

Merck & Co., Inc.  
Form 10-Q  
November 05, 2015

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, 2015

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, 2015: 2,793,543,137  
Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(Do not check if a smaller reporting company)

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

## Part I - Financial Information

## Item 1. Financial Statements

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

## INTERIM CONSOLIDATED STATEMENT OF INCOME

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

	Three Months Ended		Nine Months Ended		
	September 30,		September 30,		
	2015	2014	2015	2014	
Sales	\$10,073	\$10,557	\$29,283	\$31,755	
Costs, Expenses and Other					
Materials and production	3,761	4,223	11,084	13,019	
Marketing and administrative	2,472	2,975	7,698	8,681	
Research and development	1,500	1,659	4,906	4,897	
Restructuring costs	113	376	386	664	
Other (income) expense, net	(170	) (166	) 624	(978	)
	7,676	9,067	24,698	26,283	
Income Before Taxes	2,397	1,490	4,585	5,472	
Income Tax Provision	566	648	1,108	865	
Net Income	1,831	842	3,477	4,607	
Less: Net Income (Loss) Attributable to Noncontrolling Interests	5	(53	) 12	3	
Net Income Attributable to Merck & Co., Inc.	\$1,826	\$895	\$3,465	\$4,604	
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	\$0.65	\$0.31	\$1.23	\$1.58	
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	\$0.64	\$0.31	\$1.22	\$1.57	
Dividends Declared per Common Share	\$0.45	\$0.44	\$1.35	\$1.32	

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

## INTERIM CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

(Unaudited, \$ in millions)

	Three Months Ended		Nine Months Ended		
	September 30,		September 30,		
	2015	2014	2015	2014	
Net Income Attributable to Merck & Co., Inc.	\$1,826	\$895	\$3,465	\$4,604	
Other Comprehensive Income (Loss) Net of Taxes:					
Net unrealized (loss) gain on derivatives, net of reclassifications	(118	) 254	(42	) 149	
Net unrealized (loss) gain on investments, net of reclassifications	(67	) (29	) (35	) 33	
Benefit plan net gain (loss) and prior service credit (cost), net of amortization	29	(463	) 106	(795	)
Cumulative translation adjustment	(85	) (316	) (279	) (188	)
	(241	) (554	) (250	) (801	)
Comprehensive Income Attributable to Merck & Co., Inc.	\$1,585	\$341	\$3,215	\$3,803	

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



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

	September 30, 2015	December 31, 2014
Assets		
Current Assets		
Cash and cash equivalents	\$7,548	\$7,441
Short-term investments	4,541	8,278
Accounts receivable (net of allowance for doubtful accounts of \$163 in 2015 and \$153 in 2014) (excludes accounts receivable of \$30 in 2015 and \$80 in 2014 classified in Other assets - see Note 4)	6,414	6,626
Inventories (excludes inventories of \$1,534 in 2015 and \$1,664 in 2014 classified in Other assets - see Note 5)	5,123	5,571
Deferred income taxes and other current assets	4,941	5,257
Total current assets	28,567	33,173
Investments	13,080	13,515
Property, Plant and Equipment, at cost, net of accumulated depreciation of \$16,043 in 2015 and \$18,004 in 2014	12,482	13,136
Goodwill	17,761	12,992
Other Intangibles, Net	23,724	20,386
Other Assets	5,618	5,133
	\$101,232	\$98,335
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	\$2,543	\$2,704
Trade accounts payable	2,023	2,625
Accrued and other current liabilities	9,610	10,523
Income taxes payable	2,119	1,606
Dividends payable	1,288	1,308
Total current liabilities	17,583	18,766
Long-Term Debt	24,124	18,699
Deferred Income Taxes	5,959	4,266
Other Noncurrent Liabilities	7,887	7,813
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 2015 and 2014		
Other paid-in capital	40,139	40,423
Retained earnings	45,660	46,021
Accumulated other comprehensive loss	(4,573)	(4,323)
	83,014	83,909
Less treasury stock, at cost:		
774,869,058 shares in 2015 and 738,963,326 shares in 2014	37,427	35,262
Total Merck & Co., Inc. stockholders' equity	45,587	48,647
Noncontrolling Interests	92	144
Total equity	45,679	48,791

\$101,232      \$98,335

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

- 3 -

---

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

	Nine Months Ended September 30,	
	2015	2014
Cash Flows from Operating Activities		
Net income	\$3,477	\$4,607
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	4,815	5,118
Intangible asset impairment charges	80	1,209
Foreign currency devaluation related to Venezuela	715	—
Gain on AstraZeneca option exercise	—	(741)
Equity income from affiliates	(210)	(241)
Dividends and distributions from equity affiliates	12	132
Deferred income taxes	(846)	(1,773)
Share-based compensation	221	209
Other	697	(446)
Net changes in assets and liabilities	(787)	950
Net Cash Provided by Operating Activities	8,174	9,024
Cash Flows from Investing Activities		
Capital expenditures	(790)	(827)
Purchases of securities and other investments	(12,425)	(16,231)
Proceeds from sales of securities and other investments	16,531	11,807
Acquisition of Cubist Pharmaceuticals, Inc., net of cash acquired	(7,598)	—
Acquisition of Idenix Pharmaceuticals, Inc., net of cash acquired	—	(3,700)
Acquisitions of other businesses, net of cash acquired	(110)	—
Dispositions of businesses, net of cash divested	151	1,048
Proceeds from AstraZeneca option exercise	—	419
Other	100	(94)
Net Cash Used in Investing Activities	(4,141)	(7,578)
Cash Flows from Financing Activities		
Net change in short-term borrowings	(1,526)	3,077
Proceeds from issuance of debt	7,938	1
Payments on debt	(2,905)	(7)
Purchases of treasury stock	(3,005)	(6,083)
Dividends paid to stockholders	(3,854)	(3,911)
Proceeds from exercise of stock options	434	1,381
Other	55	72
Net Cash Used in Financing Activities	(2,863)	(5,470)
Effect of Exchange Rate Changes on Cash and Cash Equivalents	(1,063)	(227)
Net Increase (Decrease) in Cash and Cash Equivalents	107	(4,251)
Cash and Cash Equivalents at Beginning of Year	7,441	15,621
Cash and Cash Equivalents at End of Period	\$7,548	\$11,370

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



Notes to Interim Consolidated Financial Statements (unaudited)

1. Basis of Presentation

The accompanying unaudited interim 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 27, 2015.

On January 21, 2015, the Company acquired Cubist Pharmaceuticals, Inc. (Cubist) and, on July 31, 2015, Merck acquired cCAM Biotherapeutics Ltd. (cCAM). The results of Cubist's and cCAM's businesses have been included in Merck's financial statements subsequent to their respective acquisition dates.

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 presentation 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 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 annual and interim 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.

2. Restructuring

2013 Restructuring Program

In 2013, the Company initiated actions under a global restructuring program (2013 Restructuring Program) as part of a global initiative to sharpen its commercial and research and development focus. As part of the program, the Company expects to reduce its total workforce by approximately 8,500 positions. These workforce reductions will primarily come from the elimination of positions in sales, administrative and headquarters organizations, as well as research and development. The Company will also reduce its global real estate footprint and continue to improve the efficiency of its manufacturing and supply network. The Company will continue to hire employees in strategic growth areas of the business as necessary.

The Company recorded total pretax costs of \$102 million and \$437 million in the third quarter of 2015 and 2014, respectively, and \$318 million and \$826 million in the first nine months of 2015 and 2014, respectively, related to this restructuring program. Since inception of the 2013 Restructuring Program through September 30, 2015, Merck has recorded total pretax accumulated costs of approximately \$2.8 billion and eliminated approximately 7,715 positions comprised of employee separations, as well as the elimination of contractors and vacant positions. The actions under the 2013 Restructuring Program are expected to be substantially completed by the end of 2015 with the cumulative pretax costs estimated to be approximately \$3.0 billion. 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.

Merger Restructuring Program

In 2010, subsequent to the Merck and Schering-Plough Corporation (Schering-Plough) merger (Merger), the Company commenced actions under a global restructuring program (Merger Restructuring Program) designed to streamline the cost structure of the combined company. Further actions under this program were initiated in 2011. The actions under this program primarily reflect the elimination of positions in sales, administrative and headquarters organizations, as well as from the sale or closure of certain manufacturing and research and development sites and the consolidation of office facilities.

The Company recorded total pretax costs of \$115 million and \$175 million in the third quarter of 2015 and 2014, respectively, and \$452 million and \$533 million in the first nine months of 2015 and 2014, respectively, related to this



restructuring program. Since inception of the Merger Restructuring Program through September 30, 2015, Merck has recorded total pretax accumulated costs of approximately \$8.3 billion and eliminated approximately 29,420 positions comprised of employee separations, as well as the elimination of contractors and vacant positions. Approximately 2,050 position eliminations remain pending under this program as of September 30, 2015. The non-manufacturing related restructuring actions under the Merger Restructuring Program were substantially completed by the end of 2013. The remaining actions under this program primarily relate to ongoing manufacturing facility rationalizations, which are expected to be substantially completed by the end of 2016. The Company expects the estimated total cumulative pretax costs for this program to be approximately \$8.5 billion. The Company estimates that approximately two-thirds of the cumulative pretax costs relate to cash outlays, primarily related to employee separation expense.

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

Approximately one-third of the cumulative pretax costs are non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested.

For segment reporting, restructuring charges are unallocated expenses.

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

(\$ in millions)	Three Months Ended September 30, 2015				Nine Months Ended September 30, 2015			
	Separation Costs	Accelerated Depreciation	Other	Total	Separation Costs	Accelerated Depreciation	Other	Total
<b>2013 Restructuring Program</b>								
Materials and production	\$—	\$ 13	\$(12 )	\$ 1	\$—	\$ 27	\$ 2	\$ 29
Marketing and administrative	—	2	12	14	—	46	17	63
Research and development	—	8	8	16	—	24	9	33
Restructuring costs	36	—	35	71	105	—	88	193
	36	23	43	102	105	97	116	318
<b>Merger Restructuring Program</b>								
Materials and production	—	4	65	69	—	20	231	251
Marketing and administrative	—	3	—	3	—	7	—	7
Research and development	—	1	—	1	—	1	—	1
Restructuring costs	(24 )	—	66	42	(5 )	—	198	193
	(24 )	8	131	115	(5 )	28	429	452
	\$ 12	\$ 31	\$ 174	\$ 217	\$ 100	\$ 125	\$ 545	\$ 770
(\$ in millions)	Three Months Ended September 30, 2014				Nine Months Ended September 30, 2014			
	Separation Costs	Accelerated Depreciation	Other	Total	Separation Costs	Accelerated Depreciation	Other	Total
<b>2013 Restructuring Program</b>								
Materials and production	\$—	\$ 5	\$—	\$ 5	\$—	\$ 189	\$ 17	\$ 206
Marketing and administrative	—	45	—	45	—	92	—	92
Research and development	—	75	6	81	—	160	14	174
Restructuring costs	310	—	(4 )	306	387	—	(33 )	354
	310	125	2	437	387	441	(2 )	826
<b>Merger Restructuring Program</b>								
Materials and production	—	67	15	82	—	219	(48 )	171
Marketing and administrative	—	29	(6 )	23	—	54	(3 )	51
Research and development	—	—	—	—	—	—	1	1

Edgar Filing: Merck & Co., Inc. - Form 10-Q

Restructuring costs	5	—	65	70	104	—	206	310
	5	96	74	175	104	273	156	533
	\$315	\$ 221	\$76	\$612	\$491	\$ 714	\$154	\$1,359

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 2015 and 2014, approximately 425 positions and 830 positions, respectively, and in the first nine months of 2015 and 2014, approximately 1,620 positions and 3,425 positions, respectively, were eliminated under the 2013 Restructuring Program. In the third quarter of 2015 and 2014, approximately 260 positions and 185 positions, respectively, and in the first nine months of 2015 and 2014, approximately 1,015 positions and 975 positions, respectively, were eliminated under the Merger Restructuring Program. These position eliminations were comprised of actual headcount reductions and the elimination of contractors and vacant positions.

Accelerated depreciation costs primarily relate to manufacturing, research and administrative facilities and equipment to be sold or closed as part of the programs. Accelerated depreciation costs represent the difference between the depreciation expense to be recognized over the revised useful life of the site, based upon the anticipated date the site will be closed or divested, and depreciation expense as determined utilizing the useful life prior to the restructuring actions. All of the sites have and will continue to operate up through the respective closure dates and, since future undiscounted cash flows were sufficient to recover the respective book values, Merck was required to accelerate depreciation of the site assets rather than record an impairment charge. 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.

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

Other activity in 2015 and 2014 includes pretax gains and losses resulting from sales of facilities and related assets, as well as asset abandonment, shut-down and other related costs. Additionally, other activity includes certain employee-related costs associated with pension and other postretirement benefit plans (see Note 12) and share-based compensation.

The following table summarizes the charges and spending relating to restructuring activities by program for the nine months ended September 30, 2015:

(\$ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
<b>2013 Restructuring Program</b>				
Restructuring reserves January 1, 2015	\$495	\$—	\$14	\$509
Expense	105	97	116	318
(Payments) receipts, net	(308)	) —	(127)	) (435)
Non-cash activity	—	(97)	) 1	) (96)
Restructuring reserves September 30, 2015 <sup>(1)</sup>	\$292	\$—	\$4	\$296
<b>Merger Restructuring Program</b>				
Restructuring reserves January 1, 2015	\$536	\$—	\$6	\$542
Expense	(5)	) 28	429	452
(Payments) receipts, net	(224)	) —	(163)	) (387)
Non-cash activity	—	(28)	) (216)	) (244)
Restructuring reserves September 30, 2015 <sup>(1)</sup>	\$307	\$—	\$56	\$363

The cash outlays associated with the 2013 Restructuring Program are expected to be substantially completed by the end of 2015. The non-manufacturing cash outlays associated with the Merger Restructuring Program were substantially completed by the end of 2013; the remaining cash outlays are expected to be substantially completed by the end of 2016.

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

The Company continues its strategy of establishing external alliances to complement its substantial 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.

#### Acquisition of Cubist Pharmaceuticals, Inc.

In January 2015, Merck acquired Cubist, a leader in the development of therapies to treat serious infections caused by a broad range of bacteria. The acquisition complements Merck's existing hospital acute care business, which is a priority area for the Company. Total consideration transferred of \$8.3 billion includes 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. Share-based compensation payments to settle non-vested equity awards attributable to postcombination service were recognized as transaction expense in 2015. 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. The transaction was accounted for as an acquisition of a business; accordingly, the assets acquired and liabilities assumed were recorded at their respective fair values as of the acquisition date.

A preliminary allocation of the fair value of assets acquired and liabilities assumed from Cubist was made as of the acquisition date. The Company subsequently adjusted the preliminary values assigned to certain assets and liabilities in order to reflect additional information obtained since the preliminary allocation that pertained to facts and circumstances that existed as of the acquisition date. These measurement period adjustments have been reflected in the

opening balance sheet; however, since the adjustments did not have a significant impact on the Company's consolidated statements of income or cash flows in any period, the interim financial statements were not retrospectively adjusted. The revised allocation is as follows:

- 7 -

---

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

(\$ 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	
In-process research and development (IPR&D)	50	
Other noncurrent assets	184	
Current liabilities <sup>(1)</sup>	(233	)
Deferred income tax liabilities	(2,518	)
Long-term debt	(1,900	)
Other noncurrent liabilities <sup>(1)</sup>	(122	)
Total identifiable net assets	3,662	
Goodwill <sup>(2)</sup>	4,669	
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 Company’s estimates of projected net cash flows considered historical and projected pricing, margins and expense levels; the performance of competing products where applicable; relevant industry and therapeutic area growth drivers and factors; current and expected trends in technology and product life cycles; the extent and timing of potential new product introductions by the Company’s competitors; and the life of each asset’s underlying patent. The net cash flows were then probability-adjusted where appropriate to consider the uncertainties associated with the underlying assumptions, as well as the risk profile of the net cash flows utilized in the valuation. 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. The most significant intangible assets relate to Zerbaxa (ceftolozane and tazobactam), Cubicin (daptomycin for injection) and Sivextro (tedizolid phosphate).

The Company recorded the fair value of incomplete research project surotomycin (MK-4261) which, at the time of acquisition, had not reached technological feasibility and had no alternative future use. The amount was capitalized and accounted for as an indefinite-lived intangible asset, subject to impairment testing until completion or abandonment of the project. The fair value of surotomycin was determined by using an income approach, through which fair value is estimated based on 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 9%. 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 an IPR&D impairment charge (see Note 6). In connection with the Cubist acquisition, liabilities were recorded for the potential for 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.

This transaction closed on January 21, 2015; accordingly, the results of operations of the acquired business have been included in the Company's results of operations beginning after that date. Cubist contributed sales of \$362 million and \$899 million in the third quarter and first nine months of 2015, respectively, to Merck's results. The Company is no longer able to provide the results of operations attributable to Cubist during the period as the operations of Cubist have been largely integrated. During the first nine months of 2015, the Company incurred \$324 million of transaction costs directly related to the acquisition of Cubist including share-based compensation costs, severance costs and legal and advisory fees which are reflected in Marketing and administrative expenses.

- 8 -

---

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

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

(\$ in millions)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Sales	\$10,073	\$10,866	\$29,369	\$32,620
Net income attributable to Merck & Co., Inc.	1,833	703	3,645	3,789
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	0.65	0.24	1.29	1.30
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	0.65	0.24	1.28	1.29

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.

## Other transactions

In July 2015, Merck acquired cCAM, a privately held biopharmaceutical company focused on the discovery and development of novel cancer immunotherapies. The acquisition provides Merck with cCAM's lead pipeline candidate, CM-24, a novel monoclonal antibody targeting the immune checkpoint protein CEACAM1 that is currently being evaluated in a Phase 1 study for the treatment of advanced or recurrent malignancies, including melanoma, non-small-cell lung, bladder, gastric, colorectal, and ovarian cancers. 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, which the Company determined had a fair value of \$105 million at the acquisition date. The transaction was accounted for as an acquisition of a business; accordingly, the assets acquired and liabilities assumed were recorded at their respective fair values as of the acquisition date. The determination of fair value requires management to make significant estimates and assumptions. 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, through which fair value is estimated based upon the asset's probability-adjusted future net cash flows, which reflects the stage of development of the project and the associated probability of successful completion. The net cash flows were then discounted to present value using a discount rate of 10.5%. The fair value of the contingent consideration was determined utilizing a probability weighted estimated cash flow stream adjusted for the expected timing of each payment also utilizing a discount rate of 10.5%. Actual cash flows are likely to be different than those assumed. This transaction closed on July 31, 2015; accordingly, the results of operations of the acquired business have been included in the Company's results of operations beginning after that date. Pro forma financial information has not been included because 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, \$125 million of which was paid in August 2015 upon closing of the transaction and \$125 million of which is payable in April of 2016. Merck will additionally be entitled to receive potential development and commercial milestone payments and tiered double-digit royalties based on commercialization of the programs. Allergan will be fully responsible for development of the CGRP programs, as well as manufacturing and commercialization upon approval and launch of the products. The Company recorded a gain of \$250 million within Other (income) expense, net in the



third quarter and first nine months of 2015 related to the transaction.

