foreign earnings. The effective income tax rate for the first nine months of 2016 also reflects the beneficial impact of orphan drug federal income tax credits, primarily for Keytruda. The effective income tax rate for the first nine months of 2015 reflects the favorable impact of a net benefit of $370 million related to the settlement of certain federal income tax issues. In addition, the effective income tax rate for the first nine months of 2015 reflects the unfavorable effects of non-tax deductible foreign exchange losses related to Venezuela (see Note 13) and a $75 million out-of-period discrete adjustment recorded in the second quarter related to deferred taxes associated with prior year restructuring activities. Management considered the discrete adjustment to be immaterial to current and prior period financial statements as reported.

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

15. Earnings Per Share

The calculations of earnings per share are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ and shares in millions except per share amounts)	2016	2015	2016	2015
Net income attributable to Merck & Co., Inc.	$2,184	$1,826	$4,515	$3,465
Average common shares outstanding	2,765	2,814	2,769	2,825
Common shares issuable [(1)]	21	22	22	25
Average common shares outstanding assuming dilution	2,786	2,836	2,791	2,850
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	$0.79	$0.65	$1.63	$1.23
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	$0.78	$0.64	$1.62	$1.22

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

For the three months ended September 30, 2016 and 2015, 4 million and 10 million, respectively, and for the first nine months of 2016 and 2015, 13 million and 7 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)

16. Other Comprehensive Income (Loss)

Changes in AOCI by component are as follows:

	Three Months Ended September 30,				
($ in millions)	Derivatives	Investments	Employee Benefit Plans	Cumulative Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
Balance July 1, 2015, net of taxes	$606	$ 143	$ (2,909)	$ (2,172)	$ (4,332)
Other comprehensive income (loss) before reclassification adjustments, pretax	(16)	(81)	3	(87)	(181)
Tax	9	24	2	2	37
Other comprehensive income (loss) before reclassification adjustments, net of taxes	(7)	(57)	5	(85)	(144)
Reclassification adjustments, pretax	(171)[1]	(16)[2]	46[3]	—	(141)
Tax	60	6	(22)	—	44
Reclassification adjustments, net of taxes	(111)	(10)	24	—	(97)
Other comprehensive income (loss), net of taxes	(118)	(67)	29	(85)	(241)
Balance September 30, 2015, net of taxes	$488	$ 76	$ (2,880)	$ (2,257)	$ (4,573)
Balance July 1, 2016, net of taxes	$111	$ 167	$ (2,543)	$ (1,821)	$ (4,086)
Other comprehensive income (loss) before reclassification adjustments, pretax	(69)	(22)	(177)	70	(198)
Tax	24	(3)	21	12	54
Other comprehensive income (loss) before reclassification adjustments, net of taxes	(45)	(25)	(156)	82	(144)
Reclassification adjustments, pretax	(45)[1]	(5)[2]	11[3]	—	(39)
Tax	16	—	1	—	17
Reclassification adjustments, net of taxes	(29)	(5)	12	—	(22)
Other comprehensive income (loss), net of taxes	(74)	(30)	(144)	82	(166)
Balance September 30, 2016, net of taxes	$37	$ 137	$ (2,687)	$ (1,739)	$ (4,252)

	Nine Months Ended September 30,				
($ 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	464	18	18	(181)	319
Tax	(159)	(1)	(2)	(98)	(260)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	305	17	16	(279)	59
Reclassification adjustments, pretax	(534)[1]	(78)[2]	154[3]	—	(458)
Tax	187	26	(64)	—	149
Reclassification adjustments, net of taxes	(347)	(52)	90	—	(309)
Other comprehensive income (loss), net of taxes	(42)	(35)	106	(279)	(250)
Balance September 30, 2015, net of taxes	$488	$ 76	$ (2,880)	$ (2,257)	$ (4,573)

Balance January 1, 2016, net of taxes	$404	$ 41	$ (2,407)	$ (2,186)	$ (4,148)
Other comprehensive income (loss) before reclassification adjustments, pretax	(311)	108	(395)	424	(174)
Tax	109	8	88	23	228
Other comprehensive income (loss) before reclassification adjustments, net of taxes	(202)	116	(307)	447	54
Reclassification adjustments, pretax	(254) [1]	(26) [2]	25 [3]	—	(255)
Tax	89	6	2	—	97
Reclassification adjustments, net of taxes	(165)	(20)	27	—	(158)
Other comprehensive income (loss), net of taxes	(367)	96	(280)	447	(104)
Balance September 30, 2016, net of taxes	$37	$ 137	$ (2,687)	$ (1,739)	$ (4,252)

(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 12).

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

17. 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. During the third quarter of 2016, the Company made changes to the composition of the Animal Health segment that resulted in the inclusion of certain revenues and costs that were previously included in non-segment revenues and profits. Prior periods have been recast to reflect these changes on a comparable basis.

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

Sales of the Company's products were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2016	2015	2016	2015
Primary Care and Women's Health				
Cardiovascular				
Zetia	$671	$633	$1,985	$1,836
Vytorin	273	302	843	942
Diabetes				
Januvia	1,006	1,014	2,976	2,942
Janumet	548	562	1,624	1,625
General Medicine and Women's Health				
NuvaRing	195	190	571	538
Implanon/Nexplanon	148	176	446	437
Dulera	97	133	331	383
Follistim AQ	101	95	268	288
Hospital and Specialty				
Hepatitis				
Zepatier	164	—	326	—
HIV				
Isentress	372	377	1,050	1,137
Hospital Acute Care				
Cubicin	320	325	969	805
Noxafil	147	132	434	360
Invanz	152	153	409	424
Cancidas	142	139	406	436
Bridion	139	89	343	262
Primaxin	77	75	231	228
Immunology				
Remicade	311	442	999	1,398
Simponi	193	178	581	505
Oncology				
Keytruda	356	159	919	352
Emend	137	141	405	396
Temodar	78	83	216	238
Diversified Brands				
Respiratory				
Singulair	239	201	705	658
Nasonex	94	121	425	625
Other				
Cozaar/Hyzaar	131	150	389	524
Arcoxia	114	123	342	361
Fosamax	68	86	217	277
Zocor	54	56	150	168
Vaccines [1]				
Gardasil/Gardasil 9	860	625	1,631	1,410
ProQuad/M-M-R II/Varivax	496	390	1,236	1,096
RotaTeq	171	160	489	441

Zostavax	190	179	464	503
Pneumovax 23	175	138	403	354
Other pharmaceutical [2]	1,224	1,298	3,464	3,806
Total Pharmaceutical segment sales	9,443	8,925	26,247	25,755
Other segment sales [3]	977	903	2,862	2,745
Total segment sales	10,420	9,828	29,109	28,500
Other [4]	116	245	583	783
	$10,536	$10,073	$29,692	$29,283

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

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2016	2015	2016	2015
Segment profits:				
Pharmaceutical segment	$6,162	$5,641	$16,698	$16,088
Other segments	389	394	1,129	1,208
Total segment profits	6,551	6,035	17,827	17,296
Other profits	21	204	341	582
Unallocated:				
Interest income	87	68	244	214
Interest expense	(170)	(165)	(513)	(503)
Equity income from affiliates	(27)	25	(13)	161
Depreciation and amortization	(365)	(381)	(1,228)	(1,169)
Research and development	(1,444)	(1,291)	(4,651)	(4,310)
Amortization of purchase accounting adjustments	(772)	(1,180)	(2,932)	(3,658)
Restructuring costs	(161)	(113)	(386)	(386)
Gain on sale of certain migraine clinical development programs	40	250	40	250
Foreign currency devaluation related to Venezuela	—	—	—	(715)
Other unallocated, net	(873)	(1,055)	(2,714)	(3,177)
	$2,887	$2,397	$6,015	$4,585

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, expense or income related to changes in the estimated fair value of contingent consideration, and other miscellaneous income or expense items.

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

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.

In June 2016, Merck and Moderna Therapeutics announced a strategic collaboration and license agreement to develop and commercialize novel messenger RNA (mRNA)-based personalized cancer vaccines.

In July 2016, Merck acquired Afferent Pharmaceuticals (Afferent), a privately held pharmaceutical company focused on the development of therapeutic candidates targeting the P2X3 receptor for the treatment of common, poorly-managed, neurogenic conditions.

Also in July 2016, Merck acquired a majority ownership interest in The StayWell Company LLC (StayWell), a health engagement company that helps its clients engage and educate people to improve health and business results.

Additionally in July 2016, Merck announced it had executed an agreement to acquire a controlling interest in Vallée S.A. (Vallée), a leading privately held producer of animal health products in Brazil.