In February 2015, Merck and NGM Biopharmaceuticals, Inc. (NGM), a privately held biotechnology company, entered into a multi-year collaboration to research, discover, develop and commercialize novel biologic therapies across a wide range of therapeutic areas. The collaboration includes multiple drug candidates currently in preclinical development at NGM, including NP201, which is being evaluated for the treatment of diabetes, obesity and nonalcoholic steatohepatitis. NGM will lead the research and development of the existing preclinical candidates and have the autonomy to identify and pursue other discovery stage programs at its discretion. Merck will have the option to license all resulting NGM programs following human proof of concept trials. If Merck exercises this option, Merck will lead global product development and commercialization for the resulting products, if approved. Under the terms of the agreement, Merck made an upfront payment to NGM of \$94 million, which is included in Research and development expenses, and purchased a 15% equity stake in NGM for \$106 million. Merck committed up to \$250

- 9 -

---

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

million to fund all of NGM's efforts under the initial five-year term of the collaboration, with the potential for additional funding if certain conditions are met. Prior to Merck initiating a Phase 3 study for a licensed program, NGM may elect to either receive milestone and royalty payments or, in certain cases, to co-fund development and participate in a global cost and revenue share arrangement of up to 50%. The agreement also provides NGM with the option to participate in the co-promotion of any co-funded program in the United States. Merck will have the option to extend the research agreement for two additional two-year terms. Each party has certain termination rights under the agreement in the event of an uncured material breach by the other party. Additionally, Merck has certain termination rights in the event of the occurrence of certain defined conditions. Upon a termination event, depending on the circumstances, the parties have varying rights and obligations with respect to the continued development and commercialization of compounds discovered under the agreement and certain related payment obligations. In August 2014, Merck completed the acquisition of Idenix Pharmaceuticals, Inc. (Idenix) for approximately \$3.9 billion in cash (\$3.7 billion net of cash acquired). Idenix was a biopharmaceutical company engaged in the discovery and development of medicines for the treatment of human viral diseases, whose primary focus was on the development of next-generation oral antiviral therapeutics to treat hepatitis C virus (HCV) infection. The transaction was accounted for as an acquisition of a business; accordingly, the assets acquired and liabilities assumed were recorded at their respective fair values as of the acquisition date. The determination of fair value requires management to make significant estimates and assumptions. Merck recognized an intangible asset for IPR&D of \$3.2 billion related to MK-3682 (formerly IDX21437), net deferred tax liabilities of \$951 million and other net liabilities of approximately \$12 million. MK-3682 is a nucleotide prodrug in Phase 2 clinical development being evaluated for potential inclusion in the development of all oral, pan-genotypic fixed-dose combination regimens. The excess of the consideration transferred over the fair value of net assets acquired of \$1.5 billion 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 11.5%. Actual cash flows are likely to be different than those assumed. This transaction closed on August 5, 2014; accordingly, the results of operations of the acquired business have been included in the Company's results of operations beginning after that date. Pro forma financial information has not been included because Idenix's historical financial results are not significant when compared with the Company's financial results. In May 2014, Merck entered into an agreement to sell certain ophthalmic products to Santen Pharmaceutical Co., Ltd. (Santen) in Japan and markets in Europe and Asia Pacific. The agreement provided that Santen make upfront payments and additional payments based on defined sales milestones. Santen will also purchase supply of ophthalmology products covered by the agreement for a two- to five-year period. Upon closing of the transaction in most markets on July 1, 2014, the Company received \$515 million of upfront payments from Santen, net of certain adjustments, and an additional \$50 million upon closing of the remaining markets on October 1, 2014. Merck recognized gains of \$396 million and \$84 million on the transaction in the third and fourth quarters of 2014, respectively, included in Other (income) expense, net.

In March 2014, Merck divested its Sirna Therapeutics, Inc. (Sirna) subsidiary to Alnylam Pharmaceuticals, Inc. (Alnylam) for consideration of \$25 million and 2,520,044 shares of Alnylam common stock. Merck is eligible to receive future payments associated with the achievement of certain regulatory and commercial milestones, as well as royalties on future sales. Under the terms of the agreement, Merck received 85% of the Alnylam shares in the first quarter of 2014 (valued at \$172 million at the time of closing) and the remaining 15% of the shares in the second quarter of 2014 (valued at \$22 million at the time the shares were received). Merck recorded a gain of \$204 million in Other (income) expense, net in the first nine months of 2014 related to this transaction. The excess of Merck's tax basis in its investment in Sirna over the value received resulted in an approximate \$300 million tax benefit recorded in the first nine months of 2014.

In January 2014, Merck sold the U.S. marketing rights to Saphris (asenapine), an antipsychotic indicated for the treatment of schizophrenia and bipolar I disorder in adults to Forest Laboratories, Inc. (Forest). Under the terms of the agreement, Forest made upfront payments of \$232 million, which were recorded in Sales in the first nine months of

2014, and will make additional payments to Merck based on defined sales milestones. In addition, as part of this transaction, Merck agreed to supply product to Forest (subsequently acquired by Allergan) until patent expiry.

**Remicade/Simponi**

In 1998, a subsidiary of Schering-Plough entered into a licensing agreement with Centocor Ortho Biotech Inc. (Centocor), a Johnson & Johnson (J&J) company, to market Remicade (infliximab), which is prescribed for the treatment of inflammatory diseases. In 2005, Schering-Plough's subsidiary exercised an option under its contract with Centocor for license rights to develop and commercialize Simponi (golimumab), a fully human monoclonal antibody. The Company has marketing rights to both products throughout Europe, Russia and Turkey. In December 2007, Schering-Plough and Centocor revised their distribution agreement regarding the development, commercialization and distribution of both Remicade and Simponi, extending the Company's rights to exclusively market Remicade to match the duration of the Company's exclusive marketing rights for Simponi. In addition, Schering-Plough and Centocor agreed to share certain development costs relating to Simponi's auto-injector

- 10 -

---

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

delivery system. On October 6, 2009, the European Commission approved Simponi as a treatment for rheumatoid arthritis and other immune system disorders in two presentations – a novel auto-injector and a prefilled syringe. As a result, the Company's marketing rights for both products extend for 15 years from the first commercial sale of Simponi in the European Union (EU) following the receipt of pricing and reimbursement approval within the EU. Remicade lost market exclusivity in major European markets in February 2015 and no longer has market exclusivity in any of its marketing territories. The Company continues to have market exclusivity for Simponi in all of its marketing territories. All profits derived from Merck's exclusive distribution of the two products in these countries are equally divided between Merck and J&J.

#### 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 potential for longer-term unfavorable changes in foreign exchange rates to decrease the U.S. dollar value of future cash flows derived from foreign currency denominated sales, primarily the euro and Japanese yen. To achieve this objective, the Company will hedge a portion of its forecasted foreign currency denominated third-party and intercompany distributor entity sales that are expected to occur over its planning cycle, typically no more than three years into the future. The Company will layer in hedges over time, increasing the portion of third-party and intercompany distributor entity sales hedged as it gets closer to the expected date of the forecasted foreign currency denominated sales. The portion of sales hedged is based on assessments of cost-benefit profiles that consider natural offsetting exposures, revenue and exchange rate volatilities and correlations, and the cost of hedging instruments. The hedged anticipated sales are a specified component of a portfolio of similarly denominated foreign currency-based sales transactions, each of which responds to the hedged currency risk in the same manner. The Company manages its anticipated transaction exposure principally with purchased local currency put options, which provide the Company with a right, but not an obligation, to sell foreign currencies in the future at a predetermined price. If the U.S. dollar strengthens relative to the currency of the hedged anticipated sales, total changes in the options' cash flows offset the decline in the expected future U.S. dollar equivalent cash flows of the hedged foreign currency sales. Conversely, if the U.S. dollar weakens, the options' value reduces to zero, but the Company benefits from the increase in the U.S. dollar equivalent value of the anticipated foreign currency cash flows.

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

The Company may also utilize forward contracts in its revenue hedging program. If the U.S. dollar strengthens relative to the currency of the hedged anticipated sales, the increase in the fair value of the forward contracts offsets

the decrease in the expected future U.S. dollar cash flows of the hedged foreign currency sales. Conversely, if the U.S. dollar weakens, the decrease in the fair value of the forward contracts offsets the increase in the value of the anticipated foreign currency cash flows.

The fair values of these derivative contracts are recorded as either assets (gain positions) or liabilities (loss positions) in the 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

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

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 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 foreign currency denominated net monetary assets of foreign subsidiaries where the U.S. dollar is the 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. 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 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 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 gains of \$255 million and \$166 million for the first nine months of 2015 and 2014, respectively, from the euro-denominated notes.

#### Interest Rate Risk Management

The Company may use interest rate swap contracts on certain investing and borrowing transactions to manage its net exposure to interest rate changes and to reduce its overall cost of borrowing. The Company does not use leveraged swaps and, in general, does not leverage any of its investment activities that would put principal capital at risk. At September 30, 2015, the Company was a party to 30 pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes as detailed in the table below.

Debt Instrument	September 30, 2015		
	Par Value of Debt	Number of Interest Rate Swaps Held	Total Swap Notional Amount
0.70% notes due 2016	\$ 1,000	4	\$ 1,000
1.30% notes due 2018	1,000	4	1,000

Edgar Filing: Merck & Co., Inc. - Form 10-Q

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

- 12 -

---

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

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 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 Consolidated Statement of Cash Flows.

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

(\$ in millions)	Balance Sheet Caption	September 30, 2015			December 31, 2014		
		Fair Value of Derivative		U.S. Dollar	Fair Value of Derivative		U.S. Dollar
		Asset	Liability	Notional	Asset	Liability	Notional
<b>Derivatives Designated as Hedging Instruments</b>							
Interest rate swap contracts (current)	Deferred income taxes and other current assets	\$1	\$—	\$ 1,000	\$—	\$—	\$ —
Interest rate swap contracts (non-current)	Other assets	101	—	6,200	19	—	1,950
Interest rate swap contracts (non-current)	Other noncurrent liabilities	—	—	—	—	15	2,000
Foreign exchange contracts (current)	Deferred income taxes and other current assets	710	—	4,876	772	—	5,513
Foreign exchange contracts (non-current)	Other assets	491	—	4,854	691	—	6,253
Foreign exchange contracts (current)	Accrued and other current liabilities	—	1	34	—	—	—
		\$1,303	\$1	\$ 16,964	\$1,482	\$15	\$ 15,716
<b>Derivatives Not Designated as Hedging Instruments</b>							
Foreign exchange contracts (current)	Deferred income taxes and other current assets	\$154	\$—	\$ 4,615	\$365	\$—	\$ 6,966
Foreign exchange contracts (non-current)	Other assets	18	—	179	—	—	—
Foreign exchange contracts (current)	Accrued and other current liabilities	—	55	4,192	—	88	3,386
		\$172	\$55	\$ 8,986	\$365	\$88	\$ 10,352
		\$1,475	\$56	\$ 25,950	\$1,847	\$103	\$ 26,068

As noted above, the Company records its derivatives on a gross basis in the Consolidated Balance Sheet. The Company has master netting agreements with several of its financial institution counterparties (see Concentrations of Credit Risk below). The following table provides information on the Company's derivative positions subject to these master netting arrangements as if they were presented on a net basis, allowing for the right of offset by counterparty and cash collateral exchanged per the master agreements and related credit support annexes:

(\$ in millions)	September 30, 2015		December 31, 2014	
	Asset	Liability	Asset	Liability
Gross amounts recognized in the consolidated balance sheet	\$1,475	\$56	\$1,847	\$103
Gross amount subject to offset in master netting arrangements not offset in the consolidated	(31 )	(31 )	(97 )	(97 )



Edgar Filing: Merck & Co., Inc. - Form 10-Q

balance sheet

Cash collateral (received) posted

Net amounts

(1,054 )	—	(1,410 )	—
\$390	\$25	\$340	\$6

- 13 -

---

## Notes to Interim 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:

(\$ in millions)	Three Months Ended		Nine Months Ended	
	September 30, 2015	September 30, 2014	September 30, 2015	September 30, 2014
Derivatives designated in a fair value hedging relationship				
Interest rate swap contracts				
Amount of (gain) loss recognized in Other (income) expense, net on derivatives <sup>(1)</sup>	\$(130 )	\$23	\$(97 )	\$2
Amount of loss (gain) recognized in Other (income) expense, net on hedged item <sup>(1)</sup>	125	(23 )	91	(3 )
Derivatives designated in foreign currency cash flow hedging relationships				
Foreign exchange contracts				
Amount of gain reclassified from AOCI to Sales	(170 )	(42 )	(528 )	(45 )
Amount of loss (gain) recognized in OCI on derivatives	17	(433 )	(464 )	(276 )
Derivatives designated in foreign currency net investment hedging relationships				
Foreign exchange contracts				
Amount of gain recognized in Other (income) expense, net on derivatives <sup>(2)</sup>	(1 )	(1 )	(4 )	(3 )
Amount of loss (gain) recognized in OCI on derivatives	13	(116 )	(5 )	(67 )
Derivatives not designated in a hedging relationship				
Foreign exchange contracts				
Amount of gain recognized in Other (income) expense, net on derivatives <sup>(3)</sup>	(155 )	(290 )	(360 )	(314 )
Amount of loss (gain) recognized in Sales	—	5	(1 )	5

<sup>(1)</sup> There was \$5 million and \$6 million of ineffectiveness on the hedge during the third quarter and first nine months of 2015, respectively.

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

<sup>(3)</sup> These derivative contracts mitigate changes in the value of remeasured foreign currency denominated monetary assets and liabilities attributable to changes in foreign currency exchange rates.

At September 30, 2015, the Company estimates \$497 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.

## Investments in Debt and Equity Securities

Information on available-for-sale investments is as follows:

(\$ in millions)	September 30, 2015				December 31, 2014			
	Fair Value	Amortized Cost	Gross Gains	Unrealized Losses	Fair Value	Amortized Cost	Gross Gains	Unrealized Losses
Corporate notes and bonds	\$10,806	\$10,805	\$30	\$(29 )	\$10,107	\$10,102	\$22	\$(17 )
Commercial paper	2,448	2,448	—	—	6,970	6,970	—	—
Asset-backed securities	1,384	1,383	2	(1 )	1,460	1,462	1	(3 )
U.S. government and agency securities	1,272	1,268	4	—	1,774	1,775	1	(2 )

Edgar Filing: Merck & Co., Inc. - Form 10-Q

Mortgage-backed securities	737	734	4	(1 )	602	604	2	(4 )
Foreign government bonds	638	636	2	—	385	385	—	—
Equity securities	528	428	100	—	730	557	173	—
	\$17,813	\$ 17,702	\$142	\$(31 )	\$22,028	\$ 21,855	\$199	\$(26 )

Available-for-sale debt securities included in Short-term investments totaled \$4.5 billion at September 30, 2015. Of the remaining debt securities, \$11.8 billion mature within five years. At September 30, 2015 and December 31, 2014, 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:

Edgar Filing: Merck & Co., Inc. - Form 10-Q

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

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

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

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

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

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

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

(\$ in millions)	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
	September 30, 2015				December 31, 2014			
<b>Assets</b>								
<b>Investments</b>								
Corporate notes and bonds	\$—	\$ 10,806	\$ —	\$10,806	\$—	\$ 10,107	\$ —	\$10,107
Commercial paper	—	2,448	—	2,448	—	6,970	—	6,970
Asset-backed securities <sup>(1)</sup>	—	1,384	—	1,384	—	1,460	—	1,460
U.S. government and agency securities	—	1,272	—	1,272	—	1,774	—	1,774
Mortgage-backed securities <sup>(1)</sup>	—	737	—	737	—	602	—	602
Foreign government bonds	—	638	—	638	—	385	—	385
Equity securities	336	—	—	336	495	—	—	495
	336	17,285	—	17,621	495	21,298	—	21,793
<b>Other assets</b>								
Securities held for employee compensation	174	18	—	192	181	54	—	235
<b>Derivative assets <sup>(2)</sup></b>								
Purchased currency options	—	1,161	—	1,161	—	1,252	—	1,252
Forward exchange contracts	—	212	—	212	—	576	—	576
Interest rate swaps	—	102	—	102	—	19	—	19
	—	1,475	—	1,475	—	1,847	—	1,847
<b>Total assets</b>	<b>\$510</b>	<b>\$ 18,778</b>	<b>\$ —</b>	<b>\$19,288</b>	<b>\$676</b>	<b>\$ 23,199</b>	<b>\$ —</b>	<b>\$23,875</b>
<b>Liabilities</b>								
<b>Other liabilities</b>								
	\$—	\$ —	\$ 614	\$614	\$—	\$ —	\$ 428	\$428

Contingent  
consideration

## Derivative liabilities

(2)

Forward exchange contracts	—	56	—	56	—	46	—	46
Written currency options	—	—	—	—	—	42	—	42
Interest rate swaps	—	—	—	—	—	15	—	15
	—	56	—	56	—	103	—	103
Total liabilities	\$—	\$ 56	\$ 614	\$670	\$—	\$ 103	\$ 428	\$531

Primarily all of the asset-backed securities are highly-rated (Standard & Poor's rating of AAA and Moody's

(1) Investors Service rating of Aaa), secured primarily by credit card, auto loan, and home equity receivables, with weighted-average lives of primarily 5 years or less. Mortgage-backed securities represent AAA-rated securities issued or unconditionally guaranteed as to payment of principal and interest by U.S. government agencies.

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

There were no transfers between Level 1 and Level 2 during the first nine months of 2015. As of September 30, 2015, Cash and cash equivalents of \$7.5 billion included \$6.5 billion of cash equivalents (considered Level 2 in the fair value hierarchy).

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

## Contingent Consideration

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

(\$ in millions)	Nine Months Ended September 30,	
	2015	2014
Fair value January 1	\$428	\$69
Changes in fair value <sup>(1)</sup>	8	6
Additions	228	—
Payments	(50	) —
Fair value September 30	\$614	\$75

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

In the first nine months of 2015, the Company recognized liabilities for contingent consideration of \$123 million related to the acquisition of Cubist and \$105 million related to the acquisition of cCAM (see Note 3). In addition, in the first nine months of 2015, the Company paid \$50 million of contingent consideration related 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, 2015, was \$27.2 billion compared with a carrying value of \$26.7 billion and at December 31, 2014, was \$22.5 billion compared with a carrying value of \$21.4 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, 2015 and December 31, 2014, Other assets included \$30 million and \$80 million, respectively, of accounts receivable not expected to be collected within one year. At September 30, 2015, the Company's total net accounts receivable outstanding for more than one year were approximately \$130 million. The Company does not expect to have write-offs or adjustments to accounts receivable which would have a material adverse effect on its financial position, liquidity or results of operations.

Additionally, the Company continues to expand in the emerging markets. Payment terms in these markets tend to be longer, resulting in an increase in accounts receivable balances in certain of these markets.

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, 2015 and December 31, 2014, the Company had received cash collateral of \$1.1 billion and \$1.4 billion, 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, 2015 or December 31, 2014.



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

## 5. Inventories

Inventories consisted of:

(\$ in millions)	September 30, 2015	December 31, 2014
Finished goods	\$1,528	\$1,588
Raw materials and work in process	4,586	5,141
Supplies	177	197
Total (approximates current cost)	6,291	6,926
Increase to LIFO costs	366	309
	\$6,657	\$7,235

Recognized as:

Inventories	\$5,123	\$5,571
Other assets	1,534	1,664

Amounts recognized as Other assets are comprised almost entirely of raw materials and work in process inventories. At September 30, 2015 and December 31, 2014, these amounts included \$1.5 billion and \$1.6 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included \$67 million and \$74 million at September 30, 2015 and December 31, 2014, respectively, of inventories produced in preparation for product launches.

## 6. Goodwill and 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. As a result of the acquisition of Cubist in January 2015, the Company recorded \$6.9 billion of intangible assets for currently marketed products, \$50 million of IPR&D (related to surotomycin) and \$4.7 billion of goodwill (see Note 3). In addition, as a result of the acquisition of cCAM in July 2015, the Company recorded \$180 million of IPR&D (see Note 3).

During the first nine months of 2015, the Company recorded \$62 million of IPR&D impairment charges within Research and development expenses. Of this amount, \$50 million relates to the surotomycin clinical development program obtained in connection with the acquisition of Cubist. During the second quarter of 2015, the Company received unfavorable efficacy data from a clinical trial for surotomycin. The evaluation of this data, combined with an assessment of the commercial opportunity of surotomycin, resulted in the IPR&D impairment charge noted above. During the third quarter and first nine months of 2014, the Company recorded \$36 million of IPR&D impairment charges primarily as a result of changes in cash flow assumptions for certain compounds obtained in connection with the Supera joint venture. The changes in cash flow assumptions for the Supera compounds, as well as for certain currently marketed products of Supera, also resulted in the write-off of the goodwill balance related to the joint venture with Supera, which was \$93 million at existing exchange rates.

Also, during the first nine months of 2015, the Company recorded an intangible asset impairment charge of \$12 million within Materials and production costs related to Rebetol (ribavirin USP), a product marketed by the Company for the treatment of chronic HCV infection. Sales of Rebetol are being adversely affected by loss of market share as a result of the availability of newer therapeutic options, which led to changes in the cash flow assumptions for Rebetol that indicated that the Rebetol intangible asset value was not recoverable on an undiscounted cash flows basis. The Company utilized market participant assumptions to determine its best estimate of the fair value of the intangible asset related to Rebetol that, when compared with its related carrying value, resulted in the impairment charge noted above. During the third quarter and first nine months of 2014, the Company recorded intangible asset impairment charges of \$412 million and \$1.1 billion, respectively, within Materials and Production costs related to certain products marketed by the Company for the treatment of chronic HCV infection, including PegIntron (peginterferon alpha-2b), Victrelis (boceprevir) and Rebetol (ribavirin USP). Rapid developments in the competitive HCV treatment market led to market share losses that were greater than the Company had predicted, causing deterioration in cash flow projections. These revisions to cash flows indicated that the intangible asset values associated with these products were not recoverable on an undiscounted cash flows basis. The Company utilized market participant assumptions to determine its best estimate of the fair values of the intangible assets related to PegIntron, Victrelis and Rebetol that, when



compared with their related carrying values, resulted in the impairment charges noted above.

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

- 17 -

---

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

## 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, certain investments funds, as well as AstraZeneca LP (AZLP) until the termination of the Company's relationship with AZLP on June 30, 2014 as discussed below. Equity income from affiliates was \$63 million and \$24 million for the third quarter of 2015 and 2014, respectively, and \$210 million and \$241 million for the first nine months of 2015 and 2014, respectively, and is included in Other (income) expense, net (see Note 13).

## 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. (Partnership), in exchange for a 1% limited partner interest. Astra contributed the net assets of its wholly owned subsidiary, Astra USA, Inc., to the Partnership in exchange for a 99% general partner interest. The Partnership, renamed AZLP upon Astra's 1999 merger with Zeneca Group Plc, became the exclusive distributor of the products for which KBI retained rights.

On June 30, 2014, AstraZeneca exercised its option to purchase Merck's interest in KBI for \$419 million in cash. Of this amount, \$327 million reflects an estimate of the fair value of Merck's interest in Nexium and Prilosec. This portion of the exercise price, which is subject to a true-up in 2018 based on actual sales from closing in 2014 to June 2018, was deferred and is being recognized over time in Other (income) expense, net as the contingency is eliminated as sales occur. During the third quarter and first nine months of 2015, \$50 million and \$153 million, respectively, of the deferred income was recognized in Other (income) expense, net bringing the total deferred income recognized through September 30, 2015 to \$293 million. The remaining exercise price of \$91 million primarily represents a multiple of ten times Merck's average 1% annual profit allocation in the partnership for the three years prior to exercise. Merck recognized the \$91 million as a gain in the first nine months of 2014 within Other (income) expense, net. As a result of AstraZeneca's option exercise, the Company's remaining interest in AZLP was redeemed. Accordingly, the Company also recognized a non-cash gain of approximately \$650 million in the first nine months of 2014 within Other (income) expense, net resulting from the retirement of \$2.4 billion of KBI preferred stock (see Note 10), the elimination of the Company's \$1.4 billion investment in AZLP and a \$340 million reduction of goodwill. This transaction resulted in a net tax benefit of \$517 million in the first nine months of 2014 primarily reflecting the reversal of deferred taxes on the AZLP investment balance.

As a result of AstraZeneca exercising its option, as of July 1, 2014, the Company no longer records equity income from AZLP and supply sales to AZLP have terminated. Equity income from AZLP was \$192 million in 2014 through the June 30 termination date.

Summarized financial information for AZLP through the June 30, 2014 termination date is as follows:

	Six Months Ended June 30, 2014
(\$ in millions)	
Sales	\$2,205
Materials and production costs	1,044
Other expense, net	604
Income before taxes <sup>(1)</sup>	\$557

(1) Merck's partnership returns from AZLP were generally contractually determined as noted above and were not based on a percentage of income from AZLP, other than with respect to Merck's 1% limited partnership interest.

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

### 8. Long-Term Debt

In February 2015, Merck issued \$8.0 billion aggregate principal amount of senior unsecured notes consisting of \$300 million principal amount of floating rate notes due 2017, \$700 million principal amount of floating rate notes due 2020, \$1.25 billion principal amount of 1.85% notes due 2020, \$1.25 billion aggregate principal amount of 2.35% notes due 2022, \$2.5 billion aggregate principal amount of 2.75% notes due 2025 and \$2.0 billion aggregate principal amount of 3.70% notes due 2045. The Company used a portion of the net proceeds of the offering of \$7.9 billion to repay commercial paper issued to substantially finance the Company's acquisition of Cubist. Any 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 3).

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

The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available. For product liability claims, a portion of the overall accrual is actuarially determined and considers such factors as past experience, number of claims reported and estimates of claims incurred but not yet reported. Individually significant contingent losses are accrued when probable and reasonably estimable. Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. The Company's decision to obtain insurance coverage is dependent on market conditions, including cost and availability, existing at the time such decisions are made. The Company has evaluated its risks and has determined that the cost of obtaining product liability insurance outweighs the likely benefits of the coverage that is available and, as such, has no insurance for most product liabilities effective August 1, 2004.

#### Vioxx Litigation

##### Product Liability Lawsuits

As previously disclosed, Merck is a defendant in approximately 20 active federal and state lawsuits (Vioxx Product Liability Lawsuits) alleging personal injury as a result of the use of Vioxx. Most of these cases are coordinated in a multidistrict litigation in the U.S. District Court for the Eastern District of Louisiana (Vioxx MDL) before Judge Eldon E. Fallon.

As previously disclosed, Merck is also a defendant in approximately 30 putative class action lawsuits alleging economic injury as a result of the purchase of Vioxx. All but one of those cases are in the Vioxx MDL. Merck has reached a resolution, approved by Judge Fallon, of these class actions in the Vioxx MDL. Under the settlement, Merck will pay up to \$23 million to resolve all properly documented claims submitted by class members, approved attorneys' fees and expenses, and approved settlement notice costs and certain other administrative expenses. The court entered an order approving the settlement in January 2014 and the claims review process was recently completed.

Merck is also a defendant in lawsuits brought by state Attorneys General of three states — Alaska, Montana and Utah. The lawsuits are pending in state courts. These actions allege that Merck misrepresented the safety of Vioxx and seek recovery for expenditures on Vioxx by government-funded health care programs, such as Medicaid, and/or penalties for alleged Consumer Fraud Act violations. Trial has been scheduled in the Montana case for September 12, 2016, and

trial has been set in the Alaska case for January 2, 2017. Motions for judgment on the pleadings in the Alaska and Montana cases are currently pending.

Shareholder Lawsuits

As previously disclosed, in addition to the Vioxx Product Liability Lawsuits, various putative class actions and individual lawsuits have been filed against Merck and certain former employees alleging that the defendants violated federal securities laws

- 19 -

---

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

by making alleged material misstatements and omissions with respect to the cardiovascular safety of Vioxx (Vioxx Securities Lawsuits). The Vioxx Securities Lawsuits are coordinated in a multidistrict litigation in the U.S. District Court for the District of New Jersey before Judge Stanley R. Chesler, and have been consolidated for all purposes. In August 2011, Judge Chesler granted in part and denied in part Merck's motion to dismiss the Fifth Amended Class Action Complaint in the consolidated securities action. Among other things, the court dismissed certain defendants from the case, and also dismissed claims based on statements made on or after the voluntary withdrawal of Vioxx on September 30, 2004. In October 2011, the remaining defendants answered the Fifth Amended Class Action Complaint. In April 2012, plaintiffs filed a motion for class certification for the period from May 21, 1999, through September 29, 2004, which the court granted in January 2013. In March 2013, plaintiffs filed a motion for leave to amend their complaint to add certain allegations to expand the class period. In May 2013, the court denied plaintiffs' motion for leave to amend their complaint to expand the class period, but granted plaintiffs' leave to amend their complaint to add certain allegations within the existing class period. In June 2013, plaintiffs filed their Sixth Amended Class Action Complaint. In July 2013, defendants answered the Sixth Amended Class Action Complaint. Discovery has been completed and is now closed. On May 13, 2015, the court granted in part and denied in part defendants' motions for summary judgment; the court granted judgment in defendants' favor on five of the alleged misstatements, including all statements prior to March 27, 2000, but denied the motion with respect to the remaining statements. The trial in this matter is currently scheduled to begin on March 1, 2016.

As previously disclosed, 13 individual securities lawsuits filed by foreign and domestic institutional investors also are consolidated with the Vioxx Securities Lawsuits. Discovery has been completed in eight of those actions, and is ongoing in the remaining five individual actions. The allegations in the individual actions are substantially similar to the allegations in the Vioxx Securities Lawsuits. All individual securities actions are consolidated with the Vioxx Securities Lawsuits for all purposes, including for trial.

#### Insurance

The Company has Directors and Officers insurance coverage applicable to the Vioxx Securities Lawsuits with remaining stated upper limits of approximately \$145 million. As a result of the previously disclosed insurance arbitration, additional insurance coverage for these claims should also be available, if needed, under upper-level excess policies that provide coverage for a variety of risks. There are disputes with the insurers about the availability of some or all of the Company's insurance coverage for these claims and there are likely to be additional disputes. The amounts actually recovered under the 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, Canada and Europe (collectively, the Vioxx International Lawsuits). As previously disclosed, the Company has entered into an agreement to resolve all claims related to Vioxx in Canada pursuant to which the Company will pay a minimum of approximately \$21 million but not more than an aggregate maximum of approximately \$36 million. The agreement has been approved by courts in Canada's provinces.

#### Reserves

The Company believes that it has meritorious defenses to the remaining Vioxx Product Liability Lawsuits, Vioxx Securities Lawsuits and Vioxx International Lawsuits (collectively, the Vioxx Litigation) and will vigorously defend against them. In view of the inherent difficulty of predicting the outcome of litigation, particularly where there are many claimants and the claimants seek indeterminate damages, the Company is unable to predict the outcome of these matters and, at this time, cannot reasonably estimate the possible loss or range of loss with respect to the remaining Vioxx Litigation. The Company has established a reserve with respect to the Canadian settlement and certain other Vioxx Product Liability Lawsuits. The Company also has an immaterial remaining reserve relating to the previously disclosed Vioxx investigation for the non-participating states with which litigation is continuing. The Company has established no other liability reserves with respect to the Vioxx Litigation. Unfavorable outcomes in the Vioxx Litigation could have a material adverse effect on the Company's financial position, liquidity and results of operations.

#### 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, 2015, approximately 4,880 cases had been filed and were pending against Merck in either federal or state court, including one case which seeks class action certification, as well as damages and/or medical monitoring. In approximately 375 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; however, substantially all of those actions are subject to the settlement discussed below. In addition, plaintiffs in approximately 4,505 of these actions generally allege that they sustained femur fractures and/or other bone injuries (Femur Fractures) in association with the use of Fosamax.

- 20 -

---

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

Cases Alleging ONJ and/or Other Jaw Related Injuries

In August 2006, the 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. As a condition to the settlement, 100% of the state and federal ONJ plaintiffs had to agree to participate in the settlement plan or Merck could either terminate the ONJ Master Settlement Agreement, or waive the 100% participation requirement and agree to a lesser funding amount for the settlement fund. On July 14, 2014, Merck elected to proceed with the ONJ Master Settlement Agreement at a reduced funding level since the participation level was approximately 95%. Merck has fully funded the Master Settlement Agreement and the escrow agent under the agreement has begun making settlement payments to qualifying plaintiffs. In addition, the judge overseeing the Fosamax ONJ MDL granted a motion filed by Merck and has entered an order that requires the approximately 40 non-participants whose cases will remain in the Fosamax ONJ MDL once the settlement is complete to submit expert reports in order for their cases to proceed any further. 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 10, 2015, at which time the Femur Fracture MDL was reassigned from Judge Pisano to Judge Freda L. Wolfson following Judge Pisano's retirement. In the only bellwether case tried to date in the Femur Fracture MDL, Glynn v. Merck, the jury returned a verdict in Merck's favor. In addition, on June 27, 2013, the Femur Fracture MDL court granted Merck's motion for judgment as a matter of law in the Glynn case and held that the plaintiff's failure to warn claim was preempted by federal law.

In August 2013, the Femur Fracture MDL court entered an order requiring plaintiffs in the Femur Fracture MDL to show cause why those cases asserting claims for a femur fracture injury that took place prior to September 14, 2010, should not be dismissed based on the court's preemption decision in the Glynn case. Pursuant to the show cause order, on March 26, 2014, the Femur Fracture MDL court dismissed with prejudice approximately 650 cases on preemption grounds. Plaintiffs in approximately 500 of those cases are appealing that decision to the U.S. Court of Appeals for the Third Circuit. In June 2015, the Femur Fracture MDL court dismissed without prejudice another approximately 520 cases pending plaintiffs' appeal of the preemption ruling to the Third Circuit.

On June 17, 2014, Judge Pisano granted Merck summary judgment in the Gaynor v. Merck case and found that Merck's updates in January 2011 to the Fosamax label regarding atypical femur fractures were adequate as a matter of law and that Merck adequately communicated those changes. The plaintiffs in Gaynor have appealed Judge Pisano's decision to the Third Circuit. In August 2014, Merck filed a motion requesting that Judge Pisano enter a further order requiring all plaintiffs in the Femur Fracture MDL who claim that the 2011 Fosamax label is inadequate and the proximate cause of their alleged injuries to show cause why their cases should not be dismissed based on the court's preemption decision and its ruling in the Gaynor case. In November 2014, the court granted Merck's motion and entered the requested show cause order.

As of September 30, 2015, approximately 1,045 cases were pending in the Femur Fracture MDL including the 500 cases dismissed with prejudice on preemption grounds which are pending appeal and the 520 cases dismissed without prejudice.

As of September 30, 2015, approximately 3,090 cases alleging Femur Fractures have been filed in New Jersey state court and are pending before Judge Jessica Mayer in Middlesex County. The parties selected an initial group of 30 cases to be reviewed through fact discovery. Two additional groups of 50 cases each to be reviewed through fact

discovery were selected in November 2013 and March 2014, respectively. A further group of 25 cases to be reviewed through fact discovery was selected by Merck in July 2015.

As of September 30, 2015, approximately 370 cases alleging Femur Fractures have been filed and are pending in California state court. A petition was filed seeking to coordinate all Femur Fracture cases filed in California state court before a single judge in Orange County, California. The petition was granted and Judge Thierry Colaw is currently presiding over the coordinated proceedings. In March 2014, the court directed that a group of 10 discovery pool cases be reviewed through fact discovery and subsequently scheduled the Galper v. Merck case, which plaintiffs' selected, as the first trial. The Galper trial began on February 17, 2015 and the jury returned a verdict in Merck's favor on April 3, 2015. The next Femur Fracture trial in California is currently scheduled to be held on March 14, 2016.

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

- 21 -

---



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

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, 2015, approximately 1,035 product user claims were served on, and are pending against, Merck alleging generally that use of Januvia and/or Janumet caused the development of pancreatic cancer. These complaints were filed in several different state and federal courts. Most of the claims are pending 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." That proceeding 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. In addition to the cases noted above, the Company has agreed, as of September 30, 2015, to toll the statute of limitations for approximately 20 additional claims. The Company intends to defend against these lawsuits.

NuvaRing

As previously disclosed, beginning in May 2007, a number of product liability complaints were filed in various jurisdictions asserting claims against the Company and its subsidiaries relating to NuvaRing, a combined hormonal contraceptive vaginal ring. The plaintiffs contend the Company, among other things, failed to adequately design and manufacture NuvaRing and failed to adequately warn of the alleged increased risk of venous thromboembolism (VTE) posed by NuvaRing, and/or downplayed the risk of VTE. The plaintiffs seek damages for injuries allegedly sustained from their product use, including some alleged deaths, heart attacks and strokes. The majority of the cases were pending in a federal multidistrict litigation venued in Missouri.

Pursuant to a settlement agreement between Merck and negotiating plaintiffs' counsel, which became effective as of June 4, 2014, Merck paid a lump total settlement of \$100 million to resolve more than 95% of the cases filed and under retainer by counsel as of February 7, 2014. Plaintiffs in approximately 3,700 cases joined the settlement program. Each filed case is to be dismissed with prejudice once the settlement administration process is completed. Those dismissals began in the second quarter and will continue on a rolling basis throughout 2015. The Company has certain insurance coverage available to it, which is currently being used to partially fund the Company's legal fees. This insurance coverage was also used to fund the settlement.

As of September 30, 2015, there were 13 cases pending outside of the settlement program, inclusive of cases filed after the settlement program closed. Of these cases, 12 are pending in the multidistrict litigation and are subject to individual case management orders requiring plaintiffs to meet various discovery and evidentiary requirements. As of September 30, 2015, these 12 plaintiffs were meeting those requirements and continuing to prosecute their cases.

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, 2015, approximately 1,385 lawsuits have been filed by plaintiffs who allege that they have experienced persistent sexual side effects following cessation of treatment with Propecia and/or Proscar. Approximately 60 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 John Gleeson of the Eastern District of New York. The matters pending in state court in New Jersey have been consolidated before Judge Jessica Mayer in Middlesex County. In addition, there is one matter pending in state court in Massachusetts. 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. The Company has received a civil investigative demand from the U.S. Attorney's Office, Eastern District of Pennsylvania which requests information relating to the Company's contracting and pricing of Dulera Inhalation

Aerosol with certain pharmacy benefit managers and Medicare Part D plans. The Company is cooperating with the investigation.