See Note 2 to the condensed consolidated financial statements for additional information on the above transactions.

Operating Results

Sales

Worldwide sales were $10.5 billion for the third quarter of 2016, an increase of 5% compared with the third quarter of 2015. Foreign exchange unfavorably affected global sales performance by 1% in the third quarter of 2016, which includes a lower benefit from revenue hedging activities as compared with the third quarter of 2015. Sales growth was driven primarily by higher sales of Gardasil 9 (Human Papillomavirus 9-valent Vaccine, Recombinant)/Gardasil (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant), Keytruda (pembrolizumab), Zepatier (elbasvir and grazoprevir), ProQuad (Measles, Mumps, Rubella and Varicella Virus Vaccine Live), Bridion (sugammadex) Injection, Adempas (riociguat), Singulair (montelukast), Pneumovax 23 (pneumococcal vaccine polyvalent) and Zetia (ezetimibe), as well as higher sales of Animal Health products. Sales in the third quarter of 2016 benefited from approximately $150 million of additional sales in Japan resulting from the timing of shipments in anticipation of a resource planning system that was implemented by the Company in the fourth quarter of 2016. Partially offsetting revenue growth in the third quarter were declines in Remicade (infliximab) and Dulera Inhalation Aerosol (mometasone furoate/formoterol fumarate dihydrate), as well as lower sales of products within Diversified Brands including Nasonex (mometasone furoate monohydrate), Cozaar (losartan potassium) and Hyzaar (losartan potassium and hydrochlorothiazide). Sales performance in the third quarter of 2016 reflects a decline of approximately $170 million due to reduced operations in Venezuela.

Worldwide sales were $29.7 billion for the first nine months of 2016, growth of 1% as compared with the first nine months of 2015. Foreign exchange unfavorably affected global sales performance by 3% in the first nine months of 2016, which includes a lower benefit from revenue hedging activities as compared with the first nine months of 2015. Sales growth was driven primarily by higher sales of Keytruda, Zepatier, Gardasil 9/Gardasil, Zetia, Adempas, ProQuad, Bridion, Simponi (golimumab) and Noxafil (posaconazole), as well as higher sales of Animal Health products. Revenue in the first nine months of 2016 benefited from approximately one month of additional sales for products acquired in connection with the January 2015 acquisition of Cubist Pharmaceuticals, Inc. (Cubist). Sales in the first nine months of 2016 also benefited from approximately $150 million of additional sales in Japan resulting from the timing of shipments as noted above. In addition, the Company recognized revenue of $75 million in the first nine months of 2016 in connection with the sale of the U.S. marketing rights to certain products. Largely offsetting revenue growth in the first nine months of 2016 were declines in Remicade, Nasonex, Cozaar and Hyzaar, Isentress (raltegravir), Fosamax (alendronate sodium) and Dulera, as well as declines in other products within Diversified Brands. Sales performance in the first nine months of 2016 reflects a decline of approximately $620 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 nine months of 2016. The Company anticipates these pricing actions, including the biennial price reductions in Japan, and other austerity measures will continue to negatively affect revenue performance for the remainder of 2016.

Sales of the Company's products were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2016	2015	2016	2015
Primary Care and Women's Health				
Cardiovascular				
Zetia	$671	$633	$1,985	$1,836
Vytorin	273	302	843	942
Diabetes				
Januvia	1,006	1,014	2,976	2,942
Janumet	548	562	1,624	1,625
General Medicine and Women's Health				
NuvaRing	195	190	571	538
Implanon/Nexplanon	148	176	446	437
Dulera	97	133	331	383
Follistim AQ	101	95	268	288
Hospital and Specialty				
Hepatitis				
Zepatier	164	—	326	—
HIV				
Isentress	372	377	1,050	1,137
Hospital Acute Care				
Cubicin	320	325	969	805
Noxafil	147	132	434	360
Invanz	152	153	409	424
Cancidas	142	139	406	436
Bridion	139	89	343	262
Primaxin	77	75	231	228
Immunology				
Remicade	311	442	999	1,398
Simponi	193	178	581	505
Oncology				
Keytruda	356	159	919	352
Emend	137	141	405	396
Temodar	78	83	216	238
Diversified Brands				
Respiratory				
Singulair	239	201	705	658
Nasonex	94	121	425	625
Other				
Cozaar/Hyzaar	131	150	389	524
Arcoxia	114	123	342	361
Fosamax	68	86	217	277
Zocor	54	56	150	168
Vaccines [1]				
Gardasil/Gardasil 9	860	625	1,631	1,410
ProQuad/M-M-R II/Varivax	496	390	1,236	1,096

RotaTeq	171	160	489	441
Zostavax	190	179	464	503
Pneumovax 23	175	138	403	354
Other pharmaceutical [2]	1,224	1,298	3,464	3,806
Total Pharmaceutical segment sales	9,443	8,925	26,247	25,755
Other segment sales [3]	977	903	2,862	2,745
Total segment sales	10,420	9,828	29,109	28,500
Other [4]	116	245	583	783
	$10,536	$10,073	$29,692	$29,283

(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 nine months of 2016 also includes $75 million related to the sale of the U.S. marketing rights to certain products (see Note 2 to the condensed consolidated financial statements).

Product sales are recorded net of the provision for discounts, which includes indirect customer discounts that occur when a contracted customer purchases directly through an intermediary wholesale purchaser, known as chargebacks, as well as indirectly in the form of rebates owed based upon definitive contractual agreements or legal requirements with private sector and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. These discounts, in the aggregate, reduced U.S. sales by $2.6 billion and $2.1 billion for the three months ended September 30, 2016 and 2015, respectively, and by $7.1 billion and $5.8 billion for the first nine months of 2016 and 2015, respectively. Inventory levels at key U.S. wholesalers for each of the Company's major pharmaceutical products are generally less than one month.

Pharmaceutical Segment

Primary Care and Women's Health

Cardiovascular

Combined global sales of Zetia (marketed in most countries outside the United States as Ezetrol) and Vytorin (ezetimibe and simvastatin) (marketed outside the United States as Inegy), medicines for lowering LDL cholesterol, were $944 million in the third quarter of 2016, and $2.8 billion in the first nine months of 2016, increases of 1% and 2%, respectively, compared with the same periods of 2015. In addition, in the third quarter and first nine months of 2016, the Company recorded $39 million and $96 million, respectively, of sales of Atozet (ezetimibe and atorvastatin), which the Company markets in certain countries outside of the United States. Sales of the ezetimibe family (including Atozet) were $984 million in the third quarter of 2016, growth of 4% compared with the third quarter of 2015, and were $2.9 billion for the first nine months of 2016, growth of 5% compared with the same period of 2015. Foreign exchange favorably affected global sales performance by 1% in the third quarter of 2016 and unfavorably affected global sales performance by 1% in first nine months of 2016. Sales growth in both periods reflects higher pricing in the United States, as well as volume growth in Europe, and higher sales in Japan due to timing of shipments, partially offset by lower volumes in the United States and lower sales in Venezuela due to reduced operations in this country.

By agreement, a generic manufacturer may launch a generic version of Zetia in the United States in December 2016 and the Company anticipates a rapid and substantial decline in U.S. Zetia sales thereafter. The U.S. patent and exclusivity periods for Zetia and Vytorin otherwise expire in April 2017. Sales of Zetia and Vytorin in the United States were $1.3 billion and $341 million, respectively, for the first nine months of 2016. The Company has market exclusivity in major European markets for Ezetrol until April 2018 and for Inegy until April 2019.

In October 2014, Merck and Bayer AG (Bayer) announced a collaboration to market and develop novel therapies for cardiovascular disease. Under the terms of the agreement, Merck has lead commercial rights for Adempas, a novel cardiovascular drug for the treatment of pulmonary arterial hypertension, in countries outside the Americas while Bayer continues to have lead rights in the Americas, including the United States. Starting in 2016, Merck began promoting and distributing Adempas in Europe. Transition in other Merck territories will continue in 2017. Merck recorded sales of $48 million and $120 million for Adempas in the third quarter and first nine months of 2016, respectively, which includes sales in Merck's marketing territories, as well as Merck's share of profits from the sale of Adempas in Bayer's marketing territories.

In September 2016, Merck sold the marketing rights for Zontivity (vorapaxar) in the United States and Canada to Aralez Pharmaceuticals Inc. for a $25 million upfront payment and royalties at graduated rates, plus potential future consideration dependent upon the achievement of certain aggregate annual sales-based milestones. Previously, 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 an impairment charge of $252 million recorded in Materials and production costs in the first nine months of 2016.