- 22 -

---

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

## Patent Litigation

From time to time, generic manufacturers of pharmaceutical products file Abbreviated New Drug Applications with the U.S. Food and Drug Administration (FDA) seeking to market generic forms of the Company's products prior to the expiration of relevant patents owned by the Company. To protect its patent rights, the Company may file patent infringement lawsuits against such generic companies. Certain products of the Company (or products marketed via agreements with other companies) currently involved in such patent infringement litigation in the United States include: Cancidas, Cubicin, Emend for Injection, 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 mergers and acquisitions, potentially significant intangible asset impairment charges.

**Cancidas** — In February 2014, a patent infringement lawsuit was filed in the United States against Xellia Pharmaceuticals ApS (Xellia) with respect to Xellia's application to the FDA seeking pre-patent expiry approval to market a generic version of Cancidas. In June 2015, the district court found that Xellia infringed the Company's patent and ordered that Xellia's application not be approved until the patent expires in September 2017 (including pediatric exclusivity). Xellia has appealed this decision. In August 2014, a patent infringement lawsuit was filed in the United States against Fresenius Kabi USA, LLC (Fresenius) in respect of Fresenius's application to the FDA seeking pre-patent expiry approval to market a generic version of Cancidas. The lawsuit automatically stays FDA approval of Fresenius's application until December 2016 or until an adverse court decision, if any, whichever may occur earlier.

**Cubicin** — In March 2012, a patent infringement lawsuit was filed in the United States against Hospira, Inc. (Hospira), with respect to Hospira's application to the FDA seeking pre-patent expiry approval to market a generic version of Cubicin. A trial was held in February 2014, and in December 2014 the district court found the composition patent, which expires in June 2016, to be valid and infringed. Later patents, expiring in September 2019 and November 2020, were found to be invalid. Hospira has appealed the finding that the composition patent is not invalid and the Company has cross-appealed the finding that the later patents are invalid. The appeal was heard in July 2015, and the Company is currently awaiting the decision. If the decision is upheld on appeal, Hospira's application will not be approved until at least June 2016.

In October 2013, a patent infringement lawsuit was filed in the United States against Strides, Inc. and Agila Specialties Private Limited (Strides/Agila), with respect to Strides/Agila's application to the FDA seeking pre-patent expiry approval to market a generic version of Cubicin. The lawsuit automatically stays FDA approval of Strides/Agila's application until February 2016 or until an adverse court decision, if any, whichever may occur earlier. If the Hospira decision is upheld on appeal, Strides/Agila's application will not be approved until at least June 2016.

In July 2014, a patent infringement lawsuit was filed in the United States against Fresenius, with respect to Fresenius's application to the FDA seeking pre-patent expiry approval to market a generic version of Cubicin. The lawsuit automatically stays FDA approval of Fresenius's application until November 2016 or until an adverse court decision, if any, whichever may occur earlier. If the Hospira decision is upheld on appeal, Fresenius's application will not be approved until at least June 2016.

An earlier district court action against Teva Parenteral Medicines Inc., Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, Teva) resulted in a settlement whereby Teva can launch a generic version of Cubicin in December 2017 (June 2018 if the Company obtains pediatric marketing exclusivity on Cubicin). If the Hospira decision is upheld on appeal, Teva will be able to launch in June 2016.

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

institute the requested IPR proceedings.

Emend for Injection — In May 2012, a patent infringement lawsuit was filed in the United States against Sandoz Inc. (Sandoz) in respect of Sandoz's application to the FDA seeking pre-patent expiry approval to market a generic version of Emend for Injection. The lawsuit automatically stays FDA approval of Sandoz's application until July 2015 or until an adverse court decision, if any, whichever may occur earlier. The trial in the lawsuit against Sandoz was recently completed in the U.S. District Court for the District of New Jersey. In August 2015, the court found that the Company's patent was infringed and not invalid. The court ordered that Sandoz's application not be approved until the expiration of the Company's patent in 2019. In June 2012, a patent infringement lawsuit was filed in the United States against Accord Healthcare, Inc. US, Accord Healthcare, Inc. and Intas Pharmaceuticals Ltd (collectively, Intas) in respect of Intas' application to the FDA seeking pre-patent expiry approval to market a generic version of Emend for Injection. The Company agreed with Intas to stay the lawsuit until the outcome of the lawsuit with

- 23 -

---

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

Sandoz. In October 2015, following the Sandoz decision, the court found that the Company's patent was infringed and not invalid. The court ordered that Intas's application not be approved until the expiration of the Company's patent in 2019. In July 2014, a patent infringement lawsuit was filed in the United States against Fresenius in respect of Fresenius's application to the FDA seeking pre-patent expiry approval to market a generic version of Emend for Injection. The lawsuit automatically stays FDA approval of Fresenius's application until November 2016 or until an adverse court decision, if any, whichever may occur earlier. In December 2014, Apotex Inc. filed a petition for IPR at the USPTO seeking the invalidity of claims in the compound patent covering Emend for Injection. The USPTO rejected Apotex's petition in June 2015.

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. Since Hospira did not challenge an earlier patent covering Invanz, its application to the FDA will not be approved until at least that patent expires in May 2016. 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. Since Savior did not challenge an earlier patent covering Invanz, its application to the FDA will not be approved until at least that patent expires in May 2016.

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. 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.

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 allegedly differs from the generic version in the previous lawsuit.

Noxafil — In August 2015, the Company filed a lawsuit against Actavis Laboratories Fl, Inc. (Actavis) in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of Noxafil. The lawsuit automatically stays FDA approval of Actavis's application until December 2017 or until an adverse court decision, if any, whichever may occur earlier.

NuvaRing — In December 2013, the Company filed a lawsuit against a subsidiary of Allergan 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 is scheduled to begin in January 2016. 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.

#### Anti-PD-1 Antibody Patent Oppositions and Litigation

As previously disclosed, Ono Pharmaceutical Co. (Ono) has a European patent (EP 1 537 878) ('878) that broadly claims the use of an anti-PD-1 antibody, such as the Company's immunotherapy, Keytruda, for the treatment of cancer. Ono has previously licensed its commercial rights to an anti-PD-1 antibody to Bristol-Myers Squibb (BMS) in certain markets. The Company believes that the '878 patent is invalid and filed an opposition in the European Patent Office (EPO) seeking its revocation. In June 2014, the Opposition Division of the EPO found the claims in the '878 patent are valid. The Company received the Opposition Division's written opinion in September 2014 and the Company submitted its substantive appeal in February 2015. In April 2014, the Company, and three other companies, opposed another European patent (EP 2 161 336) ('336) owned by BMS and Ono that it believes is invalid. The '336 patent, if

valid, broadly claims anti-PD-1 antibodies that could include Keytruda. BMS and Ono recently submitted a request to amend the claims of the '336 patent. If the EPO allows this amendment, the claims of the '336 patent would no longer broadly claim anti-PD-1 antibodies such as Keytruda.

In May 2014, the Company filed a lawsuit in the United Kingdom (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.

- 24 -

---

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

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 will seek leave to appeal this judgment.

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 recently notified the company that it will amend the claims of the '336 patent so that the claims of the '336 patent would no longer broadly claim anti-PD-1 antibodies such as Keytruda. Trial regarding the validity and infringement of the '878 patent is scheduled to begin in January 2016.

The Company can file lawsuits seeking revocation of the '336 and '878 patents in other national courts in Europe at any time, and Ono and BMS can file patent infringement actions against the Company in other national courts in Europe at or around the time the Company launches Keytruda. If a national court determines that the Company infringed a valid claim in the '878 or '336 patent, Ono and BMS may be entitled to monetary damages, including royalties on future sales of Keytruda, and potentially could seek an injunction to prevent the Company from marketing Keytruda in that country.

The USPTO granted US Patent Nos. 8,728,474 to Ono and 8,779,105 to Ono and BMS. These patents are equivalent to the '878 and '336 patents, respectively. In September 2014, BMS and Ono filed a lawsuit in the United States alleging that, by marketing Keytruda, the Company will infringe US Patent No. 8,728,474. BMS and Ono are not seeking to prevent or stop the marketing of Keytruda in the United States. The trial in this matter is currently scheduled to begin in November 2016. The Company believes that the 8,728,474 patent and the 8,779,105 patent are both invalid. Recently, Ono filed lawsuits in the United States alleging that, by marketing Keytruda, the Company will infringe US Patent Nos. 9,067,999 and 9,073,994, which are patents related to the 8,728,474 patent. The Company believes the 9,067,999 and 9,073,994 patents are also invalid.

In September 2014, the Company filed a lawsuit in Australia seeking the revocation of Australian patent No. 2011203119, which is equivalent to the '336 patent. In March 2015, BMS and Ono counterclaimed in this matter alleging that the Company's manufacture and supply of Keytruda to the Australian market will infringe Australian patent No. 2011203119.

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.

#### 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, 2015 and December 31, 2014 of approximately \$255 million and \$215 million, respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.





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

## 10. Equity

(\$ and shares in millions)	Common Stock		Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock		Non- Controlling Interests	Total
	Shares	Par Value				Shares	Cost		
Balance at January 1, 2014	3,577	\$ 1,788	\$ 40,508	\$ 39,257	\$ (2,197 )	650	\$(29,591)	\$ 2,561	\$ 52,326
Net income attributable to Merck & Co., Inc.	—	—	—	4,604	—	—	—	—	4,604
Cash dividends declared on common stock	—	—	—	(3,872 )	—	—	—	—	(3,872 )
Treasury stock shares purchased	—	—	—	—	—	106	(6,083 )	—	(6,083 )
Share-based compensation plans and other	—	—	(168 )	—	—	(40 )	1,779	46	1,657
Other comprehensive loss	—	—	—	—	(801 )	—	—	—	(801 )
AstraZeneca option exercise	—	—	—	—	—	—	—	(2,400 )	(2,400 )
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	3	3
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(74 )	(74 )
Balance at September 30, 2014	3,577	\$ 1,788	\$ 40,340	\$ 39,989	\$ (2,998 )	716	\$(33,895)	\$ 136	\$ 45,360
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
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
Other comprehensive loss	—	—	—	—	(250 )	—	—	—	(250 )
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

In connection with the 1998 restructuring of Astra Merck Inc., the Company assumed \$2.4 billion par value preferred stock with a dividend rate of 5% per annum, which was carried by KBI and included in Noncontrolling interests on the Consolidated Balance Sheet. As discussed in Note 7, on June 30, 2014, AstraZeneca exercised its option to acquire Merck's interest in AZLP and this preferred stock obligation was retired.

## 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. In addition, employees, non-employee directors and employees of certain of the Company's equity method investees 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 Consolidated Statement of Income:

Edgar Filing: Merck & Co., Inc. - Form 10-Q

(\$ in millions)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Pretax share-based compensation expense	\$75	\$75	\$221	\$209
Income tax benefit	(23 )	(23 )	(69 )	(64 )
Total share-based compensation expense, net of taxes	\$52	\$52	\$152	\$145

Amounts in the table above do not reflect share-based compensation costs to settle non-vested Cubist equity awards attributable to postcombination service that were recognized as transaction expense in 2015 (see Note 3).

During the first nine months of 2015 and 2014, the Company granted 4 million RSUs with a weighted-average grant date fair value of \$59.79 per RSU and 5 million RSUs with a weighted-average grant date fair value of \$58.15 per RSU, respectively. During the first nine months of 2015 and 2014, the Company granted 5 million stock options with a weighted-average exercise price of \$59.82 per option and 5 million stock options with a weighted-average exercise price of \$58.15 per option, respectively. The weighted-average fair value of options granted for the first nine months of 2015 and 2014 was \$6.46 and \$6.79 per option, respectively, and was determined using the following assumptions:

- 26 -

---

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

	Nine Months Ended September 30,			
	2015		2014	
Expected dividend yield	4.1	%	4.3	%
Risk-free interest rate	1.7	%	2.0	%
Expected volatility	19.9	%	22.0	%
Expected life (years)	6.2		6.4	

At September 30, 2015, there was \$488 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 2.0 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 of such plans consisted of the following components:

(\$ in millions)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2015		2014		2015		2014	
	U.S.	International	U.S.	International	U.S.	International	U.S.	International
Service cost	\$65	\$ 61	\$62	\$ 66	\$230	\$ 190	\$227	\$ 202
Interest cost	108	52	105	68	326	156	319	204
Expected return on plan assets	(203 )	(95 )	(195 )	(105 )	(614 )	(286 )	(585 )	(316 )
Net amortization	33	26	27	13	119	79	55	40
Termination benefits	2	—	16	1	20	1	42	5
Curtailments	(1 )	(2 )	(10 )	(7 )	(10 )	(3 )	(43 )	(6 )
Settlements	—	1	8	—	—	4	8	—
	\$4	\$ 43	\$13	\$ 36	\$71	\$ 141	\$23	\$ 129

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 of such plans consisted of the following components:

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	Service cost	\$22	\$18	\$61
Interest cost	28	27	83	84
Expected return on plan assets	(36 )	(35 )	(107 )	(104 )
Net amortization	(13 )	(18 )	(44 )	(53 )
Termination benefits	1	5	6	13
Curtailments	(1 )	(7 )	(8 )	(33 )
	\$1	\$(10 )	\$(9 )	\$(37 )

In connection with restructuring actions (see Note 2), 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.

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

## 13. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

(\$ in millions)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Interest income	\$(68 )	\$(69 )	\$(214 )	\$(190 )
Interest expense	165	191	503	567
Exchange losses	228	61	1,038	114
Equity income from affiliates	(63 )	(24 )	(210 )	(241 )
Other, net	(432 )	(325 )	(493 )	(1,228 )
	\$(170 )	\$(166 )	\$624	\$(978 )

The increase in exchange losses in the third quarter and first nine months of 2015 as compared with the corresponding periods of 2014 were driven by exchange losses related to Venezuela of \$138 million and \$853 million, respectively. 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 official rate of 6.30 VEF per U.S. dollar. Accordingly, during the second quarter of 2015, the Company recorded a charge of \$715 million to revalue its net monetary assets in Venezuela to an amount that includes the Company's estimate of the U.S. dollar amount that will ultimately be collected. During the third quarter of 2015, the Company recorded additional exchange losses of \$138 million reflecting the ongoing effect of translating current quarter transactions and net monetary assets consistent with the second quarter. It is possible that the Company may record additional charges for devaluations or ongoing translation exchange losses in the future.

The increase in equity income from affiliates in the third quarter of 2015 as compared with the third quarter of 2014 was driven primarily by higher equity income from certain research investment funds. The decline in equity income from affiliates for the first nine months of 2015 as compared with the same period in 2014 was due to the termination of the Company's relationship with AZLP on June 30, 2014 (see Note 7), partially offset by higher equity income from certain research investment funds.

Other, net (as reflected in the table above) 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 3). In addition, Other, net in the third quarter and first nine months of 2015 includes the recognition of \$50 million and \$153 million, respectively, of deferred income related to AstraZenca's option exercise (see Note 7) compared with \$36 million in the third quarter and first nine months of 2014. 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. Other, net in the third quarter and first nine months of 2014 includes a \$396 million gain on the divestiture of certain ophthalmic products in several international markets (see Note 3) and a \$93 million goodwill impairment charge related to the Company's joint venture with Supera (see Note 6). Other, net in the first nine months of 2014 also includes a gain of \$741 million related to AstraZeneca's option exercise (see Note 7) and a gain of \$204 million related to the divestiture of Sirna (see Note 3). Interest paid for the nine months ended September 30, 2015 and 2014 was \$452 million and \$544 million, respectively.

## 14. Taxes on Income

The effective income tax rates of 23.6% and 43.5% for the third quarter of 2015 and 2014, respectively, and 24.2% and 15.8% for the first nine months of 2015 and 2014, 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 2015 also reflects the favorable impact of a net benefit of \$370 million related to the settlement of certain federal income tax issues, as well as the unfavorable effects of foreign exchange losses related to Venezuela for which no tax benefit was recorded 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 effective income tax rate for the first nine months of 2014 also reflects a net tax benefit of \$517 million recorded in connection with AstraZeneca's option exercise (see Note 7) and a benefit of approximately \$300 million

associated with a capital loss generated in the first quarter related to the sale of Sirna (see Note 3). 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 their 2006 through 2008 examination. The Company

- 28 -

---

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

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:

(\$ and shares in millions except per share amounts)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Net income attributable to Merck & Co., Inc.	\$1,826	\$895	\$3,465	\$4,604
Average common shares outstanding	2,814	2,879	2,825	2,909
Common shares issuable <sup>(1)</sup>	22	32	25	33
Average common shares outstanding assuming dilution	2,836	2,911	2,850	2,942
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	\$0.65	\$0.31	\$1.23	\$1.58
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	\$0.64	\$0.31	\$1.22	\$1.57

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

For the three months ended September 30, 2015 and 2014, 10 million and 5 million, respectively, and for the first nine months of 2015 and 2014, 7 million and 4 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.

## 16. Other Comprehensive Income (Loss)

Changes in AOCI by component are as follows:

(\$ in millions)	Three Months Ended September 30,					Accumulated Other Comprehensive Income (Loss)
	Derivatives	Investments	Employee Benefit Plans	Cumulative Translation Adjustment		
Balance July 1, 2014, net of taxes	\$27	\$ 116	\$(1,241 )	\$(1,346 )		\$ (2,444 )
Other comprehensive income (loss) before reclassification adjustments, pretax	434	(26 )	(715 )	(244 )		(551 )
Tax	(152 )	(7 )	226	(72 )		(5 )
Other comprehensive income (loss) before reclassification adjustments, net of taxes	282	(33 )	(489 )	(316 )		(556 )
Reclassification adjustments, pretax	(44 )	5	34	—		(5 )
Tax	16	(1 )	(8 )	—		7
Reclassification adjustments, net of taxes	(28 ) <sup>(1)</sup>	4 <sup>(2)</sup>	26 <sup>(3)</sup>	—		2
Other comprehensive income (loss), net of taxes	254	(29 )	(463 )	(316 )		(554 )
Balance September 30, 2014, net of taxes	\$281	\$ 87	\$(1,704 )	\$(1,662 )		\$ (2,998 )
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 )	(16 )	46	—		(141 )
Tax	60	6	(22 )	—		44

Edgar Filing: Merck & Co., Inc. - Form 10-Q

Reclassification adjustments, net of taxes	(111 ) <sup>(1)</sup>	(10 ) <sup>(2)</sup>	24 <sup>(3)</sup>	—	(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 )

- 29 -

---

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

(\$ in millions)	Nine Months Ended September 30,					Accumulated Other Comprehensive Income (Loss)
	Derivatives	Investments	Employee Benefit Plans	Cumulative Translation Adjustment		
Balance January 1, 2014, net of taxes	\$ 132	\$ 54	\$(909 )	\$(1,474 )		\$ (2,197 )
Other comprehensive income (loss) before reclassification adjustments, pretax	277	13	(1,287 )	(123 )		(1,120 )
Tax	(97 )	(2 )	449	(65 )		285
Other comprehensive income (loss) before reclassification adjustments, net of taxes	180	11	(838 )	(188 )		(835 )
Reclassification adjustments, pretax	(48 )	35	54	—		41
Tax	17	(13 )	(11 )	—		(7 )
Reclassification adjustments, net of taxes	(31 ) <sup>(1)</sup>	22 <sup>(2)</sup>	43 <sup>(3)</sup>	—		34
Other comprehensive income (loss), net of taxes	149	33	(795 )	(188 )		(801 )
Balance September 30, 2014, net of taxes	\$ 281	\$ 87	\$(1,704 )	\$(1,662 )		\$ (2,998 )
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 )	(78 )	154	—		(458 )
Tax	187	26	(64 )	—		149
Reclassification adjustments, net of taxes	(347 ) <sup>(1)</sup>	(52 ) <sup>(2)</sup>	90 <sup>(3)</sup>	—		(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 )

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

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

<sup>(3)</sup> Includes net amortization of prior service cost and actuarial gains and losses included in net periodic benefit cost (see Note 12).