Diabetes

Worldwide combined sales of Januvia (sitagliptin) and Janumet (sitagliptin/metformin HCl) , medicines that help lower blood sugar levels in adults with type 2 diabetes, were $1.6 billion in the third quarter of 2016, a decline of 1%

compared with the third quarter of 2015 including a 1% favorable effect from foreign exchange. The decline reflects lower sales in the United States driven by pricing pressures, as well as the timing of customer purchases in the third quarter of 2015 that resulted in an unfavorable comparison to this quarter, partially offset by higher demand. The decline also reflects no sales in Venezuela in the third quarter of 2016 due to the Company's reduced operations in that country. These declines were partially offset by higher sales in Japan reflecting the timing of shipments, as well as volume growth in Europe and certain emerging markets. Global sales of Januvia and Janumet were $4.6 billion for the first nine months of 2016, an increase of 1% compared with the same period of 2015. Sales growth was driven primarily by higher sales in Japan reflecting the timing of shipments, as well as higher volumes in Europe, Canada and certain emerging markets. These increases were partially offset by lower sales in the United States, reflecting pricing pressures and the timing of customer purchases in the prior year as noted above, partially offset by higher demand, as well as lower sales in Venezuela due to the Company's reduced operations in that country.

General Medicine and Women's Health

Worldwide sales of NuvaRing (etonogestrel/ethinyl estradiol vaginal ring), a vaginal contraceptive product, increased 3% in the third quarter of 2016 to $195 million and grew 6% in the first nine months of 2016 to $571 million compared with the same periods of 2015. Sales growth in both periods primarily reflects higher pricing in the United States, partially offset by volume declines in Europe. Foreign exchange unfavorably affected global sales performance by 1% in the first nine months of 2016. In August 2016, the U.S. District Court ruled that the Company's delivery system patent for NuvaRing is invalid. The Company is appealing this verdict to the U.S. Court of Appeals for the Federal Circuit. However, given the U.S. District Court's decision, there may be generic entrants into the U.S. market in advance of the April 2018 patent expiration. If this should occur, the Company anticipates a significant decline in U.S. NuvaRing sales thereafter. U.S. sales of NuvaRing were $421 million for the first nine months of 2016. As a result of the unfavorable U.S. District Court decision, the Company evaluated the intangible asset related to NuvaRing, which had a carrying value of $365 million at September 30, 2016, for impairment and concluded that it was not impaired.

Worldwide sales of Implanon/Nexplanon (etonogestrel implant), single-rod subdermal contraceptive implants, declined 16% to $148 million in the third quarter of 2016 compared with the third quarter of 2015 reflecting declines in certain emerging markets, particularly in Venezuela due to reduced operations in this country, as well as lower sales in the United States. Global sales of Implanon/Nexplanon increased 2% to $446 million in the first nine months of 2016 compared with the same period of 2015 driven primarily by higher demand in the United States, partially offset by declines in certain emerging markets, particularly in Venezuela. Foreign exchange unfavorably affected global sales performance by 3% for both the third quarter and first nine months of 2016.

Global sales of Dulera Inhalation Aerosol, a combination medicine for the treatment of asthma, decreased 27% to $97 million in the third quarter of 2016 and declined 14% to $331 million in the first nine months of 2016 compared with the same periods of 2015, driven by lower sales in the United States reflecting competitive pricing pressures that were partially offset by higher demand.

Global sales of Follistim AQ (follitropin beta injection) (marketed in most countries outside the United States as Puregon), a fertility treatment, were $101 million in the third quarter of 2016, an increase of 6% compared with the third quarter of 2015 including a 2% unfavorable effect from foreign exchange. Sales growth reflects volume increases in the United States resulting from the resolution of a supply issue, partially offset by volume declines in Europe. Worldwide sales of Follistim AQ were $268 million in the first nine months of 2016, a decrease of 7% compared with the same period of 2015 including a 2% unfavorable effect from foreign exchange. The sales decline primarily reflects lower demand in Europe and certain emerging markets.

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

Hospital and Specialty

Hepatitis

Global sales of Zepatier were $164 million and $326 million in the third quarter and first nine months of 2016, respectively. In January 2016, the U.S. 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. Zepatier is also approved in certain other markets.

In July 2016, the European Commission (EC) approved Zepatier for the treatment of chronic HCV in adult patients, allowing marketing of Zepatier in all 28 European Union (EU) member states. The Company continues to work to

supply the EU market, with product launches estimated to begin between the fourth quarter of 2016 and the first quarter of 2017. In the course of the European review for Zepatier, the European Medicines Agency (EMA) cited Merck's third-party manufacturer for issues largely related to inadequate record-keeping and the need for improvement in their quality management systems. The Company does not believe that these problems will affect the supply to the U.S. market.

HIV

Global sales of Isentress, an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection, were $372 million in the third quarter of 2016, a decline of 1% compared with the third quarter of 2015 including a 2% unfavorable effect from foreign exchange. The decline reflects lower demand and pricing in Europe and lower volumes in the United States due to competitive pressures, partially offset by a favorable adjustment to discount reserves

in the United States. Worldwide sales of Isentress were $1.1 billion for the first nine months of 2016, a decline of 8% compared with the same period of 2015 including a 3% 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 a favorable adjustment to discount reserves in the United States and higher volumes in certain emerging markets.

Hospital Acute Care

Sales of Cubicin, an I.V. antibiotic for complicated skin and skin structure infections or bacteremia when caused by designated susceptible organisms, were $320 million in the third quarter of 2016, a decline of 2% compared with the third quarter of 2015. The decline was driven primarily by lower sales in the United States resulting from the June 2016 expiration of the U.S. composition patent for Cubicin. This decline was partially offset by sales of Cubicin in certain international markets for which the Company acquired marketing rights in the fourth quarter of 2015 (including Europe, Latin America, Australia, New Zealand, China, South Africa and certain other Asia Pacific countries). Sales of Cubicin were $969 million in the first nine months of 2016 compared with $805 million in the first nine months of 2015. Cubicin was acquired in connection with the purchase of Cubist on January 21, 2015. Accordingly, the increase in sales in the first nine months of 2016 compared with the first nine months of 2015 is largely attributable to nearly one month of additional sales in 2016. Additionally, the sales increase reflects sales of Cubicin in certain international markets for which the Company acquired marketing rights as noted above. As a result of the June 2016 expiration of the U.S. composition patent for Cubicin, the Company anticipates a significant decline in U.S. Cubicin sales. U.S. sales of Cubicin were $824 million in the first nine months of 2016.

Worldwide sales of Noxafil, for the prevention of invasive fungal infections, grew 11% in the third quarter of 2016 to $147 million and increased 21% in the first nine months of 2016 to $434 million compared with the same periods of 2015. Sales growth in both periods was driven primarily by higher 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 3% in both the third quarter and first nine months of 2016.

Global sales of Cancidas (caspofungin acetate), an anti-fungal product, were $142 million in the third quarter of 2016, an increase of 2% compared with the third quarter of 2015 including a 4% unfavorable effect from foreign exchange. Worldwide sales of Cancidas were $406 million for the first nine months of 2016, a decline of 7% compared with the same prior year period, including a 4% unfavorable effect from foreign exchange. The sales decline in the year-to-date period was driven primarily by lower volumes in certain emerging markets, as well as lower pricing in Europe.

Worldwide sales of Bridion, for the reversal of two types of neuromuscular blocking agents used during surgery, were $139 million in the third quarter of 2016, an increase of 56% compared with the third quarter of 2015 including a 7% favorable effect from foreign exchange. Global sales of Bridion were $343 million for the first nine months of 2016, an increase of 31% compared with the same period of 2015 including a 1% favorable effect from foreign exchange. Sales growth in both periods reflects volume growth in most markets, including in the United States where it was approved by the FDA in December 2015, partially offset by declines in Venezuela due to reduced operations by the Company in this country. Sales growth in both periods was benefited by the timing of shipments in Japan.

Immunology

Sales of Remicade, a treatment for inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were $311 million in the third quarter of 2016 and $999 million for the first nine months of 2016, declines of 30% and 29%, respectively, compared with the same periods of 2015. Foreign exchange unfavorably affected sales performance by 2% in both the third quarter and first nine months of 2016. In February 2015, the Company lost market exclusivity for Remicade in major European markets and no longer has market exclusivity in any of its marketing territories. The Company is experiencing pricing and volume declines in these markets as a result of biosimilar competition and expects the declines to continue.