#### 17. Segment Reporting

The Company's operations are principally managed on a products basis and include the Pharmaceutical, Animal Health and Alliances operating segments. The Animal Health 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 Alliances segment includes revenue and equity income from AZLP until its termination on June 30, 2014. On October 1, 2014, the Company sold its Consumer Care segment that developed, manufactured and marketed over-the-counter, foot care and sun care products.

- 30 -

---

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

Sales of the Company's products were as follows:

(\$ in millions)	Three Months Ended		Nine Months Ended	
	September 30, 2015	2014	September 30, 2015	2014
Primary Care and Women's Health				
Cardiovascular				
Zetia	\$633	\$660	\$1,836	\$1,988
Vytorin	302	369	942	1,146
Diabetes				
Januvia	1,014	933	2,942	2,849
Janumet	562	505	1,625	1,500
General Medicine and Women's Health				
NuvaRing	190	186	538	531
Implanon/Nexplanon	176	158	437	379
Dulera	133	124	383	328
Follistim AQ	95	97	288	309
Hospital and Specialty				
Hepatitis				
PegIntron	40	84	148	300
HIV				
Isentress	377	412	1,137	1,255
Hospital Acute Care				
Cubicin <sup>(1)</sup>	325	7	805	18
Cancidas	139	183	436	505
Invanz	153	141	424	390
Noxafil	132	107	360	280
Bridion	89	90	262	245
Primaxin	75	91	228	243
Immunology				
Remicade	442	604	1,398	1,815
Simponi	178	170	505	500
Oncology				
Emend	141	136	396	402
Keytruda	159	4	352	4
Temodar	83	88	238	264
Diversified Brands				
Respiratory				
Singulair	201	218	658	773
Nasonex	121	261	625	830
Clarinx	39	49	145	180
Other				
Cozaar/Hyzaar	150	195	524	614
Arcoxia	123	132	361	400
Fosamax	86	114	277	358
Zocor	56	61	168	194
Propecia	41	66	133	197
Vaccines <sup>(2)</sup>				
Gardasil/Gardasil 9	625	590	1,410	1,382
ProQuad/M-M-R II/Varivax	390	421	1,096	1,027

Edgar Filing: Merck & Co., Inc. - Form 10-Q

Zostavax	179	181	503	479
RotaTeq	160	174	441	490
Pneumovax 23	138	197	354	400
Other pharmaceutical <sup>(3)</sup>	1,178	1,326	3,380	4,097
Total Pharmaceutical segment sales	8,925	9,134	25,755	26,672
Other segment sales <sup>(4)</sup>	846	1,321	2,578	4,657
Total segment sales	9,771	10,455	28,333	31,329
Other <sup>(5)</sup>	302	102	950	426
	\$10,073	\$10,557	\$29,283	\$31,755

(1) Sales of Cubicin in 2015 represent sales subsequent to the Cubist acquisition date. Sales of Cubicin in 2014 reflect sales in Japan pursuant to a previously existing licensing agreement.

(2) These amounts do not reflect sales of vaccines sold in most major European markets through the Company's joint venture, Sanofi Pasteur MSD, 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 Sanofi Pasteur MSD.

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

(4) Represents the non-reportable segments of Animal Health and Alliances, as well as Consumer Care until its divestiture on October 1, 2014. The Alliances segment includes revenue from the Company's relationship with AZLP until its termination on June 30, 2014 (see Note 7).

(5) Other revenues are primarily comprised of miscellaneous corporate revenues, including revenue hedging activities, as well as third-party manufacturing sales. Other revenues in the first nine months of 2014 also include \$232 million received by Merck in connection with the sale of the U.S. marketing rights to Saphris (see Note 3).

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

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

(\$ in millions)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Segment profits:				
Pharmaceutical segment	\$5,641	\$5,772	\$16,088	\$16,475
Other segments	429	539	1,310	2,050
Total segment profits	6,070	6,311	17,398	18,525
Other profits (losses)	195	79	538	370
Unallocated:				
Interest income	68	69	214	190
Interest expense	(165 )	(191 )	(503 )	(567 )
Equity income from affiliates	25	(22 )	161	62
Depreciation and amortization	(383 )	(595 )	(1,175 )	(1,895 )
Research and development	(1,291 )	(1,332 )	(4,310 )	(3,984 )
Amortization of purchase accounting adjustments	(1,184 )	(1,008 )	(3,662 )	(3,198 )
Restructuring costs	(113 )	(376 )	(386 )	(664 )
Gain on sale of certain migraine clinical development programs	250	—	250	—
Foreign currency devaluation related to Venezuela	—	—	(715 )	—
Gain on divestiture of certain ophthalmic products	—	396	—	396
Gain on AstraZeneca option exercise	—	—	—	741
Other unallocated, net	(1,075 )	(1,841 )	(3,225 )	(4,504 )
	\$2,397	\$1,490	\$4,585	\$5,472

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 (losses) are primarily comprised of miscellaneous corporate profits (losses), as well as operating profits (losses) related to third-party manufacturing sales.

Other unallocated, net includes expenses from corporate and manufacturing cost centers, goodwill and product intangible asset impairment charges, gains or losses on sales of businesses and other miscellaneous income or expense items.

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

### Business Developments

In January 2015, Merck acquired Cubist Pharmaceuticals, Inc. (Cubist) (see Note 3 to the interim consolidated financial statements). Cubist was a leader in the development of therapies to treat serious infections caused by a broad range of bacteria. This transaction closed on January 21, 2015; accordingly, the results of operations of the acquired business have been included in the Company's results of operations beginning after that date.

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 (see Note 3 to the interim consolidated financial statements).

In July 2015, Merck acquired cCAM Biotherapeutics Ltd. (cCAM), a privately held biopharmaceutical company focused on the discovery and development of novel cancer immunotherapies (see Note 3 to the interim consolidated financial statements). This transaction closed on July 31, 2015; accordingly, the results of operations of the acquired business have been included in the Company's results of operations beginning after that date.

### Operating Results

#### Sales

Worldwide sales were \$10.1 billion for the third quarter of 2015, a decline of 5% compared with the third quarter of 2014. Foreign exchange unfavorably affected global sales performance by 7% in the third quarter of 2015. Excluding the unfavorable effect of foreign exchange, sales growth reflects the addition of \$362 million of revenues from Cubist products as a result of the acquisition, as well as higher sales of Keytruda (pembrolizumab), Januvia (sitagliptin) and Janumet (sitagliptin and metformin HCl), and higher third-party manufacturing sales, partially offset by declines in Remicade (infliximab), Nasonex (mometasone furoate monohydrate), Zetia (ezetimibe) and Vytorin (ezetimibe and simvastatin), Pneumovax 23 (pneumococcal vaccine polyvalent), ProQuad (Measles, Mumps, Rubella and Varicella Virus Vaccine Live), Cozaar (losartan potassium) and Hyzaar (losartan potassium and hydrochlorothiazide), PegIntron (peginterferon alpha-2b) and Victrelis (boceprevir). In addition, the divestiture of Merck's Consumer Care (MCC) business and certain ophthalmic product divestitures in 2014 as discussed below unfavorably affected sales performance in the third quarter of 2015.

Global sales were \$29.3 billion for the first nine months of 2015, a decline of 8% compared with the same period in 2014 including a 6% unfavorable effect from foreign exchange. The sales decline in the first nine months of 2015 was driven primarily by the MCC and product divestitures discussed below, as well as by lower revenue as a result of the termination in 2014 of the Company's relationship with AstraZeneca LP (AZLP) also discussed below. In addition, the revenue decline was attributable to the sale of the U.S. marketing rights to Saphris (asenapine) that resulted in revenue of \$232 million in the first nine months of 2014. Sales performance in the first nine months of 2015 as compared with the corresponding period of 2014 also reflects the addition of \$899 million of revenues from Cubist products as a result of the acquisition, as well as higher sales of Keytruda, Januvia and Janumet, Noxafil (posaconazole), Implanon/Nexplanon (etonogestrel implant), Dulera Inhalation Aerosol (mometasone furoate/formoterol fumarate dihydrate), and higher third-party manufacturing sales, partially offset by declines in Remicade, Zetia and Vytorin, Nasonex, PegIntron, Victrelis, Isentress (raltegravir), and Singulair (montelukast sodium).

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 2015. The Company anticipates these pricing actions and other austerity measures will continue to negatively affect revenue performance for the remainder of 2015.

In 2014, the Company divested certain ophthalmic products in several international markets (most of which closed on July 1, 2014). In addition, on October 1, 2014, the Company divested its MCC business. The sales decline in the third quarter of 2015 attributable to these divestitures was approximately \$480 million of which \$400 million related to the Consumer Care segment and \$80 million related to the Pharmaceutical segment. The sales decline in the first nine

months of 2015 attributable to these divestitures was approximately \$1.9 billion of which \$1.5 billion related to the Consumer Care segment and \$400 million related to the Pharmaceutical segment. Also, as discussed in Note 7 to the interim consolidated financial statements, the Company's relationship with AZLP terminated on June 30, 2014; therefore, effective July 1, 2014, the Company no longer records supply sales to AZLP. These supply sales were \$463 million in 2014 through the termination date and were reflected in the Alliances segment.

- 33 -

---

Sales of the Company's products were as follows:

(\$ in millions)	Three Months Ended		Nine Months Ended	
	September 30, 2015	September 30, 2014	September 30, 2015	September 30, 2014
Primary Care and Women's Health				
Cardiovascular				
Zetia	\$633	\$660	\$1,836	\$1,988
Vytorin	302	369	942	1,146
Diabetes				
Januvia	1,014	933	2,942	2,849
Janumet	562	505	1,625	1,500
General Medicine and Women's Health				
NuvaRing	190	186	538	531
Implanon/Nexplanon	176	158	437	379
Dulera	133	124	383	328
Follistim AQ	95	97	288	309
Hospital and Specialty				
Hepatitis				
PegIntron	40	84	148	300
HIV				
Isentress	377	412	1,137	1,255
Hospital Acute Care				
Cubicin <sup>(1)</sup>	325	7	805	18
Cancidas	139	183	436	505
Invanz	153	141	424	390
Noxafil	132	107	360	280
Bridion	89	90	262	245
Primaxin	75	91	228	243
Immunology				
Remicade	442	604	1,398	1,815
Simponi	178	170	505	500
Oncology				
Emend	141	136	396	402
Keytruda	159	4	352	4
Temodar	83	88	238	264
Diversified Brands				
Respiratory				
Singulair	201	218	658	773
Nasonex	121	261	625	830
Clarinx	39	49	145	180
Other				
Cozaar/Hyzaar	150	195	524	614
Arcoxia	123	132	361	400
Fosamax	86	114	277	358
Zocor	56	61	168	194
Propecia	41	66	133	197
Vaccines <sup>(2)</sup>				
Gardasil/Gardasil 9	625	590	1,410	1,382

Edgar Filing: Merck & Co., Inc. - Form 10-Q

ProQuad/M-M-R II/Varivax	390	421	1,096	1,027
Zostavax	179	181	503	479
RotaTeq	160	174	441	490
Pneumovax 23	138	197	354	400
Other pharmaceutical <sup>(3)</sup>	1,178	1,326	3,380	4,097
Total Pharmaceutical segment sales	8,925	9,134	25,755	26,672
Other segment sales <sup>(4)</sup>	846	1,321	2,578	4,657
Total segment sales	9,771	10,455	28,333	31,329
Other <sup>(5)</sup>	302	102	950	426
	\$10,073	\$10,557	\$29,283	\$31,755

(1) Sales of Cubicin in 2015 represent sales subsequent to the Cubist acquisition date. Sales of Cubicin in 2014 reflect sales in Japan pursuant to a previously existing licensing agreement.

(2) These amounts do not reflect sales of vaccines sold in most major European markets through the Company's joint venture, Sanofi Pasteur MSD, the results of which are reflected in equity income affiliates which is included in Other (income) expense, net. These amounts do, however, reflect supply sales to Sanofi Pasteur MSD.

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

(4) Represents the non-reportable segments of Animal Health and Alliances, as well as Consumer Care until its divestiture on October 1, 2014. The Alliances segment includes revenue from the Company's relationship with AZLP until its termination on June 30, 2014.

(5) Other revenues are primarily comprised of miscellaneous corporate revenues, including revenue hedging activities, as well as third-party manufacturing sales. Other revenues in the first nine months of 2014 also include \$232 million received by Merck in connection with the sale of the U.S. marketing rights to Saphris.



The provision for discounts includes indirect customer discounts that occur when a contracted customer purchases directly through an intermediary wholesale purchaser, known as chargebacks, as well as indirectly in the form of rebates owed based upon definitive contractual agreements or legal requirements with private sector and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. These discounts, in the aggregate, reduced sales by \$2.1 billion and \$1.7 billion for the three months ended September 30, 2015 and 2014, respectively, and by \$5.8 billion and \$4.8 billion for the nine months ended September 30, 2015 and 2014, 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 (marketed outside the United States as Inegy), medicines for lowering LDL cholesterol, were \$936 million in the third quarter of 2015, a decline of 9% compared with the third quarter of 2014 including a 7% unfavorable effect from foreign exchange. Combined worldwide sales of Zetia and Vytorin were \$2.8 billion in the first nine months of 2015, a decline of 11% compared with the same period in 2014 including a 7% unfavorable effect from foreign exchange. The declines in both periods were driven primarily by lower volumes of Ezetrol in Canada where it lost market exclusivity in September 2014, as well as by lower volumes in the United States, partially offset by higher pricing in the United States.

In November 2014, Merck announced that the investigational IMPROVE-IT study (IMPROved Reduction of Outcomes: Vytorin Efficacy International Trial) met its primary and all secondary composite efficacy endpoints. In IMPROVE-IT, patients taking Vytorin - which combines simvastatin with Zetia - experienced significantly fewer major cardiovascular events (as measured by a composite of cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, re-hospitalization for unstable angina or coronary revascularization occurring at least 30 days after randomization) than patients treated with simvastatin alone. The results from this 18,144 patient study of high-risk patients presenting with acute coronary syndromes were presented at the American Heart Association 2014 Scientific Sessions. In April 2015, Merck submitted the data from IMPROVE-IT to the U.S. Food and Drug Administration (FDA) to support a new indication for reduction of cardiovascular events for Vytorin and Zetia. Vytorin and Zetia are currently indicated for use along with a healthy diet to reduce elevated LDL cholesterol in patients with hyperlipidemia. The current U.S. Prescribing Information for both products states that the effect of ezetimibe on cardiovascular morbidity and mortality, alone or incremental to statin therapy, has not been determined.

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

In May 2014, Merck announced that the FDA approved Zontivity (vorapaxar) for the reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction or with peripheral arterial disease. The U.S. prescribing information for Zontivity includes a boxed warning regarding bleeding risk. In January 2015, Zontivity was approved by the European Commission (EC) for coadministration with acetylsalicylic acid and, where appropriate, clopidogrel, to reduce atherothrombotic events in adult patients with a history of myocardial infarction. Merck currently plans to begin launching Zontivity in certain European markets in 2016. The Company continues to monitor and assess Zontivity and the related intangible asset. Merck continues to focus on building product awareness in the United States for Zontivity. If the Company's efforts to build product awareness in the United States or the launches in Europe are not successful, the Company may take a non-cash impairment charge with respect to the Zontivity intangible asset which was \$299 million at September 30, 2015.

##### Diabetes

Worldwide combined sales of Januvia and Janumet, medicines that help lower blood sugar levels in adults with type 2 diabetes, were \$1.6 billion in the third quarter of 2015 and \$4.6 billion for the first nine months of 2015, increases of 10% and 5%, respectively, compared with the same periods of 2014. Foreign exchange unfavorably affected global sales performance by 7% in both the third quarter and first nine months of 2015. Sales growth in both periods was driven primarily by higher volumes and pricing in the United States, as well as by volume growth in the emerging markets and Europe. The timing of customer buying in the United States benefited the third quarter and first nine months of 2015 by approximately \$100 million and will therefore unfavorably affect sales performance in the fourth quarter or subsequent quarters. Volume declines of co-marketed sitagliptin in Japan partially offset growth in the first nine months of 2015.

In June 2015, Merck announced the primary results of the Trial Evaluating Cardiovascular Outcomes with Sitagliptin (TECOS), a placebo-controlled study of the cardiovascular (CV) safety of Merck's DPP-4 inhibitor, Januvia (sitagliptin), added to usual care in more than 14,000 patients. The study achieved its primary composite CV endpoint of non-inferiority (defined as the time to the first confirmed event of any of the following: CV-related death, nonfatal myocardial infarction, nonfatal stroke, or hospitalization for unstable angina) compared to usual care without sitagliptin. In addition, there was no increase in hospitalization

for heart failure and rates of all-cause mortality were similar in both treatments groups, which were two key secondary endpoints. These data were presented at the annual scientific meeting of the American Diabetes Association in June 2015.

In September 2015, Merck announced that the Japanese Pharmaceuticals and Medical Devices Agency approved Marizev (omarigliptin) 25 mg and 12.5 mg tablets, an oral, once-weekly DPP-4 inhibitor indicated for the treatment of adults with type 2 diabetes. Japan is the first country to have approved omarigliptin. Merck plans to submit omarigliptin for regulatory approval in the United States by the end of 2015. Other worldwide regulatory submissions will follow.

#### General Medicine and Women's Health

Worldwide sales of NuvaRing (etonogestrel/ethinyl estradiol vaginal ring), a vaginal contraceptive product, increased 2% in the third quarter of 2015 to \$190 million and grew 1% in the first nine months of 2015 to \$538 million compared with the same periods of 2014, primarily reflecting higher pricing in the United States. Foreign exchange unfavorably affected global sales performance by 7% in both the third quarter and first nine months of 2015.

Worldwide sales of Implanon/Nexplanon, single-rod subdermal contraceptive implants, grew 11% to \$176 million in the third quarter of 2015 and increased 15% to \$437 million in the first nine months of 2015 compared with the same periods of 2014 driven primarily by higher demand in the United States and in certain emerging markets. Foreign exchange unfavorably affected global sales performance by 6% in both the third quarter and first nine months of 2015. Global sales of Dulera Inhalation Aerosol, a combination medicine for the treatment of asthma, grew 7% to \$133 million in the third quarter of 2015 and rose 17% to \$383 million in the first nine months of 2015 compared with the same periods of 2014 driven primarily by higher demand in the United States.

Global sales of Follistim AQ (follitropin beta injection) (marketed in most countries outside the United States as Puregon), a fertility treatment, were \$95 million in the third quarter of 2015, a decline of 2% compared with the third quarter of 2014 including a 10% unfavorable effect from foreign exchange. Sales performance in the third quarter reflects timing of government tenders in certain emerging markets. Worldwide sales of Follistim AQ were \$288 million in the first nine months of 2015, a decline of 7% compared with the same period of 2014 including a 9% unfavorable effect from foreign exchange. Sales performance in the first nine months of 2015 reflects volume declines in the emerging markets that were offset by higher pricing in the United States. The patent that provided market exclusivity for Follistim AQ in the United States expired in June 2015.

#### Hospital and Specialty

##### Hepatitis

Worldwide sales of PegIntron, a treatment for chronic hepatitis C virus (HCV), were \$40 million in the third quarter of 2015 and \$148 million in the first nine months of 2015, declines of 52% and 51%, respectively, compared with the corresponding periods of 2014. The sales declines were driven by lower volumes in nearly all regions as the availability of newer therapeutic options continues to reduce market share. Foreign exchange unfavorably affected global sales performance by 5% in the third quarter of 2015 and by 6% in the first nine months of 2015.

Worldwide sales of Victrelis, an oral medicine for the treatment of chronic HCV, were \$15 million in the first nine months of 2015 (the Company had virtually no sales of Victrelis in the third quarter of 2015) compared with \$27 million of sales in the third quarter of 2014 and \$132 million of sales in the first nine months of 2014. The sales declines were driven by lower volumes in Europe and the emerging markets as the availability of newer therapeutic options has resulted in loss of market share.

##### 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 \$377 million in the third quarter of 2015, a decline of 9% compared with the third quarter of 2014 including an 8% unfavorable effect from foreign exchange. Worldwide sales of Isentress were \$1.1 billion in the first nine months of 2015, a decrease of 9% compared with the same period of 2014 including a 7% unfavorable effect from foreign exchange. The sales decline was driven primarily by lower volumes in the United States and lower demand and pricing in Europe, partially offset by higher volumes in Latin America and higher pricing in the United States.

Hospital Acute Care

In January 2015, Merck acquired Cubist, a leader in the development of therapies to treat serious infections caused by a broad range of bacteria. Cubist's products include Cubicin (daptomycin for injection), an I.V. antibiotic for complicated skin and skin structure infections or bacteremia, when caused by designated susceptible organisms. Sales of Cubicin were \$325 million in the third quarter of 2015 and \$805 million subsequent to the acquisition through September 30, 2015. In many markets outside of the United States, Cubicin is commercialized by other companies in accordance with distribution agreements established prior to Merck's acquisition of Cubist. See Note 9 to the interim consolidated financial statements for a discussion of patent litigation related to Cubicin.

- 36 -

---

Cubist's products also include Zerbaxa (ceftolozane and tazobactam), a combination product approved by the FDA in December 2014 for the treatment of adults with complicated urinary tract infections caused by designated susceptible Gram-negative organisms or with complicated intra-abdominal infections caused by designated susceptible Gram-negative and Gram-positive organisms, and Sivextro (tedizolid phosphate), a product approved by the FDA in June 2014 for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults caused by designated susceptible Gram-positive organisms. Sivextro was also approved by the EC in March 2015 for the treatment of ABSSSI in adults. The Company began launching Sivextro in the second quarter of 2015. In September 2015, Zerbaxa was approved by the EC for the treatment of complicated intra-abdominal infections, acute pyelonephritis, and complicated urinary tract infections in adults.

Global sales of Cancidas (caspofungin acetate), an anti-fungal product, decreased 24% in the third quarter of 2015 to \$139 million and declined 14% in the first nine months of 2015 to \$436 million compared with the same prior year periods. Sales performance in the third quarter and first nine months of 2015 reflect 11% and 12% unfavorable effects from foreign exchange, respectively, and volume declines in certain emerging markets.

Worldwide sales of Noxafil, for the prevention of invasive fungal infections, grew 23% in the third quarter of 2015 to \$132 million and increased 29% in the first nine months of 2015 to \$360 million compared with the same periods of 2014 driven by pricing and higher demand in the United States and volume growth in Europe reflecting a positive impact from the approval of new formulations. Foreign exchange unfavorably affected global sales performance by 11% and 13% in the third quarter and first nine months of 2015, respectively.

Bridion (sugammadex) Injection, for the reversal of two types of neuromuscular blocking agents used during surgery, is approved and has been launched in many countries outside of the United States. Sales of Bridion were \$89 million in the third quarter of 2015, nearly flat compared with the third quarter of 2014 including a 20% unfavorable effect from foreign exchange, and were \$262 million in the first nine months of 2015, an increase of 7% compared with the same period of 2014 including a 19% unfavorable effect from foreign exchange. Sales performance in both periods reflects volume growth in most markets. In September 2013, the Company received a Complete Response Letter (CRL) from the FDA for the resubmission of the New Drug Application (NDA) for Bridion. To address the CRL, the Company conducted a new hypersensitivity study and, in October 2014, resubmitted the NDA to the FDA. In April 2015, the Company received a CRL from the FDA for Bridion in which the FDA requested additional sensitivity analysis related to a hypersensitivity study (Protocol 101). In July 2015, the FDA accepted Merck's resubmission of the NDA for Bridion with a Prescription Drug User Fee Act (PDUFA) action date of December 19, 2015. The FDA plans to hold an advisory committee meeting with respect to Bridion on November 6, 2015.

#### Immunology

Sales of Remicade, a treatment for inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were \$442 million in the third quarter of 2015, a decline of 27% compared with the third quarter of 2014, and were \$1.4 billion in the first nine months of 2015, a decrease of 23% compared with the same period in 2014. Foreign exchange unfavorably affected sales performance by 14% and 15% in the third quarter and first nine months of 2015, respectively. 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 Remicade sales decline to accelerate in the fourth quarter of 2015 and throughout 2016.

Sales of Simponi (golimumab), a once-monthly subcutaneous treatment for certain inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were \$178 million in the third quarter of 2015 and \$505 million for the first nine months of 2015, growth of 5% and 1%, respectively, compared with the same periods in 2014. Foreign exchange unfavorably affected global sales performance by 20% in both the third quarter and first nine months of 2015. The sales growth reflects higher demand in Europe reflecting in part an ongoing positive impact from the ulcerative colitis indication.

#### Other

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

Oncology

Global sales of Emend (aprepitant), for the prevention of chemotherapy-induced and post-operative nausea and vomiting, were \$141 million in the third quarter of 2015, an increase of 4% including a 6% unfavorable effect from foreign exchange. Sales growth reflects higher pricing in the United States and volume growth in Europe and the emerging markets. Worldwide sales of Emend were \$396 million in the first nine months of 2015, a decline of 1% compared with the same period in 2014 reflecting a 6% unfavorable effect from foreign exchange that was partially offset by higher pricing in the United States and volume growth in Europe.

Sales of Keytruda, an anti-PD-1 (programmed death receptor-1) therapy, were \$159 million in the third quarter of 2015 and \$352 million for the first nine months of 2015. In September 2014, the FDA granted accelerated approval of Keytruda at a dose of 2 mg/kg every three weeks for the treatment of patients with unresectable or metastatic melanoma and disease progression

- 37 -

---

following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor. In July 2015, Merck announced that the EC approved Keytruda for the treatment of advanced (unresectable or metastatic) melanoma in adults. The approval allows marketing of Keytruda in all 28 European Union (EU) member states at the approved dose of 2 mg/kg every three weeks. In October 2015, Merck announced the National Institute for Health and Care Excellence (NICE) of the United Kingdom has issued a draft recommendation, in the form of a Final Appraisal Determination, recommending Keytruda as a first-line treatment option for adults with advanced melanoma. In addition, NICE issued final guidance recommending Keytruda for the treatment of advanced melanoma after disease progression with ipilimumab.

In October 2015, the FDA granted accelerated approval of Keytruda at a dose of 2 mg/kg every three weeks for the treatment of patients with metastatic non-small-cell lung cancer (NSCLC) whose tumors express PD-L1 as determined by an FDA-approved test and who have disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Keytruda. In addition to approving Keytruda for NSCLC, the FDA approved the first companion diagnostic that will enable physicians to determine the level of PD-L1 expression in a patient's tumor. In August 2015, Merck announced that the FDA accepted for review an sBLA for Keytruda for the first-line treatment of unresectable or metastatic melanoma patients. The FDA granted Priority Review with a PDUFA action date of December 19, 2015. The sBLA submission was based in part on data from KEYNOTE-006, a Phase 3 study which evaluated Keytruda in patients with unresectable or metastatic melanoma with progression of disease. In March 2015, Merck announced that the KEYNOTE-006 study investigating Keytruda compared to ipilimumab in the first-line treatment of patients with advanced melanoma met its two primary endpoints of progression-free survival and overall survival. In KEYNOTE-006, Keytruda demonstrated a statistically significant and clinically meaningful improvement in overall survival and progression-free survival compared to ipilimumab. The safety profile of Keytruda in this trial was similar to the safety profile previously reported in advanced melanoma. The Company has also submitted data from the KEYNOTE-002 study in ipilimumab-refractory melanoma as part of an sBLA to the FDA with a PDUFA action date of December 24, 2015.

The Company has made additional regulatory filings in other countries and further filings are planned. The Keytruda clinical development program includes studies across a broad range of cancer types (see "Research and Development" below).

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

#### Diversified Brands

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

#### Respiratory

Worldwide sales of Singulair, a once-a-day oral medicine for the chronic treatment of asthma and for the relief of symptoms of allergic rhinitis, were \$201 million in the third quarter of 2015, a decrease of 8% compared with the third quarter of 2014 including a 14% unfavorable effect from foreign exchange. Global sales of Singulair were \$658 million in the first nine months of 2015, a decline of 15% compared with the same period in 2014 including an 11% unfavorable effect from foreign exchange. Sales performance in the year-to-date period primarily reflects lower volumes in Japan and lower demand in Europe as a result of generic competition. The Company has lost market exclusivity for Singulair in the United States and in most major international markets with the exception of Japan and expects generic competition in these markets to continue. The patent that provides market exclusivity for Singulair in Japan will expire in 2016.

Global sales of Nasonex, an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, declined 54% to \$121 million in the third quarter of 2015 and decreased 25% to \$625 million in the first nine months of 2015 compared with the same periods of 2014. Foreign exchange unfavorably affected global sales performance by 6% and 7% in the third quarter and first nine months of 2015, respectively. The declines were driven primarily by lower

volumes in the United States reflecting competition from alternative generic treatment options, as well as from supply constraints. The supply issue was resolved and Nasonex became available again in October. In addition, lower volumes and pricing in Europe from ongoing generic erosion, particularly in the year-to-date period, also contributed to the Nasonex sales decline. By agreement, generic manufacturers were able to launch a generic version of Nasonex in most European markets on January 1, 2014 and generic versions of Nasonex have since launched in most of these markets. Accordingly, the Company continues to experience volume and pricing declines in Nasonex sales in Europe. In 2009, Apotex Inc. and Apotex Corp. (collectively, Apotex) filed an application with the FDA seeking approval to sell its generic version of Nasonex. In June 2012, the U.S. District Court for the District of New Jersey ruled against the Company in a patent infringement suit against Apotex holding that Apotex's generic version of Nasonex does not infringe on the Company's formulation patent. In June 2013, the Court of Appeals for the Federal Circuit issued a decision affirming the U.S. District Court decision and the Company has exhausted all of its appeal options. Apotex has not yet launched a generic version

- 38 -

---



of Nasonex in the United States; however, if Apotex's generic version becomes available, significant losses of U.S. Nasonex sales could occur. U.S. sales of Nasonex were \$308 million for the first nine months of 2015.

#### Other

Global sales of Cozaar and Hyzaar (a combination of Cozaar and hydrochlorothiazide), treatments for hypertension, were \$150 million in the third quarter of 2015, a decline of 23% compared with the third quarter of 2014 including a 9% unfavorable effect from foreign exchange. The sales decline reflects lower volumes in the emerging markets and Japan. Worldwide sales of Cozaar and Hyzaar were \$524 million in the first nine months of 2015, a decline of 15% compared with the same period of 2014 including an 8% unfavorable effect from foreign exchange. The sales decline in the year-to-date period was driven primarily by lower volumes in Japan and Europe that were partially offset by higher demand in China and Latin America. The patents that provided market exclusivity for Cozaar and Hyzaar in the United States and in most major international markets have expired. Accordingly, the Company is experiencing declines in Cozaar and Hyzaar sales and expects the declines to continue.

Other products contained in Diversified Brands include among others, Clarinex (desloratadine), a non-sedating antihistamine; Arcoxia (etoricoxib) for the treatment of arthritis and pain; Fosamax (alendronate sodium) (marketed as Fosamac in Japan) and Fosamax Plus D (alendronate sodium/cholecalciferol) (marketed as Fosavance throughout the EU) for the treatment and, in the case of Fosamax, prevention of osteoporosis; Zocor (simvastatin), a statin for modifying cholesterol; and Propecia (finasteride), a product for the treatment of male pattern hair loss.

#### 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.

Merck's sales of Gardasil (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant)/Gardasil 9 (Human Papillomavirus 9-valent Vaccine, Recombinant), vaccines to help prevent certain diseases caused by certain types of human papillomavirus (HPV), grew 6% in the third quarter of 2015 to \$625 million driven by higher sales in the United States due to pricing. Merck's sales of Gardasil/Gardasil 9 increased 2% in the first nine months of 2015 to \$1.4 billion compared with the same prior year period reflecting higher sales in the United States due to pricing, partially offset by declines in certain emerging markets, particularly in Latin America due to the timing of government tenders. Foreign exchange unfavorably affected global sales performance by 1% in both the third quarter and first nine months of 2015. In December 2014, the Company announced that the FDA approved Gardasil 9, Merck's 9-valent HPV vaccine. Gardasil 9 includes the greatest number of HPV types in any available HPV vaccine.

Merck's sales of ProQuad, a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, were \$70 million in the third quarter of 2015 compared with \$119 million in the third quarter of 2014 and were \$292 million in the first nine months of 2015 compared with \$278 million in the first nine months of 2014. Sales performance in both periods reflects the timing of sales activity related to the U.S. Centers for Disease Control and Prevention Pediatric Vaccine Stockpile. Merck's sales of M M R II, a vaccine to help protect against measles, mumps and rubella, were \$103 million for the third quarter of 2015 compared with \$86 million for the third quarter of 2014 driven by higher volumes in the emerging markets and higher pricing in the United States. Merck's sales of M-M-R II were \$285 million in the first nine months of 2015 compared with \$249 million in the first nine months of 2014. Sales growth for M-M-R II in the year-to-date period was driven primarily by higher sales in the United States reflecting higher demand resulting from measles outbreaks and higher pricing. Merck's sales of Varivax, a vaccine to help prevent chickenpox (varicella), were \$218 million for the third quarter of 2015 compared with \$216 million for the third quarter of 2014 and were \$519 million in the first nine months of 2015 compared with \$500 million in the first nine months of 2014. Sales growth in the first nine months of 2015 reflects higher volumes in certain emerging markets and higher pricing in the United States, partially offset by lower volumes in the United States.

Merck's sales of RotaTeq (Rotavirus Vaccine, Live Oral, Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and children, were \$160 million in the third quarter of 2015, a decline of 8% compared with

the third quarter of 2014, and were \$441 million in the first nine months of 2015, a decrease of 10% compared with the same period of 2014. Foreign exchange unfavorably affected global sales performance by 3% in both the third quarter and first nine months of 2015. The sales decline in both periods was primarily driven by the effects of public sector purchasing in the United States.

Merck's sales of Zostavax (Zoster Vaccine Live), a vaccine to help prevent shingles (herpes zoster) in adults 50 years of age and older, were \$179 million in the third quarter of 2015, a decline of 1% compared with the third quarter of 2014 including a 2% unfavorable effect from foreign exchange. Merck's sales of Zostavax were \$503 million in the first nine months of 2015, an increase of 5% compared with the same period of 2014 including a 2% unfavorable effect from foreign exchange. Sales performance in both periods primarily reflects higher volumes in Canada and higher pricing in the United States, partially offset by lower

volumes in the United States. The Company is continuing to educate U.S. customers on the broad managed care coverage for Zostavax and the process for obtaining reimbursement. Merck is continuing to launch Zostavax outside of the United States.

Merck's sales of Pneumovax 23, a vaccine to help prevent pneumococcal disease, declined 30% in the third quarter of 2015 to \$138 million and decreased 12% to \$354 million in the first nine months of 2015 compared with the same periods in 2014. Foreign exchange unfavorably affected global sales performance by 3% and 4% in the third quarter and first nine months of 2015, respectively. The sales decline primarily reflects lower demand in the United States due to competitive pressures and lower sales in the emerging markets. In the year-to-date period, these declines were partially offset by higher volumes in Japan.

#### Other Segments

The Company's other segments are the Animal Health and Alliances segments, which are not material for separate reporting. Prior to its disposition on October 1, 2014, the Company also had a Consumer Care segment which had sales of \$401 million and \$1.5 billion in the third quarter and first nine months of 2014, respectively.

#### 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 \$825 million for the third quarter of 2015, a decline of 7% compared with the third quarter of 2014 including a 14% unfavorable effect from foreign exchange. Sales of Animal Health products were \$2.5 billion for the first nine months of 2015, a decline of 3% compared with the first nine months of 2015 including a 13% unfavorable effect from foreign exchange. Sales performance in both periods reflects volume growth in companion animal products, driven primarily by higher sales of Bravecto (fluralaner) chewable tablets for dogs to treat fleas and ticks that began launching in Europe and the United States in the second quarter of 2014, as well as higher sales of swine and aqua products, including PORCILIS PCV M Hyo, a new swine vaccine.

#### Alliances

The Alliances segment includes results from the Company's relationship with AZLP. On June 30, 2014, AstraZeneca exercised its option to buy Merck's interest in a subsidiary and, through it, Merck's interest in Nexium and Prilosec. As a result, as of July 1, 2014, the Company no longer records equity income from AZLP and supply sales to AZLP, primarily relating to sales of Nexium and Prilosec, have terminated (see "Selected Joint Venture and Affiliate Information" below). Revenue from AZLP was \$463 million in 2014 through the June 30 termination date.

#### Costs, Expenses and Other

In 2013, the Company initiated actions under a global restructuring program (2013 Restructuring Program) as part of a global initiative to sharpen its commercial and research and development focus. As part of the program, the Company expects to reduce its total workforce by approximately 8,500 positions. These workforce reductions will primarily come from the elimination of positions in sales, administrative and headquarters organizations, as well as research and development. The Company will also reduce its global real estate footprint and continue to improve the efficiency of its manufacturing and supply network. The Company will continue to hire employees in strategic growth areas of the business as necessary. The Company recorded total pretax costs of \$102 million and \$437 million in the third quarter of 2015 and 2014, respectively, and \$318 million and \$826 million in the first nine months of 2015 and 2014, respectively, related to this restructuring program. The actions under the 2013 Restructuring Program are expected to be substantially completed by the end of 2015 with the cumulative pretax costs estimated to be approximately \$3.0 billion. 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. The Company has met its projected \$2.0 billion in annual net cost savings for actions under the 2013 Restructuring Program. The Company has also met its annual net cost savings projection of \$2.5 billion compared with full-year 2012 expense levels pursuant to actions under the 2013 Restructuring Program, combined with actions under the Merger Restructuring Program (discussed below).