Sales of Simponi, a once-monthly subcutaneous treatment for certain inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were $193 million in the third quarter of 2016 and $581 million for the first nine months of 2016, growth of 8% and 15%, respectively, compared with the same periods in 2015. Foreign

exchange unfavorably affected sales performance by 3% for both the third quarter and first nine months of 2016. Sales growth in both periods was driven primarily by higher volumes in Europe reflecting in part an ongoing positive impact from the ulcerative colitis indication.

Oncology

Global sales of Keytruda, an anti-PD-1 (programmed death receptor-1) therapy, were $356 million in the third quarter of 2016 compared with $159 million in the third quarter of 2015 and were $919 million for the first nine months of 2016 compared with $352 million for the first nine months of 2015. Sales growth in both periods primarily reflects higher sales in Europe, the United States and emerging markets as the Company continues to launch Keytruda.

In October 2016, Merck announced that the FDA approved Keytruda for the first-line treatment of patients with non-small-cell lung cancer (NSCLC) whose tumors have high PD-L1 expression (tumor proportion score [TPS] of 50% or more) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations. With this new indication, Keytruda is

now the only anti-PD-1 therapy to be approved in the first-line treatment setting for these patients. In addition, the FDA approved a labeling update to include data from KEYNOTE-010 in the second-line or greater treatment setting for patients with metastatic NSCLC whose tumors express PD-L1 (TPS of 1% or more) as determined by an FDA-approved test, with disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Keytruda.

In August 2016, Merck announced that the FDA approved Keytruda for the treatment of patients with recurrent or metastatic head and neck cancer (HNSCC) with disease progression on or after platinum-containing chemotherapy. Keytruda is now approved in the United States for the treatment of previously untreated metastatic NSCLC in patients whose tumors express high levels of PD-L1 and previously treated metastatic NSCLC in patients whose tumors express PD-L1, as well as advanced melanoma and previously treated recurrent or metastatic HNSCC. Keytruda is also approved in the EU for the treatment of advanced (unresectable or metastatic) melanoma in adults and for the treatment of patients with locally advanced or metastatic NSCLC in patients whose tumors express PD-L1 and who have received at least one prior chemotherapy regimen. The Company has launched Keytruda for the treatment of melanoma in more than 50 markets outside of the United States.

The Company plans additional regulatory filings in the United States and other countries. The Keytruda clinical development program includes studies across a broad range of cancer types (see “Research and Development” below). See Note 9 to the condensed consolidated financial statements for a discussion of patent litigation related to Keytruda.

Global sales of Emend (aprepitant), for the prevention of chemotherapy-induced and post-operative nausea and vomiting, were $137 million in the third quarter of 2016, a decline of 3% compared with the third quarter of 2015 including a 1% unfavorable effect from foreign exchange. Worldwide sales of Emend were $405 million in the first nine months of 2016, growth of 2% compared with the first nine months of 2015 including a 3% unfavorable effect from foreign exchange. Sales growth in the year-to-date period reflects higher pricing in the United States, partially offset by volume declines in Japan. 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.

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 $239 million in the third quarter of 2016, an increase of 19% compared with the third quarter of 2015 and were $705 million for the first nine months of 2016, an increase of 7% compared with the first nine months of 2015. The increase in both periods was driven primarily by higher sales in Japan reflecting the timing of shipments and the favorable effect of foreign exchange. Foreign exchange favorably affected global sales performance by 9% in the third quarter of 2016 and by 2% in the first nine months of 2016. The patents that provided market exclusivity for Singulair in Japan expired in February and October of 2016. As a result, the Company anticipates a significant decline in Singulair sales in Japan in future periods. Singulair sales in Japan were $367 million in the first nine months of 2016. The Company no longer has market exclusivity for Singulair in any major market.

Global sales of Nasonex, an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, declined 23% to $94 million in the third quarter of 2016 and decreased 32% to $425 million in the first nine months of 2016 compared with the same periods of 2015. Foreign exchange favorably affected global sales performance by 2% in the third quarter of 2016 and unfavorably affected global sales performance by 1% in the first nine months of 2016. The sales declines were driven primarily by lower volumes in the United States from generic competition. In March 2016,

Apotex launched a generic version of Nasonex in the United States pursuant to a June 2012 U.S. District Court for the District of New Jersey ruling (upheld on appeal to the U.S. Court of Appeals for the Federal Circuit) holding that Apotex's generic version of Nasonex does not infringe on the Company's formulation patent. Accordingly, the Company is experiencing a substantial decline in U.S. Nasonex sales and expects the decline to continue. The declines in global Nasonex sales in the third quarter and first nine months of 2016 were also driven by lower volumes and pricing in Europe from ongoing generic erosion and lower sales in Venezuela due to reduced operations by the Company in this country.

Other

Global sales of Cozaar and its companion agent Hyzaar (a combination of Cozaar and hydrochlorothiazide), treatments for hypertension, were $131 million in the third quarter of 2016 and $389 million for the first nine months of 2016, declines of 12% and 26%, respectively, compared with the same periods of 2015. Foreign exchange favorably affected global sales performance

by 1% in the third quarter of 2016 and unfavorably affected global sales performance by 4% in the first nine months of 2016. The sales declines primarily reflect lower sales in emerging markets, particularly in Venezuela due to reduced operations by the Company in this country. Lower volumes in Japan also contributed to the year-to-date decline. 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.

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 9/Gardasil, vaccines to help prevent diseases caused by certain types of human papillomavirus (HPV), grew 38% in the third quarter of 2016 to $860 million and increased 16% in the first nine months of 2016 to $1.6 billion compared with the corresponding prior year periods. Sales growth in both periods was driven primarily by higher sales in the United States from pricing, as well as higher volumes reflecting in part the timing of public sector purchases. Sales growth in the third quarter of 2016 also reflects higher demand in emerging markets, partially driven by government tenders in Brazil. In October 2016, the FDA approved a 2-dose vaccination regimen for Gardasil 9, for use in girls and boys 9 through 14 years of age, and the U.S. Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices voted to recommend the 2-dose vaccination regimen for certain 9 through 14 year olds. The Company anticipates the 2-dose vaccination regimen will have an unfavorable effect on sales of Gardasil 9 going forward.

Merck's sales of ProQuad, a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, were $150 million in the third quarter of 2016 compared with $70 million in the third quarter of 2015 and were $389 million in the first nine months of 2016 compared with $292 million in the first nine months of 2015 driven primarily by the effects of public sector purchasing, as well as higher demand and pricing in the United States. Merck's sales of M M R II (Measles, Mumps and Rubella Virus Vaccine Live), a vaccine to help protect against measles, mumps and rubella, were $115 million for the third quarter of 2016 compared with $103 million for the third quarter of 2015 and were $269 million for the first nine months of 2016 compared with $285 million for the first nine months of 2015. The sales decline in the year-to-date period largely reflects higher demand in the prior year period due to measles outbreaks in the United States, partially offset by higher pricing. Merck's sales of Varivax (Varicella Virus Vaccine Live), a vaccine to help prevent chickenpox (varicella), were $232 million for the third quarter of 2016 compared with $218 million for the third quarter of 2015, primarily reflecting volume growth in certain emerging markets. Merck's sales of Varivax were $578 million for the first nine months of 2016 compared with $519 million in the first nine months of 2015 primarily driven by higher sales in the United States reflecting the effects of public sector purchasing and higher pricing that were partially offset by lower demand. Volume growth in certain emerging markets also contributed to the sales increase in the year-to-date period.

Merck's sales of RotaTeq (Rotavirus Vaccine, Live Oral, Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and children, were $171 million in the third quarter of 2016, an increase of 7% compared with the third quarter of 2015, primarily reflecting higher pricing and volumes in the United States. Merck's sales of RotaTeq were $489 million in the first nine months of 2016, growth of 11% compared with the same period of 2015 including a 1% unfavorable effect from foreign exchange. The increase was driven primarily driven by the effects of public sector purchasing in the United States, as well as volume growth in certain emerging markets.

Merck's sales of Zostavax (Zoster Vaccine Live), a vaccine to help prevent shingles (herpes zoster) in adults 50 years of age and older, were $190 million in the third quarter of 2016, an increase of 6% compared with the third quarter of 2015. Sales growth was driven primarily by volume growth in certain emerging markets and in Canada, partially offset by lower demand in the United States. Merck's sales of Zostavax were $464 million for the first nine months of

2016, a decline of 8% compared with the first nine months of 2015 including a 1% unfavorable effect from foreign exchange. The sales decline in the year-to-date period was driven primarily by lower volumes in the United States, partially offset by higher pricing in the United States and higher demand in emerging markets. 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, a vaccine to help prevent pneumococcal disease, grew 27% in the third quarter of 2016 to $175 million driven primarily by higher pricing and demand in the United States, as well as by higher sales in Japan due to the timing of shipments. Merck's sales of Pneumovax 23 increased 14% in the first nine months of 2016 to $403 million compared with the same prior year period primarily reflecting higher pricing in the United States, higher demand in certain emerging markets, as well as higher sales in Japan due to the timing of shipments. Foreign exchange favorably affected global sales performance by 3% and 1% in the third quarter and first nine months of 2016, respectively.

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 $865 million for the third quarter of 2016, an increase of 5% compared with the third quarter of 2015 including a 2% unfavorable effect from foreign exchange. Sales of Animal Health products were $2.6 billion in the first nine months of 2016, an increase of 4% compared with the same period of 2015 including a 5% unfavorable effect from foreign exchange. Sales growth in both periods reflects volume growth across most species areas, particularly in products for companion animals, driven primarily by higher sales of Bravecto (fluralaner) chewable tablets for dogs to treat fleas and ticks.

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

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

Costs, Expenses and Other

Materials and Production

Materials and production costs were $3.4 billion for the third quarter of 2016 and $10.6 billion for the first nine months of 2016, declines of 9% and 5%, respectively, compared with the same periods of 2015. Costs in the third quarter of 2016 and 2015 include $772 million and $1.2 billion, respectively, and for the first nine months of 2016 and 2015 include $2.9 billion and $3.6 billion, respectively, of expenses for the amortization of intangible assets recognized in connection with business acquisitions. Costs for the first nine months of 2016 also include intangible asset impairment charges of $347 million related to marketed products (see Note 6 to the condensed consolidated financial statements). The Company may recognize additional non-cash impairment charges in the future 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. In addition, expenses for the first nine months of 2015 include $76 million of amortization of purchase accounting adjustments to Cubist's inventories. Included in materials and production costs are costs associated with restructuring activities which amounted to $36 million and $70 million in the third quarter of 2016 and 2015, respectively, and $149 million and $280 million for the first nine months of 2016 and 2015, respectively, including accelerated depreciation and asset write-offs related to the planned sale or closure of manufacturing facilities. Separation costs associated with manufacturing-related headcount reductions have been incurred and are reflected in Restructuring costs as discussed below.

Gross margin was 67.6% in the third quarter of 2016 compared with 62.7% in the third quarter of 2015 and was 64.4% in the first nine months of 2016 compared with 62.1% in the first nine months of 2015. The improvement in gross margin in the third quarter and first nine months of 2016 as compared with the corresponding prior year periods was driven primarily by lower amortization of intangible assets and purchase accounting adjustments to inventories, as well as lower restructuring and intangible asset impairment charges as noted in the above, which reduced gross margin by 7.7 and 11.6 percentage points in the third quarter and first nine months of 2016, respectively, compared with 12.4 and 13.6 percentage points for the third quarter and first nine months of 2015, respectively. The increase in gross margin in both periods was also attributable to the favorable effects of product mix. In the year-to-date period, foreign exchange and lower inventory write-offs also contributed to the gross margin improvement.

Marketing and Administrative

Marketing and administrative expenses decreased 3% to $2.4 billion in the third quarter of 2016 compared with the third quarter of 2015. The decline was driven primarily by lower selling and promotional spending as a result of the Company's prioritization of investments in key brands, the favorable effects of foreign exchange, as well as lower

restructuring costs, partially offset by higher acquisition and divestiture-related costs. Marketing and administrative expenses declined 7% to $7.2 billion in the first nine months of 2016 compared with the same period of 2015. The decline largely reflects lower acquisition and divestiture-related costs, the favorable effects of foreign exchange, lower administrative expenses, such as legal defense costs, as well as lower selling costs. The decline in the year-to-date period was partially offset by higher promotional spending largely related to product launches and higher restructuring costs. Marketing and administrative expenses include acquisition and divestiture-related costs of $36 million and $26 million in the third quarter of 2016 and 2015, respectively, and $56 million and $389 million in the first nine months of 2016 and 2015, respectively, consisting of integration, transaction, and certain other costs related to business acquisitions, including severance costs which are not part of the Company’s formal restructuring programs, as well as transaction

and certain other costs related to divestitures of businesses. Acquisition and divestiture-related costs in the first nine months of 2015 include costs related to the acquisition of Cubist (see Note 2 to the condensed consolidated financial statements.) Marketing and administrative expenses for the third quarter of 2016 and 2015 also include $1 million and $17 million, respectively, and for the first nine months of 2016 and 2015 include $91 million and $70 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 third quarter of 2016, an increase of 11% compared with the third quarter of 2015. The increase primarily reflects higher clinical development spending in 2016 combined with a reduction of expenses in the third quarter of 2015 related to changes in the estimated fair value of liabilities for contingent consideration. Research and development expenses were $5.5 billion for the first nine months of 2016, an increase of 12% compared with the same period of 2015, reflecting increased clinical development spending, higher in-process research and development (IPR&D) impairment charges, higher restructuring costs and increased licensing costs, partially offset by the favorable effects of foreign exchange.

Research and development expenses are comprised of the costs directly incurred by Merck Research Laboratories (MRL), the Company's research and development division that focuses on human health-related activities, which were approximately $1.1 billion and $950 million in the third quarter of 2016 and 2015, respectively, and $3.2 billion and $2.9 billion for the first nine months of 2016 and 2015, respectively. Also included in research and development expenses are costs incurred by other divisions in support of research and development activities, including depreciation, production and general and administrative, as well as licensing activity, and certain costs from operating segments, including the Pharmaceutical and Animal Health segments, which in the aggregate were approximately $525 million and $600 million for the third quarter of 2016 and 2015, respectively, and $1.9 billion and $2.0 billion for the first nine months of 2016 and 2015, respectively. In addition, research and development expenses include IPR&D impairment charges of $225 million and $62 million for the first nine months of 2016 and 2015, respectively (see Note 6 to the condensed consolidated financial statements). The Company may recognize additional non-cash impairment charges in the future related to the cancellation or delay of other pipeline programs that were measured at fair value and capitalized in connection with business acquisitions and such charges could be material. Research and development expenses also include expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration recorded in connection with acquisitions. During the first nine months of 2016, the Company recognized charges of $30 million compared with a reduction in expenses of $71 million in the first nine months of 2015 resulting from changes in the estimated fair value of liabilities for contingent consideration. Research and development expenses also reflect accelerated depreciation and asset abandonment costs associated with restructuring activities of $14 million and $17 million in the third quarter of 2016 and 2015, respectively, and $133 million and $34 million for the first nine months of 2016 and 2015, respectively (see Note 3 to the condensed consolidated financial statements).

Restructuring Costs

The Company incurs substantial costs for restructuring program activities related to Merck's productivity and cost reduction initiatives, as well as in connection with the integration of certain acquired businesses. In 2010 and 2013, the Company commenced actions under global restructuring programs designed to streamline its cost structure. The actions under these programs include the elimination of positions in sales, administrative and headquarters organizations, as well as the sale or closure of certain manufacturing and research and development sites and the consolidation of office facilities. The Company also continues to reduce its global real estate footprint and improve the efficiency of its manufacturing and supply network. The non-facility related restructuring actions under these programs are substantially complete; the remaining activities primarily relate to ongoing facility rationalizations. Restructuring costs, primarily representing separation and other related costs associated with these restructuring activities, were $161 million and $113 million for the third quarter of 2016 and 2015, respectively, and were $386 million for both the first nine months of 2016 and the first nine months of 2015. Separation costs were incurred

associated with actual headcount reductions, as well as estimated expenses under existing severance programs for headcount reductions that were probable and could be reasonably estimated. Merck eliminated approximately 300 positions and 685 positions in the third quarter of 2016 and 2015, respectively, and approximately 1,355 positions and 2,635 positions in the first nine months of 2016 and 2015, respectively, related to these restructuring activities. These position eliminations are comprised of actual headcount reductions, and the elimination of contractors and vacant positions. Also included in restructuring costs are asset abandonment, shut-down and other related costs, as well as employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans and share-based compensation plan costs. For segment reporting, restructuring costs are unallocated expenses.