In 2010, subsequent to the Merck and Schering-Plough Corporation (Schering-Plough) merger (Merger), the Company commenced actions under a global restructuring program (Merger Restructuring Program) designed to streamline the cost structure of the combined company. Further actions under this program were initiated in 2011. The actions under this program primarily reflect the elimination of positions in sales, administrative and headquarters organizations, as well as from the sale or closure of certain manufacturing and research and development sites and the consolidation of office facilities. The Company recorded total pretax costs of \$115 million and \$175 million in the third quarter of 2015 and 2014, respectively, and \$452 million and \$533 million in the first nine months of 2015 and 2014, respectively, related to this restructuring program. The non-manufacturing related restructuring actions under the Merger Restructuring Program were substantially completed by the end of 2013. The remaining actions under this program primarily relate to ongoing manufacturing facility rationalizations, which are expected to be substantially completed by the end of 2016. The Company expects the estimated total cumulative pretax costs for this program

- 40 -

---

to be approximately \$8.5 billion. The Company estimates that approximately two-thirds of the cumulative pretax costs relate to 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. The Company expects the Merger Restructuring Program to yield annual savings upon completion of the program of approximately \$4.0 billion to \$4.6 billion.

The Company anticipates that total costs associated with restructuring activities in 2015 for both the 2013 Restructuring Program and the Merger Restructuring Program will be in the range of \$900 million to \$1.0 billion. The costs associated with all of these restructuring activities are primarily comprised of accelerated depreciation recorded in Materials and production, Marketing and administrative and Research and development and separation costs recorded in Restructuring costs (see Note 2 to the interim consolidated financial statements).

#### Materials and Production

Materials and production costs were \$3.8 billion for the third quarter of 2015, a decrease of 11% compared with the third quarter of 2014 and were \$11.1 billion in the first nine months of 2015, a decline of 15% compared with the same period of 2014. Costs in the third quarter of 2015 and 2014 include \$1.2 billion and \$1.0 billion, respectively, and for the first nine months of 2015 and 2014 include \$3.6 billion and \$3.2 billion, respectively, of expenses for the amortization of intangible assets recognized in connection with acquisitions. In addition, expenses for the third quarter and first nine months of 2015 include \$11 million and \$76 million, respectively, of amortization of purchase accounting adjustments to Cubist's inventories. Costs also include intangible asset impairment charges of \$12 million for the first nine months of 2015 and \$412 million and \$1.1 billion for the third quarter and first nine months of 2014, respectively (see Note 6 to the interim consolidated financial statements). Included in materials and production costs are costs associated with restructuring activities which amounted to \$70 million and \$87 million in the third quarter of 2015 and 2014, respectively, and \$280 million and \$377 million in the first nine months of 2015 and 2014, 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 62.7% in the third quarter of 2015 compared with 60.0% in the third quarter of 2014 and was 62.1% in the first nine months of 2015 compared with 59.0% in the first nine months of 2014. The amortization of intangible assets and purchase accounting adjustments to inventories, as well as the restructuring and impairment charges noted above reduced gross margin by 12.4 and 14.3 percentage points for the third quarter of 2015 and 2014, respectively, and by 13.6 and 14.6 percentage points for the first nine months of 2015 and 2014, respectively.

Excluding the impact of these items, the gross margin increase in the third quarter and first nine months of 2015 compared with the corresponding prior year periods was driven primarily by lower inventory write-offs and the favorable effects of foreign exchange. In addition, in the first nine months of 2015, product mix, including the impacts of acquisitions and divestitures, also contributed to the gross margin improvement.

#### Marketing and Administrative

Marketing and administrative expenses decreased 17% to \$2.5 billion in the third quarter of 2015 compared with the third quarter of 2014 and declined 11% to \$7.7 billion in the first nine months of 2015 compared with the same period of 2014. The declines largely reflect the prior year divestiture of MCC, favorable effects from foreign exchange, additional expenses in the prior year periods related to the health care reform fee as discussed below, lower restructuring costs, as well as lower selling costs, partially offset by higher promotional spending largely related to product launches, as well as higher costs related to the January acquisition of Cubist and, for the year-to-date period, higher acquisition and divestiture-related costs. Expenses for the third quarter of 2015 and 2014 include \$17 million and \$68 million, respectively, and for the first nine months of 2015 and 2014 include \$70 million and \$143 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. Marketing and administrative expenses also include acquisition and divestiture-related costs of \$26 million and \$110 million in the third quarter of 2015 and 2014, respectively, and \$389 million and \$153 million in the first nine months of 2015 and 2014, 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.

On July 28, 2014, the Internal Revenue Service (IRS) issued final regulations on the annual non-tax deductible health care reform fee imposed by the Patient Protection and Affordable Care Act that is based on an allocation of a company's market share of prior year branded pharmaceutical sales to certain government programs. The final IRS regulations accelerated the recognition criteria for the fee obligation by one year to the year in which the underlying sales used to allocate the fee occurred rather than the year in which the fee was paid. As a result of this change, Merck recorded an additional year of expense of \$193 million during the third quarter and first nine months of 2014.

- 41 -

---

### Research and Development

Research and development expenses were \$1.5 billion for the third quarter of 2015, a decline of 10% compared with the third quarter of 2014, reflecting a reduction in expenses resulting from a decrease in the estimated fair value of liabilities for contingent consideration, the favorable effects of foreign exchange, lower restructuring costs and the prior year divestiture of MCC, partially offset by higher costs related to the acquisition of Cubist. Research and development expenses were \$4.9 billion for the first nine months of 2015, essentially flat compared with the same period in 2014, driven primarily by the acquisition of Cubist, higher licensing costs and IPR&D impairment charges, partially offset by the favorable effects of foreign exchange, lower restructuring costs and the prior year divestiture of MCC.

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 \$950 million and \$970 million in the third quarter of 2015 and 2014, respectively, and were \$2.9 billion and \$2.7 billion for the first nine months of 2015 and 2014, 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 \$600 million and \$575 million for the third quarter of 2015 and 2014, respectively, and \$2.0 billion for both the first nine months of 2015 and 2014. Research and development expenses also include IPR&D impairment charges of \$62 million for the first nine months of 2015 and \$36 million for the third quarter and first nine months of 2014 (see Note 6 to the interim consolidated financial statements). In addition, during the third quarter of 2015, the Company recorded a reduction in expenses of \$71 million resulting from a decrease in the estimated fair value of liabilities for contingent consideration (see Note 4 to the interim consolidated financial statements). Research and development expenses also reflect accelerated depreciation and asset abandonment costs associated with restructuring activities of \$17 million and \$81 million in the third quarter of 2015 and 2014, respectively, and \$34 million and \$175 million for the first nine months of 2015 and 2014, respectively.

### Restructuring Costs

Restructuring costs, primarily representing separation and other related costs associated with restructuring activities, were \$113 million and \$376 million for the third quarter of 2015 and 2014, respectively, and were \$386 million and \$664 million for the first nine months of 2015 and 2014, respectively. Costs in the third quarter of 2015 and 2014 include \$71 million and \$306 million, respectively, and in the first nine months of 2015 and 2014 include \$193 million and \$354 million, respectively, of expenses related to the 2013 Restructuring Program. The remaining costs in 2015 and 2014 related to the Merger Restructuring Program. Separation costs were incurred that were associated with actual headcount reductions, as well as estimated expenses under existing severance programs for headcount reductions that were probable and could be reasonably estimated. Merck eliminated approximately 685 positions in the third quarter of 2015 (425 related to the 2013 Restructuring Program and 260 related to the Merger Restructuring Program). During the first nine months of 2015, Merck eliminated approximately 2,635 positions (1,620 related to the 2013 Restructuring Program and 1,015 related to the Merger Restructuring Program). Merck eliminated approximately 1,015 positions in the third quarter of 2014 (830 related to the 2013 Restructuring Program and 185 related to the Merger Restructuring Program) and 4,400 positions in the first nine months of 2014 (3,425 related to the 2013 Restructuring Program and 975 related to the Merger Restructuring Program). These position eliminations are comprised of actual headcount reductions, and the elimination of contractors and vacant positions. Also included in restructuring costs are curtailment, settlement and termination charges associated with pension and other postretirement benefit plans, share-based compensation and shutdown 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.

### Other (Income) Expense, Net

Other (income) expense, net was \$170 million of income in the third quarter of 2015 compared with \$166 million of income in the third quarter of 2014 driven primarily by a \$250 million gain in 2015 on the sale of certain migraine

clinical development programs (see Note 3 to the interim consolidated financial statements) and a \$93 million goodwill impairment charge related to the Company's joint venture with Supera in 2014 (see Note 6 to the interim consolidated financial statements), partially offset by a \$396 million gain in 2014 on the divestiture of certain ophthalmic products in several international markets (see Note 3 to the interim consolidated financial statements), \$138 million of foreign exchange losses in 2015 related to Venezuela as discussed below, and lower equity income from affiliates.

Other (income) expense, net in the first nine months of 2015 was \$624 million of expense compared with \$978 million of income in the same period of 2014. The unfavorability was driven primarily by gains recognized in 2014, including a \$741 million gain on AstraZeneca's option exercise (see Note 7 to the interim consolidated financial statements), a \$396 million gain on the divestiture of certain ophthalmic products in several international markets as noted above, and a \$204 million gain related to the sale of the Company's Sirna Therapeutics, Inc. (Sirna) subsidiary (see Note 3 to the interim consolidated financial statements), as well as foreign exchange losses of \$853 million in 2015 related to Venezuela, lower equity income from AZLP, and an expense of \$78 million for a contribution of investments in equity securities to the Merck Foundation in 2015. Partially offsetting the

- 42 -

---



unfavorability of these items was a gain in 2015 on sale of certain migraine clinical development programs as noted above, higher equity income from certain research investment funds, higher recognition of deferred income, as well as a goodwill impairment charge in 2014 as noted above.

In March 2013, the Venezuelan government announced the creation of a foreign exchange mechanism called the “Complimentary System of Foreign Currency Acquirement” (known as SICAD1) that operates similar to an auction system and allows entities in specific sectors to bid for U.S. dollars to be used for payments related to international investments and certain intangibles. In March 2014, the Venezuelan government launched another foreign exchange mechanism (known as SICAD2) and indicated that all industry sectors would be able to access SICAD2 and its use would not be restricted as to purpose. Neither SICAD1 nor SICAD2 eliminated or changed the official rate of 6.30 VEF per U.S. dollar. In February 2015, the Venezuelan government replaced SICAD2 with the Sistema Marginal de Divisas (known as SIMADI). The SIMADI market is intended to operate based on the principles of supply and demand with buyers and sellers exchanging offers to transact. The SICAD1 mechanism remains unchanged.

Announcements by the Venezuelan government have indicated that essential goods, including food and medicine, will remain at the official rate of 6.30 VEF per U.S. dollar. Both the SICAD1 and SIMADI average rates are published by the Central Bank of Venezuela and, at September 30, 2015, the average exchange rates inferred were 13.50 VEF per U.S. dollar and 199.42 VEF per U.S. dollar, respectively.

Year-to-date through September 30, 2015, the Company has received approximately \$37 million from Venezuela for transactions that were settled at the official rate of 6.30 VEF per U.S. dollar. 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 official rate. Accordingly, during the second quarter of 2015, the Company recorded a charge of \$715 million within Other (income) expense, net to revalue its net monetary assets in Venezuela to an amount that represented the Company’s estimate of the U.S. dollar amount that will ultimately be collected. During the third quarter of 2015, the Company recorded additional exchange losses of \$138 million within Other (income) expense, net reflecting the ongoing effect of translating current quarter transactions and net monetary assets consistent with the second quarter. At September 30, 2015, the Company had approximately \$250 million (U.S. dollar equivalent) of remaining net monetary assets in its Venezuelan entities, of which the large majority was cash. While the remaining net monetary assets at September 30, 2015, include the Company’s estimate of the U.S. dollar amount that will be collected, it is possible that not all of these amounts will be collected and the Company may record additional charges for devaluations or ongoing translation exchange losses in the future. The Company will work with the government of Venezuela to continue to import essential medicines into the country and to ensure continued positive U.S. dollar cash flows from Merck’s operations.

#### Segment Profits

(\$ in millions)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Pharmaceutical segment profits	\$5,641	\$5,772	\$16,088	\$16,475
Other non-reportable segment profits	429	539	1,310	2,050
Other	(3,673 )	(4,821 )	(12,813 )	(13,053 )
Income before income taxes	\$2,397	\$1,490	\$4,585	\$5,472

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 the amortization of purchase accounting adjustments and other acquisition and divestiture-related costs, intangible asset impairment charges, restructuring costs, taxes paid at the joint venture level and a portion of equity income.

Additionally, segment profits do not reflect other expenses from corporate and manufacturing cost centers and other miscellaneous income or expense. These unallocated items are reflected in “Other” in the above table. Also included in “Other” are miscellaneous corporate profits (losses), as well as operating profits (losses) related to third-party manufacturing sales.

Pharmaceutical segment profits declined 2% in both the third quarter and first nine months of 2015 as compared with the corresponding prior year periods primarily reflecting the unfavorable effect of foreign exchange.

- 43 -

---

### Taxes on Income

The effective income tax rates of 23.6% and 43.5% for the third quarter of 2015 and 2014, respectively, and 24.2% and 15.8% for the first nine months of 2015 and 2014, 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 2015 also reflects the favorable impact of a net benefit of \$370 million related to the settlement of certain federal income tax issues, as well as the unfavorable effect of foreign exchange losses related to Venezuela for which no tax benefit was recorded (see Note 13 to the to the interim 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 effective income tax rate for the first nine months of 2014 also reflects a net tax benefit of \$517 million recorded in connection with AstraZeneca's option exercise (see Note 7 to the interim consolidated financial statements), and a benefit of approximately \$300 million associated with a capital loss generated in the first quarter related to the sale of Sirna (see Note 3 to the interim consolidated financial statements).

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 IRS relating to their 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 (Loss) Attributable to Noncontrolling Interests

Net income (loss) attributable to noncontrolling interests was \$5 million and \$(53) million in the third quarter of 2015 and 2014, respectively, and was \$12 million and \$3 million in the first nine months of 2015 and 2014, respectively. The amounts for the third quarter and first nine months of 2014 include the portion of intangible asset and goodwill impairment charges related to the Company's joint venture with Supera (see Note 6 to the interim consolidated financial statements) that are attributable to noncontrolling interests. In addition, the amounts in 2015 reflect the termination of the Company's relationship with AZLP and the resulting retirement of KBI preferred stock (see Note 7 to the interim consolidated financial statements).

### Net Income and Earnings per Common Share

Net income attributable to Merck & Co., Inc. was \$1.8 billion for the third quarter of 2015 compared with \$895 million for the third quarter of 2014 and was \$3.5 billion in the first nine months of 2015 compared with \$4.6 billion in the first nine months of 2014. Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders (EPS) for the third quarter of 2015 were \$0.64 compared with \$0.31 in the third quarter of 2014 and were \$1.22 in the first nine months of 2015 compared with \$1.57 in the first nine months of 2014.

### Non-GAAP Income and Non-GAAP EPS

Non-GAAP income and non-GAAP EPS are alternative views of the Company's performance used by management that Merck is providing because management believes this information enhances investors' understanding of the Company's results. Non-GAAP income and non-GAAP EPS exclude certain items because of the nature of these items and the impact that they have on the analysis of underlying business performance and trends. The excluded items consist of acquisition and divestiture-related costs, restructuring costs and certain other items. These excluded items are significant components in understanding and assessing financial performance. Therefore, the information on non-GAAP income and non-GAAP EPS should be considered in addition to, but not in lieu of, net income and EPS prepared in accordance with generally accepted accounting principles in the United States (GAAP). Additionally, since non-GAAP income and non-GAAP EPS are not measures determined in accordance with GAAP, they have no standardized meaning prescribed by GAAP and, therefore, may not be comparable to the calculation of similar measures of other companies.

Non-GAAP income and non-GAAP EPS are important internal measures for the Company. Senior management receives a monthly analysis of operating results that includes non-GAAP income and non-GAAP EPS and the performance of the Company is measured on this basis along with other performance metrics. Senior management's annual compensation is derived in part using non-GAAP income and non-GAAP EPS.

- 44 -

---

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

	Three Months		Nine Months	
	Ended		Ended	
	September 30,		September 30,	
(\$ in millions except per share amounts)	2015	2014	2015	2014
Pretax income as reported under GAAP	\$2,397	\$1,490	\$4,585	\$5,472
Increase (decrease) for excluded items:				
Acquisition and divestiture-related costs	1,146	1,659	4,134	4,552
Restructuring costs	217	612	770	1,359
Other items:				
Gain on sale of certain migraine clinical development programs	(250 )	—	(250 )	—
Foreign currency devaluation related to Venezuela	—	—	715	—
Gain on the divestiture of certain ophthalmic products	—	(396 )	—	(396 )
Additional year of expense for health care reform fee	—	193	—	193
Gain on AstraZeneca option exercise	—	—	—	(741 )
Other	(33 )	5	(47 )	5
	3,477	3,563	9,907	10,444
Taxes on income as reported under GAAP	566	648	1,108	865
Estimated tax benefit on excluded items <sup>(1)</sup>	186	295	831	1,509
Net tax benefit from settlement of certain federal income tax issues	—	—	370	—
Tax benefit related to sale of Sirna Therapeutics, Inc. subsidiary	—	—	—	300
	752	943	2,309	2,674
Non-GAAP net income	2,725	2,620	7,598	7,770
Less: Net income (loss) attributable to noncontrolling interests as reported under GAAP	5	(53 )	12	3
Acquisition and divestiture-related costs attributable to non-controlling interests	—	(56 )	—	(56 )
	5	3	12	59
Non-GAAP net income attributable to Merck & Co., Inc.	\$2,720	\$2,617	\$7,586	\$7,711
EPS assuming dilution as reported under GAAP	\$0.64	\$0.31	\$1.22	\$1.57
EPS difference <sup>(2)</sup>	0.32	0.59	1.44	1.05
Non-GAAP EPS assuming dilution	\$0.96	\$0.90	\$2.66	\$2.62

(1) Amount for the nine months ended September 30, 2014 includes a net benefit of \$517 million recorded in connection with AstraZeneca's option exercise.

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

(2) than the amount calculated by dividing the impact of the excluded items by the weighted-average shares for the applicable period.