Additional costs associated with the Company’s restructuring activities are included in Materials and production, Marketing and administrative and Research and development as discussed above (see Note 3 to the condensed consolidated

financial statements). The Company recorded aggregate pretax costs of $212 million and $217 million in the third quarter of 2016 and 2015, respectively, and $759 million and $770 million for the first nine months of 2016 and 2015, respectively, related to restructuring program activities. The Company expects to substantially complete the remaining actions under the programs by the end of 2017 and incur approximately $800 million of additional pretax costs. The Company anticipates that total costs associated with restructuring program activities in 2016 will be approximately $900 million.

Other (Income) Expense, Net

Other (income) expense, net was $22 million of expense in the third quarter of 2016 compared with $170 million of income in the third quarter of 2015 driven primarily by a $250 million gain recognized in 2015 on the sale of certain migraine clinical development programs (see Note 2 to the condensed consolidated financial statements) and lower equity income in 2016 from certain research investment funds, partially offset by lower foreign exchange losses in 2016 related to Venezuela as discussed below. Other (income) expense, net was $88 million of expense in the first nine months of 2016 compared with $624 million of expense in the first nine months of 2015 driven primarily by lower foreign exchange losses related to Venezuela, as well as a gain of $117 million in 2016 related to the settlement of certain patent litigation (see Note 9 to the condensed consolidated financial statements), partially offset by the gain recognized in 2015 related to the sale of certain migraine clinical development programs and lower equity income in 2016 from certain research investment funds.

Since January 2010, Venezuela has been designated hyperinflationary and, as a result, local foreign operations are remeasured in U.S. dollars with the impact recorded in results of operations. In the second quarter of 2015, the Venezuelan government identified multiple exchange rates, which included the CENCOEX rate (6.3 VEF per U.S. dollar at June 30, 2015) and the SIMADI rate (197.30 VEF per U.S. dollar at June 30, 2015). While the Venezuelan government had indicated that essential goods, including food and medicine, would remain at the CENCOEX rate, during the second quarter of 2015, upon evaluation of evolving economic conditions in Venezuela and volatility in the country, combined with a decline in transactions that were being settled at the CENCOEX rate, the Company determined it was unlikely that all outstanding net monetary assets would be settled at the CENCOEX rate. Accordingly, during the second quarter of 2015, the Company recorded a charge of $715 million within Other (income) expense, net to devalue its net monetary assets in Venezuela to an amount that represented the Company's estimate of the U.S. dollar amount that would ultimately be collected. During the third quarter of 2015, the Company recorded additional exchange losses of $138 million in the aggregate reflecting the ongoing effect of translating transactions and net monetary assets consistent with the second quarter. As a result of the further deterioration of economic conditions in Venezuela and continued declines in transactions which were settled at the CENCOEX rate (subsequently replaced by the DIPRO rate), in the fourth quarter of 2015, the Company began using the SIMADI rate (subsequently replaced with the DICOM rate) to report its Venezuelan operations. At September 30, 2016, the DICOM rate was 658.89 VEF per U.S. dollar.

Segment Profits

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2016	2015	2016	2015
Pharmaceutical segment profits	$6,162	$5,641	$16,698	$16,088
Other non-reportable segment profits	389	394	1,129	1,208
Other	(3,664)	(3,638)	(11,812)	(12,711)
Income before income taxes	$2,887	$2,397	$6,015	$4,585

Segment profits are comprised of segment sales less standard costs, certain operating expenses directly incurred by the segment, components of equity income or loss from affiliates and certain depreciation and amortization expenses. For internal management reporting presented to the chief operating decision maker, Merck does not allocate materials and production costs, other than standard costs, the majority of research and development expenses or general and administrative expenses, nor the cost of financing these activities. Separate divisions maintain responsibility for

monitoring and managing these costs, including depreciation related to fixed assets utilized by these divisions and, therefore, they are not included in segment profits. Also excluded from the determination of segment profits are acquisition and divestiture-related costs, including the amortization of purchase accounting adjustments and intangible asset impairment charges, restructuring costs, taxes paid at the joint venture level and a portion of equity income. Additionally, segment profits do not reflect other expenses from corporate and manufacturing cost centers and other miscellaneous income or expense. These unallocated items are reflected in “Other” in the above table. Also included in “Other” are miscellaneous corporate profits (losses), as well as operating profits (losses) related to third-party manufacturing sales.

Pharmaceutical segment profits grew 9% in the third quarter of 2016 and increased 4% in the first nine months of 2016 compared with the corresponding prior year periods primarily reflecting higher sales.

Taxes on Income

The effective income tax rates of 24.2% and 23.6% for the third quarter of 2016 and 2015, respectively, and 24.7% and 24.2% for the first nine months of 2016 and 2015, respectively, reflect the impacts of acquisition and divestiture-related costs and restructuring costs, partially offset by the beneficial impact of foreign earnings. The effective income tax rate for the first nine months of 2016 also reflects the beneficial impact of orphan drug federal income tax credits, primarily for Keytruda. The effective income tax rate for the first nine months of 2015 reflects the favorable impact of a net benefit of $370 million related to the settlement of certain federal income tax issues. In addition, the effective income tax rate for the first nine months of 2015 reflects the unfavorable effects of non-tax deductible foreign exchange losses related to Venezuela (see Note 13 to the condensed consolidated financial statements) and a $75 million out-of-period discrete adjustment recorded in the second quarter related to deferred taxes associated with prior year restructuring activities. Management considered the discrete adjustment to be immaterial to current and prior period financial statements as reported.

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

Net Income and Earnings per Common Share

Net income attributable to Merck & Co., Inc. was $2.2 billion for the third quarter of 2016 compared with $1.8 billion for the third quarter of 2015 and was $4.5 billion for the first nine months of 2016 compared with $3.5 billion for the first nine months of 2015. Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders (EPS) for the third quarter of 2016 were $0.78 compared with $0.64 in the third quarter of 2015 and were $1.62 for the first nine months of 2016 compared with $1.22 for the first nine months of 2015.

Non-GAAP Income and Non-GAAP EPS

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions except per share amounts)	2016	2015	2016	2015
Pretax income as reported under GAAP	$2,887	$2,397	$6,015	$4,585
Increase (decrease) for excluded items:				
Acquisition and divestiture-related costs	834	1,146	3,602	4,134
Restructuring costs	212	217	759	770
Other items:				
Gain on the sale of certain migraine clinical development programs	—	(250)	—	(250)
Foreign currency devaluation related to Venezuela	—	—	—	715
Other	(6)	(33)	(6)	(47)
	3,927	3,477	10,370	9,907
Taxes on income as reported under GAAP	699	566	1,487	1,108
Estimated tax benefit on excluded items [1]	235	186	801	831
Net tax benefit from settlement of certain federal income tax issues	—	—	—	370
	934	752	2,288	2,309
Non-GAAP net income	2,993	2,725	8,082	7,598
Less: Net income attributable to noncontrolling interests	4	5	13	12
Non-GAAP net income attributable to Merck & Co., Inc.	$2,989	$2,720	$8,069	$7,586
EPS assuming dilution as reported under GAAP	$0.78	$0.64	$1.62	$1.22
EPS difference [2]	0.29	0.32	1.27	1.44
Non-GAAP EPS assuming dilution	$1.07	$0.96	$2.89	$2.66

[1] The estimated tax impact on the excluded items is determined by applying the statutory rate of the originating territory of the non-GAAP adjustments.

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

Acquisition and Divestiture-Related Costs

Non-GAAP income and non-GAAP EPS exclude the impact of certain amounts recorded in connection with acquisitions and divestitures. These amounts include the amortization of intangible assets and amortization of purchase accounting adjustments to inventories, as well as intangible asset impairment charges and expense or income related to changes in the estimated fair value measurement of contingent consideration. Also excluded are integration, transaction, and certain other costs associated with business acquisitions, including severance costs which are not part of the Company’s formal restructuring programs, as well as transaction and certain other costs associated with divestitures of businesses.

Restructuring Costs

Non-GAAP income and non-GAAP EPS exclude costs related to restructuring actions (see Note 3 to the condensed consolidated financial statements). These amounts include employee separation costs and accelerated depreciation associated with facilities to be closed or divested. Accelerated depreciation costs represent the difference between the depreciation expense to be recognized over the revised useful life of the asset, based upon the anticipated date the site will be closed or divested or the equipment disposed of, and depreciation expense as determined utilizing the useful life prior to the restructuring actions. Restructuring costs also include asset abandonment, shut-down and other related costs, as well as employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans and share-based compensation costs.

Certain Other Items

Non-GAAP income and non-GAAP EPS exclude certain other items. These items are adjusted for after evaluating them on an individual basis, considering their quantitative and qualitative aspects, and typically consist of items that are difficult to project, unusual in nature, significant to the results of a particular period or not indicative of future operating results. Excluded from non-GAAP income and non-GAAP EPS in 2015 is a gain on the sale of certain migraine clinical development programs (see Note 2 to the condensed consolidated financial statements), foreign exchange losses related to the devaluation of the Company's net monetary assets in Venezuela (see Note 13 to the condensed consolidated financial statements), as well as a net tax benefit related to the settlement of certain federal income tax issues (see Note 14 to the condensed consolidated financial statements).

Research and Development Update

In October 2016, Merck announced that the FDA approved Keytruda for the first-line treatment of patients with NSCLC whose tumors have high PD-L1 expression (TPS of 50% or more) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations. With this new indication, Keytruda is now the only anti-PD-1 therapy to be approved in the first-line treatment setting for these patients. In addition, the FDA approved a labeling update to include data from KEYNOTE-010 in the second-line or greater treatment setting for patients with metastatic NSCLC whose tumors express PD-L1 (TPS of 1% or more) 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. Also in October 2016, Merck announced results from KEYNOTE-021, Cohort G, which included patients with metastatic non-squamous NSCLC regardless of PD-L1 expression level, which showed that Keytruda plus chemotherapy (carboplatin plus pemetrexed) achieved a 55% objective response rate compared to 29% for chemotherapy alone, the standard of care, and reduced the risk of disease progression or death by 47%. To date, Keytruda is the only anti-PD-1 therapy to demonstrate superior efficacy in combination with chemotherapy compared to chemotherapy alone in patients receiving first-line treatment.

Additionally, in October 2016, Merck announced that the Phase 3 KEYNOTE-045 trial investigating the use of Keytruda in patients with previously treated advanced urothelial cancer, met the primary endpoint of overall survival. In this trial, Keytruda was superior compared to investigator choice chemotherapy. Based on a pre-specified interim analysis, an independent Data Monitoring Committee (DMC) recommended that the trial be stopped early.

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). 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. 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.

The Keytruda clinical development program includes patients with more than 30 tumor types in more than 360 clinical trials, including more than 200 trials that combine Keytruda with other cancer treatments. Registration-enabling trials of Keytruda are currently enrolling patients in melanoma, NSCLC, head and neck cancer, bladder cancer, gastric cancer, colorectal cancer, esophageal cancer, breast cancer, ovarian cancer, hepatocellular carcinoma, Hodgkin lymphoma, non-Hodgkin lymphoma, multiple myeloma, nasopharyngeal cancer, prostate cancer, renal cancer and other tumors, with further trials in planning for other cancers.

In October 2016, Merck announced the FDA approved Zinplava (bezlotoxumab) Injection 25 mg/mL. Zinplava is indicated to reduce recurrence of Clostridium difficile infection (CDI) in patients 18 years of age or older who are receiving antibacterial drug treatment of CDI and are at high risk for CDI recurrence. Merck anticipates making Zinplava available in the first quarter of 2017. Bezlotoxumab is also under review in the EU.

Also in October 2016, Merck announced that the pivotal Phase 3 clinical study of letermovir, an investigational antiviral medicine, met its primary endpoint. The global, multicenter, randomized, placebo-controlled study evaluated the efficacy and safety of letermovir for the prevention of clinically-significant cytomegalovirus (CMV) infection in adult (18 years and older) CMV-seropositive recipients of an allogeneic hematopoietic stem cell transplant. Merck will submit results from the study for presentation at a future scientific conference.

In September 2016, Merck in partnership with Pfizer Inc. (Pfizer) announced that a Phase 3 study (VERTIS SITA2) of ertugliflozin, an investigational oral SGLT2 inhibitor for the treatment of patients with type 2 diabetes, met its primary endpoint. Both 5 mg and 15 mg daily doses of ertugliflozin showed significantly greater reductions in A1C (an average measure of blood glucose over the past two to three months) when added to patients on a background of sitagliptin and metformin. Merck and Pfizer plan to submit New Drug Applications to the FDA for ertugliflozin and two fixed-dose combinations (ertugliflozin plus Januvia [sitagliptin] and ertugliflozin plus metformin) by the end of 2016, with additional regulatory submissions outside of the United States to follow in 2017. Under the terms of the

collaboration agreement with Pfizer, Merck will make a $90 million milestone payment to Pfizer once the filing is accepted by the FDA.

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

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

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

MK-0859, anacetrapib, is an investigational inhibitor of the cholesteryl ester transfer protein (CETP) in development for raising HDL-C and reducing LDL-C. Anacetrapib is being evaluated in a 30,000 patient, event-driven cardiovascular clinical outcomes trial sponsored by Oxford University, REVEAL (Randomized EValuation of the Effects of Anacetrapib Through Lipid-modification), involving patients with preexisting vascular disease. In November 2015, Merck announced that the DMC of the REVEAL outcomes study completed its planned review of unblinded study data and recommended the study continue with no changes. The DMC reviewed safety and efficacy data from the study, which included an assessment of futility. Merck remains blinded to the actual results of this analysis and to other REVEAL safety and efficacy data. Under the study, the last patient, last visit is expected to occur in January 2017. The Company anticipates receiving the top-line results from the study mid-year 2017.

In September 2016, Merck announced that it is discontinuing the development of odanacatib, an investigational cathepsin K inhibitor for osteoporosis, and will not seek regulatory approval for its use. Merck previously reported a numeric imbalance in adjudicated stroke events in the pivotal Phase 3 fracture outcomes study in postmenopausal women. The Company has decided to discontinue development after an independent adjudication and analysis of major adverse cardiovascular events confirmed an increased risk of stroke.

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

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

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

The chart below reflects the Company's research pipeline as of November 1, 2016. Candidates shown in Phase 3 include specific products and the date such candidate entered into Phase 3 development. Candidates shown in Phase 2 include the most advanced compound with a specific mechanism or, if listed compounds have the same mechanism, they are each currently intended for commercialization in a given therapeutic area. Small molecules and biologics are given MK-number designations and vaccine candidates are given V-number designations. Except as otherwise noted, candidates in Phase 1, additional indications in the same therapeutic area (other than with respect to Keytruda) and additional claims, line extensions or formulations for in-line products are not shown.

Phase 2

Asthma
MK-1029
Cancer
MK-3475 Keytruda
Advanced Solid Tumors
PMBCL (Primary Mediastinal Large B-Cell Lymphoma)
Nasopharyngeal
Ovarian
Prostate
MK-2206
MK-8628
Cough, including cough with IPF
MK-7264
Diabetes Mellitus
MK-8521
Hepatitis C
MK-3682B (MK-3682/MK-5172 (grazoprevir)/MK-8408 (ruzasvir))
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)
Hepatocellular (May 2016)
Hodgkin Lymphoma (July 2016)
Multiple Myeloma (December 2015)
Renal (October 2016)
CMV Prophylaxis in Transplant Patients
MK-8228 (letermovir) (June 2014)
Diabetes Mellitus
MK-8835 (ertugliflozin) (November 2013)[1]
MK-8835A (ertugliflozin+sitagliptin) (September 2015)[1]
MK-8835B (ertugliflozin+metformin) (August 2015)[1]
MK-0431J (sitagliptin+ipragliflozin) (October 2015) (Japan)[1]
Ebola Vaccine
V920 (March 2015)
Heart Failure
MK-1242 (vericiguat) (September 2016)[1]
Herpes Zoster
V212 (inactivated VZV vaccine) (December 2010)
HIV
MK-1439 (doravirine) (December 2014)

Under Review
New Molecular Entities/Vaccines
Allergy
MK-8237, House Dust Mite (U.S.)[2]
Clostridium difficile Infection
MK-6072 Zinplava (EU)
Diabetes Mellitus
MK-1293 (U.S./EU)[1]
Pediatric Hexavalent Combination Vaccine
V419 (U.S.)[3]

Certain Supplemental Filings
Cancer
Keytruda
1st Line Non-Small-Cell Lung Cancer (EU)

Footnotes:
[1] Being developed in a collaboration.
[2] MK-8237 was being developed as part of a North America partnership with ALK. Merck has given ALK six months' notice that it is terminating the agreement and therefore this compound will be returned to ALK.
[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.

Selected Joint Venture and Affiliate Information

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 $351 million and $318 million in the third quarter of 2016 and 2015, respectively, and were $725 million and $655 million for the first nine months of 2016 and 2015, respectively. SPMSD sales of Gardasil/Gardasil 9 were $61 million and $46 million for the third quarter of 2016 and 2015, respectively, and were $161 million and $126 million for the first nine months of 2016 and 2015, respectively. The Company records the results from its interest in SPMSD and other equity method affiliates in Other (income) expense, net.

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

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 $76 million of such income in the first nine months of 2016.

Liquidity and Capital Resources

($ in millions)	September 30, 2016	December 31, 2015
Cash and investments	$24,724	$26,466
Working capital	13,885	10,550
Total debt to total liabilities and equity	25.6 %	26.0 %

Cash provided by operating activities was $6.7 billion in the first nine months of 2016 compared with $8.3 billion in the first nine months of 2015. Cash provided by operating activities continues to be the Company's primary source of funds to finance operating needs, capital expenditures, a portion of treasury stock purchases and dividends paid to shareholders. Cash provided by operating activities in the first nine months of 2016 reflects a net payment of approximately $680 million to fund the Vioxx shareholder class action litigation settlement not covered by insurance proceeds (see Note 9 to the condensed consolidated financial statements).

Cash used in investing activities was $647 million in the first nine months of 2016 compared with $4.1 billion in the first nine months of 2015. The lower use of cash in 2016 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, the use of cash in 2016 for the acquisitions Afferent and StayWell, as well as increased capital expenditures.

Cash used in financing activities was $7.1 billion in the first nine months of 2016 compared with $3.0 billion in the first nine months of 2015 driven primarily by lower proceeds from the issuance of debt, partially offset by an increase in short-term borrowings, lower payments on debt, lower purchases of treasury stock and higher proceeds from the exercise of stock options.

At September 30, 2016, the total of worldwide cash and investments was $24.7 billion, including $13.1 billion of cash, cash equivalents and short-term investments and $11.7 billion of long-term investments. Generally 80%-90% of cash and investments are held by foreign subsidiaries that would be subject to significant tax payments if such cash and investments were repatriated in the form of dividends. The Company records U.S. deferred tax liabilities for certain unremitted earnings, but when amounts earned overseas are expected to be indefinitely reinvested outside of the United States, no accrual for U.S. taxes is provided. The amount of cash and investments held by U.S. and foreign subsidiaries fluctuates due to a variety of factors including the timing and receipt of payments in the normal course of business. Cash provided by operating activities in the United States continues to be the Company's primary source of funds to finance domestic operating needs, capital expenditures, a portion of treasury stock purchases and dividends paid to shareholders.

Capital expenditures totaled $1.1 billion and $790 million for the first nine months of 2016 and 2015, respectively. Dividends paid to stockholders were $3.9 billion for both the first nine months of 2016 and 2015. In May 2016, the Board of Directors declared a quarterly dividend for the third quarter of $0.46 per share on the Company's common stock that was paid in July 2016. In July 2016, the Board of Directors declared a quarterly dividend for the fourth quarter of $0.46 per share on the Company's common stock that was paid in October 2016.

In March 2015, Merck's board of directors authorized additional purchases of up to $10 billion of Merck's common stock for its treasury. The treasury stock purchase has no time limit and will be made over time in open-market transactions, block transactions on or off an exchange, or in privately negotiated transactions. During the first nine months of 2016, the Company purchased $2.4 billion (44 million shares) for its treasury. As of September 30, 2016, the Company's remaining share repurchase authorization was $6.1 billion.

In November 2016, the Company issued €1.0 billion principal amount of senior unsecured notes consisting of €500 million principal amount of 0.50% notes due 2024 and €500 million principal amount of 1.375% notes due 2036. The Company intends to use the net proceeds of the offering of $1.1 billion for general corporate purposes, including without limitation the repayment of outstanding commercial paper borrowings and other indebtedness with upcoming maturities.

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

repaid.

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

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

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

Critical Accounting Policies

The Company's significant accounting policies, which include management's best estimates and judgments, are included in Note 2 to the consolidated financial statements for the year ended December 31, 2015 included in Merck's Form 10 K filed on February 26, 2016. Certain of these accounting policies are considered critical as disclosed in the Critical Accounting Policies section of Management's Discussion and Analysis of Financial Condition and Results of Operations included in Merck's Form 10-K because of the potential for a significant impact on the financial statements due to the inherent uncertainty in such estimates. There have been no significant changes in the Company's critical accounting policies since December 31, 2015.

Recently Issued Accounting Standards

In May 2014, the Financial Accounting Standards Board (FASB) issued amended accounting guidance on revenue recognition that will be applied to all contracts with customers. The objective of the new guidance is to improve comparability of revenue recognition practices across entities and to provide more useful information to users of financial statements through improved disclosure requirements. In August 2015, the FASB approved a one-year deferral of the effective date making this guidance effective for interim and annual periods beginning in 2018. Reporting entities may choose to adopt the standard as of the original effective date. The Company is currently assessing the impact of adoption on its consolidated financial statements.

In January 2016, the FASB issued revised guidance for the accounting and reporting of financial instruments. The new guidance requires that equity investments with readily determinable fair values currently classified as available-for-sale be measured at fair value with changes in fair value recognized in net income. The new guidance also simplifies the impairment testing of equity investments without readily determinable fair values and changes certain disclosure requirements. This guidance is effective for interim and annual periods beginning in 2018. Early adoption is not permitted. The Company is currently assessing the impact of adoption on its consolidated financial statements.

In February 2016, the FASB issued new accounting guidance for the accounting and reporting of leases. The new guidance requires that lessees recognize a right-of-use asset and a lease liability recorded on the balance sheet for each of its leases (other than leases that meet the definition of a short-term lease). Leases will be classified as either operating or finance. Operating leases will result in straight-line expense in the income statement (similar to current operating leases) while finance leases will result in more expense being recognized in the earlier years of the lease term (similar to current capital leases). The new guidance will be effective for interim and annual periods beginning in 2019. Early adoption is permitted. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

In June 2016, the FASB issued amended guidance on the accounting for credit losses on financial instruments within its scope. The guidance introduces an expected loss model for estimating credit losses, replacing the incurred loss model. The new guidance also changes the impairment model for available-for-sale debt securities, requiring the use of an allowance to record estimated credit losses (and subsequent recoveries). The new guidance is effective for interim and annual periods beginning in 2020, with earlier application permitted in 2019. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

In August 2016, the FASB issued guidance on the classification of certain cash receipts and payments in the statement of cash flows intended to reduce diversity in practice. The guidance is effective for interim and annual periods beginning in 2018. Early adoption is permitted. The guidance is to be applied retrospectively to all periods presented but may be applied prospectively if retrospective application would be impracticable. The Company is currently evaluating the effect of the standard on its Consolidated Statement of Cash Flows.

In October 2016, the FASB issued guidance on the accounting for the income tax consequences of intra-entity transfers of assets other than inventory. Under existing guidance, the recognition of current and deferred income taxes

for an intra-entity asset transfer is prohibited until the asset has been sold to a third party. The new guidance will require the recognition of the income tax consequences of an intra-entity transfer of an asset (with the exception of inventory) when the intra-entity transfer occurs. The guidance is effective for interim and annual periods beginning in 2018. Early adoption is permitted. The new guidance is to be applied on a modified retrospective basis through a cumulative-effect adjustment directly to retained earnings in the beginning of the period of adoption. The Company does not anticipate the adoption of the new guidance will have a material effect on its financial statements.

Item 4. Controls and Procedures

Management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures over financial reporting for the period covered by this Form 10–Q. Based on this assessment, the Company's Chief Executive Officer and Chief Financial Officer have concluded that as of September 30, 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 9 included in Part I, Item 1, Financial Statements (unaudited) — Notes to Condensed Consolidated Financial Statements.

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

Issuer purchases of equity securities for the three months ended September 30, 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]
July 1 - July 31	3,391,145	$58.56	$6,718
August 1 - August 31	5,007,108	$61.94	$6,408
September 1 - September 30	5,387,193	$62.55	$6,071
Total	13,785,446	$61.35	$6,071

(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 September 30, 2016, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Statement of Income, (ii) the Condensed Consolidated Statement of Comprehensive Income, (iii) the Condensed Consolidated Balance Sheet, (iv) the Condensed Consolidated Statement of Cash Flows, and (v) Notes to the Condensed Consolidated Financial Statements.

Signatures

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

MERCK & CO., INC.

Date: November 7, 2016 /s/ Michael J. Holston
MICHAEL J. HOLSTON
Executive Vice President and General Counsel

Date: November 7, 2016 /s/ Rita A. Karachun
RITA A. KARACHUN
Senior Vice President Finance - Global Controller

EXHIBIT INDEX

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