#### Acquisition and Divestiture-Related Costs

Non-GAAP income and non-GAAP EPS exclude the impact of certain amounts recorded in connection with acquisitions and divestitures. These amounts include the amortization of intangible assets and amortization of purchase accounting to inventories, as well as intangible asset impairment charges and expense or income related to changes in the fair value measurement of contingent consideration. Also excluded are incremental, third-party integration costs associated with acquisitions, such as costs related to legal entity and systems integration, severance costs which are not part of the Company's formal restructuring programs, as well as transaction and certain other costs associated with business acquisitions and divestitures. These costs should not be considered non-recurring; however, management excludes these amounts from non-GAAP income and non-GAAP EPS because it believes it is helpful for understanding the performance of the continuing business.

#### Restructuring Costs

Non-GAAP income and non-GAAP EPS exclude costs related to restructuring actions (see Note 2 to the interim consolidated financial statements). These amounts include employee separation costs and accelerated depreciation associated with facilities to be closed or divested. Accelerated depreciation costs represent the difference between the depreciation expense to be recognized over the revised useful life of the site, based upon the anticipated date the site will be closed or divested, and depreciation expense as determined utilizing the useful life prior to the restructuring actions. Restructuring costs also include asset abandonment, shut-down and other related costs, as well as employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans and share-based compensation costs. The Company has undertaken restructurings of different types during the covered periods and, therefore, these charges should not be considered non-recurring;

- 45 -

---

however, management excludes these amounts from non-GAAP income and non-GAAP EPS because it believes it is helpful for understanding the performance of the continuing business.

#### Certain Other Items

Non-GAAP income and non-GAAP EPS exclude certain other items. These items represent substantive, unusual items that are evaluated on an individual basis. Such evaluation considers both the quantitative and the qualitative aspect of their unusual nature and generally represent items that, either as a result of their nature or magnitude, management would not anticipate that they would occur as part of the Company's normal business on a regular basis. 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 3 to the interim consolidated financial statements), foreign exchange losses related to the revaluation of the Company's net monetary assets in Venezuela (see Note 13 to the interim 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 interim consolidated financial statements). Excluded from non-GAAP income and non-GAAP EPS in 2014 is a gain recognized in conjunction with AstraZeneca's option exercise, including a related net tax benefit on the transaction (see Note 7 to the interim consolidated financial statements), a gain on the divestiture of certain ophthalmic products in several international markets (see Note 3 to the interim consolidated financial statements), an additional year of expense related to the health care reform fee as discussed above, as well as a tax benefit from the sale of Sirna (see Note 3 to the interim consolidated financial statements).

#### Research and Development Update

In October 2015, the FDA granted accelerated approval of Keytruda at a dose of 2 mg/kg every three weeks for the treatment of patients with metastatic NSCLC whose tumors express PD-L1 (programmed death ligand-1) as determined by an FDA-approved test and who have 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 addition to approving Keytruda for NSCLC, the FDA approved the first companion diagnostic that will enable physicians to determine the level of PD-L1 expression in a patient's tumor. Keytruda was approved by the FDA in September 2014 at a dose of 2 mg/kg every three weeks for the treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor. In July 2015, Merck announced that the EC approved Keytruda for the treatment of advanced (unresectable or metastatic) melanoma in adults.

In August 2015, Merck announced that the FDA accepted for review an sBLA for Keytruda for the first-line treatment of unresectable or metastatic melanoma patients. The FDA granted Priority Review with a PDUFA action date of December 19, 2015. The sBLA submission was based in part on data from KEYNOTE-006, a Phase 3 study which evaluated Keytruda in patients with unresectable or metastatic melanoma with progression of disease. In March 2015, Merck announced that the KEYNOTE-006 study investigating Keytruda compared to ipilimumab in the first-line treatment of patients with advanced melanoma met its two primary endpoints of progression-free survival and overall survival. In KEYNOTE-006, Keytruda demonstrated a statistically significant and clinically meaningful improvement in overall survival and progression-free survival compared to ipilimumab. The safety profile of Keytruda in this trial was similar to the safety profile previously reported in advanced melanoma. The Company has also submitted data from the KEYNOTE-002 study in ipilimumab-refractory melanoma as part of an sBLA to the FDA with a PDUFA action date of December 24, 2015.

In October 2015, Merck announced topline results from the KEYNOTE-010 study of Keytruda in advanced NSCLC demonstrating that the trial met its primary objective. KEYNOTE-010 is a randomized, pivotal Phase 2/3 trial comparing two doses of Keytruda (the FDA-approved 2mg/kg dose and a higher, investigational 10mg/kg dose, each given every 3 weeks) to docetaxel, a commonly used chemotherapy. Patients were enrolled who had failed prior systemic therapy for advanced NSCLC and whose tumors had PD-L1 expression tumor proportion scores (TPS) of at least 1%. Outcomes were assessed in patients whose tumors were strongly PD-L1 positive (defined as TPS of 50%) and in all PD-L1 positive patients. A topline analysis revealed that treatment with Keytruda was associated with longer overall survival compared with docetaxel treatment. This was true for both the approved and the investigational dose of Keytruda, which showed similar efficacy. It was also true in both the first set of patients analyzed - those with

a TPS of 50% or greater - and for all enrolled patients, all of whom had a TPS of 1% or greater. Treatment with Keytruda, at both doses, also provided superior progression-free survival versus that achieved following treatment with docetaxel in patients whose tumors had TPS values equal to or greater than 50%. For progression-free survival, Keytruda treatment was numerically but not statistically superior to docetaxel in the all PD-L1 positive group, again at both doses. The safety profile of Keytruda in this trial was consistent with that observed in previously reported studies in patients with advanced NSCLC.

- 46 -

---



In November 2015, Merck announced that the FDA granted Breakthrough Therapy Designation to Keytruda for the treatment of patients with microsatellite instability high metastatic colorectal cancer. The FDA's Breakthrough Therapy Designation is intended to expedite the development and review of a candidate that is planned for use, alone or in combination, to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Keytruda was previously granted breakthrough status for advanced melanoma and advanced NSCLC. Merck is conducting a Phase 2 registration study (KEYNOTE-164) to evaluate the efficacy and safety of Keytruda based on microsatellite instability status in patients with previously treated advanced colorectal cancers, and is also planning a Phase 3 study (KEYNOTE-177) in a treatment naïve patient population.

In September 2015, Merck presented new data investigating the anti-tumor activity of Keytruda across a broad range of advanced cancers at the European Cancer Congress. With these and other presentations, data on the potential role of Keytruda will have been presented in more than 17 different cancers. The Keytruda clinical development program includes studies in more than 30 cancer types including: bladder, colorectal, gastric, head and neck, melanoma, non-small-cell lung, renal, triple negative breast and hematological malignancies. In addition, the Company has announced a number of collaborations with other pharmaceutical companies to evaluate novel combination regimens with Keytruda.

In July 2015, the Company announced that the FDA accepted for review Merck's NDA for MK-5172A, elbasvir/grazoprevir (50mg/100mg), an investigational once-daily, single tablet combination therapy consisting of an NS5A replication complex inhibitor (elbasvir) and an NS3/4A protease inhibitor (grasoprevir) for the treatment of adult patients infected with chronic HCV genotypes (GT) 1, 4 or 6. The FDA granted priority review for elbasvir/grazoprevir, with a PDUFA action date of January 28, 2016. The FDA previously granted Breakthrough Therapy designation status for elbasvir/grazoprevir for the treatment of patients infected with chronic HCV GT1 with end stage renal disease on hemodialysis and for patients infected with chronic HCV GT4. Breakthrough Therapy designation is intended to expedite the development and review of a candidate that is planned for use, alone or in combination, to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Merck's broad clinical trials program for elbasvir/grazoprevir includes multiple HCV genotypes and patients with difficult-to-treat conditions such as HIV/HCV co-infection, advanced chronic kidney disease, inherited blood disorders, cirrhosis and those on opiate substitution therapy. Also, in July 2015, the Company announced that the EMA accepted for review the marketing authorization application (MAA) for elbasvir/grazoprevir for the treatment of adult patients with chronic HCV GT 1, 3, 4 or 6 infection. The EMA will initiate review of the MAA under accelerated assessment timelines. The Company plans to submit additional license applications in other markets by the end of 2015.

In September 2015, the Company announced that omarigliptin, Merck's investigational once-weekly DPP-4 inhibitor in development for adults with type 2 diabetes, achieved its primary efficacy endpoint in a Phase 3 study.

Omarigliptin was found to be non-inferior to Januvia, at reducing patients' A1C (an estimate of a person's blood glucose over a two-to three-month period) levels from baseline, with similar A1C reductions achieved in both groups. The head-to-head study was designed to evaluate once-weekly treatment with omarigliptin 25 mg compared to 100 mg of Januvia once daily, a widely prescribed DPP-4 inhibitor worldwide. Results were presented during an oral session at the 51st European Association for the Study of Diabetes Annual Meeting. Also in September 2015, Merck announced that the Japanese Pharmaceuticals and Medical Devices Agency approved Marizev (omarigliptin) 25 mg and 12.5 mg tablets. Japan is the first country to have approved omarigliptin. Merck plans to submit omarigliptin for regulatory approval in the United States by the end of 2015. Other worldwide regulatory submissions will follow.

In September 2015, Merck announced that the two pivotal Phase 3 clinical studies for bezlotoxumab, its investigational antitoxin for prevention of *Clostridium difficile* (*C. difficile*) infection recurrence, met their primary efficacy endpoint: the reduction in *C. difficile* recurrence through week 12 compared to placebo, when used in conjunction with standard of care antibiotics for the treatment of *C. difficile*. Based on these results, the Company plans to submit new drug applications seeking regulatory approval of bezlotoxumab in the United States and EU by

the end of 2015 and in Canada in 2016. Currently, there are no therapies approved for the prevention of recurrent disease caused by *C. difficile*.

MK-0822, odanacatib, is an oral, once-weekly investigational treatment for patients with osteoporosis. Osteoporosis is a disease that reduces bone density and strength and results in an increased risk of bone fractures. Odanacatib is a cathepsin K inhibitor that selectively inhibits the cathepsin K enzyme. Cathepsin K is known to play a central role in the function of osteoclasts, which are cells that break down existing bone tissue, particularly the protein components of bone. Inhibition of cathepsin K is a novel approach to the treatment of osteoporosis. In September 2014, Merck announced data from the pivotal Phase 3 fracture outcomes study for odanacatib in postmenopausal women with osteoporosis. In the Long-Term Odanacatib Fracture Trial (LOFT), odanacatib met its primary endpoints and significantly reduced the risk of three types of osteoporotic fractures (radiographically-assessed vertebral, clinical hip, and clinical non-vertebral) compared to placebo and also reduced the risk of the secondary endpoint of clinical vertebral fractures. In addition, treatment with odanacatib led to progressive increases over five years in bone mineral density at the lumbar spine and total hip. The rates of adverse events overall in LOFT were generally balanced between patients taking odanacatib and placebo. Adjudicated events of morphea-like skin lesions and atypical femoral fractures occurred more often in the odanacatib group than in the placebo group. Adjudicated major adverse cardiovascular events were generally balanced

- 47 -

---

overall between the treatment groups. There were numerically more adjudicated stroke events with odanacatib than with placebo. Adjudicated atrial fibrillation was reported more often in the odanacatib group than in the placebo group. A numeric imbalance in mortality was observed; this numeric difference does not appear to be related to a particular reported cause or causes of death. Merck continues to collect data from the blinded extension study and is planning additional analyses of data from the trial, including an independent re-adjudication of major adverse cardiovascular events (MACE), in support of regulatory submissions. Merck now plans to submit an NDA to the FDA for odanacatib in 2016 following completion of the independent adjudication and analysis of MACE. Merck also plans to submit applications to the EMA and the Ministry of Health, Labour, and Welfare in Japan.

V920 is an investigational rVSV-EBOV (Ebola) vaccine candidate being studied in large scale Phase 2/3 clinical trials currently underway in West Africa. In November 2014, Merck and NewLink Genetics announced an exclusive licensing and collaboration agreement for the investigational Ebola vaccine.

On November 2, 2015, the FDA issued a CRL with respect to the Biologics License Application for V419, the investigational pediatric hexavalent combination vaccine, DTaP5-IPV-Hib-HepB, which is being developed and, if approved, will be commercialized through a partnership of Merck and Sanofi Pasteur. This vaccine is designed to help protect against six important diseases - diphtheria, tetanus, pertussis (whooping cough), polio (poliovirus types 1, 2, and 3), invasive disease caused by *Haemophilus influenzae* type b (Hib), and hepatitis B. Both companies are currently reviewing the CRL and plan to have further communication with the FDA.

In September 2013, the Company received a CRL from the FDA for the resubmission of the NDA for Bridion. To address the CRL, the Company conducted a new hypersensitivity study and, in October 2014, resubmitted the NDA to the FDA. In April 2015, the Company received a CRL from the FDA for Bridion in which the FDA requested additional sensitivity analysis related to a hypersensitivity study (Protocol 101). In July 2015, the FDA accepted Merck's resubmission of the NDA for Bridion with a PDUFA action date of December 19, 2015. The FDA plans to hold an advisory committee meeting with respect to Bridion on November 6, 2015.

During the second quarter of 2015, the Company received unfavorable efficacy data from a randomized, double-blinded, active-controlled study in patients with *Clostridium difficile* associated diarrhea for MK-4261, surotomycin. The evaluation of this data, combined with an assessment of the commercial opportunity of surotomycin, resulted in an IPR&D impairment charge (see Note 6 to the interim consolidated financial statements). In July 2015, Merck acquired cCAM, a privately held biopharmaceutical company focused on the discovery and development of novel cancer immunotherapies (see Note 3 to the interim consolidated financial statements). The acquisition provides Merck with cCAM's lead pipeline candidate, CM-24, a novel monoclonal antibody targeting the immune checkpoint protein CEACAM1 that is currently being evaluated in a Phase 1 study for the treatment of advanced or recurrent malignancies, including melanoma, non-small-cell lung, bladder, gastric, colorectal, and ovarian cancers.

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 (see Note 3 to the interim consolidated financial statements).

MK-8962, corifollitropin alfa injection, is an investigational fertility treatment for controlled ovarian stimulation in women participating in assisted reproductive technology. In July 2014, Merck received a CRL from the FDA for its NDA for corifollitropin alfa injection. Merck has made a decision to discontinue development of corifollitropin alfa injection in the United States for business reasons. Corifollitropin alfa injection is marketed as Elonva in certain markets outside of the United States.

MK-2402, bevenopran, is an oral investigational therapy in development as a potential treatment for opioid induced constipation in patients with chronic, non-cancer pain. Merck acquired bevenopran as a part of its purchase of Cubist. The Company has made the decision not to continue development of this program and is seeking to out-license the asset.



The chart below reflects the Company's research pipeline as of October 31, 2015. Candidates shown in Phase 3 include specific products and the date such candidate entered into Phase 3 development. Candidates shown in Phase 2 include the most advanced compound with a specific mechanism or, if listed compounds have the same mechanism, they are each currently intended for commercialization in a given therapeutic area. Small molecules and biologics are given MK-number designations and vaccine candidates are given V-number designations. Except as otherwise noted, candidates in Phase 1, additional indications in the same therapeutic area and additional claims, line extensions or formulations for in-line products are not shown.

Phase 2	Phase 3 (Phase 3 entry date)	Under Review
Alzheimer's Disease	Allergy	Hepatitis C
MK-7622	MK-8237, House Dust Mite (March 2014) <sup>(1,2)</sup>	MK-5172A (elbasvir/grazoprevir) (U.S./EU)
Asthma	Alzheimer's Disease	Neuromuscular Blockade Reversal
MK-1029	MK-8931 (verubecestat) (December 2013)	MK-8616 Bridion (U.S.) <sup>(3)</sup>
Cancer	Atherosclerosis	Pediatric Hexavalent Combination Vaccine
MK-3475 Keytruda	MK-0859 (anacetrapib) (May 2008)	V419 (U.S./EU) <sup>(4)</sup>
Colorectal	Bacterial Infection	
Hodgkin Lymphoma	MK-7655A	Footnotes:
MK-2206	(relebactam+imipenem/cilastatin)	(1) Being developed in a collaboration.
MK-8628	(October 2015)	(2) North American rights only.
Diabetes Mellitus	Cancer	(3) In April 2015, Merck received a CRL from the FDA for the resubmission of the NDA for Bridion (MK-8616). In June 2015, the FDA accepted Merck's resubmission in response to the CRL.
MK-8521	MK-3475 Keytruda	(4) V419 is being developed in partnership with Sanofi Pasteur and, if approved, will be co-promoted via a U.S. partnership and marketed via the SPMSD joint venture in Europe. On November 2, 2015, the FDA issued a CRL with respect to V419. Both companies are currently reviewing the CRL and plan to have further communication with the FDA.
Heart Failure	Bladder (October 2014)	
MK-1242 (vericiguat) <sup>(1)</sup>	Breast (October 2015)	
Hepatitis C	Gastric (May 2015)	
MK-3682A (MK-3682/MK-8742)	Head and Neck (November 2014)	
(elbasvir)/	Non-Small-Cell Lung (September 2014) (EU)	
MK-5172 (grazoprevir)	Clostridium difficile Infection	
MK-3682B	MK-6072 (bezlotoxumab) (November 2011)	
(MK-3682/MK-8408/MK-5172)	MK-4261 (surotomycin) (July 2012)	
(grazoprevir)	CMV Prophylaxis in Transplant Patients	
Pneumoconjugate Vaccine	MK-8228 (letermovir) (June 2014)	
V114	Contraception, Next Generation Ring	
	MK-8342B (September 2015)	
	Diabetes Mellitus	
	MK-3102 (omarigliptin) (September 2012)	
	MK-8835 (ertugliflozin) (November 2013) <sup>(1)</sup>	
	MK-8835A (ertugliflozin+sitagliptin) (September 2015) <sup>(1)</sup>	
	MK-8835B (ertugliflozin+metformin) (August 2015) <sup>(1)</sup>	
	MK-1293 (February 2014) <sup>(1)</sup>	

Ebola Vaccine  
V920 (March 2015)  
Herpes Zoster  
V212 (inactivated VZV vaccine)  
(December 2010)  
HIV  
MK-1439 (doravirine) (December  
2014)  
Osteoporosis  
MK-0822 (odanacatib)  
(September 2007)

#### Selected Joint Venture and Affiliate Information

##### AstraZeneca LP

In 1998, Merck and Astra completed the restructuring of the ownership and operations of their existing joint venture whereby Merck acquired Astra's interest in KBI Inc. (KBI) and contributed KBI's operating assets to a new U.S. limited partnership, Astra Pharmaceuticals L.P. (Partnership), in exchange for a 1% limited partner interest. Astra contributed the net assets of its wholly owned subsidiary, Astra USA, Inc., to the Partnership in exchange for a 99% general partner interest. 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.

On June 30, 2014, AstraZeneca exercised its option to purchase Merck's interest in KBI for \$419 million in cash. Of this amount, \$327 million reflects an estimate of the fair value of Merck's interest in Nexium and Prilosec. This portion of the exercise price, which is subject to a true-up in 2018 based on actual sales from closing in 2014 to June 2018, was deferred and is being recognized over time in Other (income) expense, net as the contingency is eliminated as sales occur. During the third quarter and first nine months of 2015, \$50 million and \$153 million, respectively, of the deferred income was recognized in Other income (expense), net bringing the total deferred income recognized through September 30, 2015 to \$293 million. The remaining exercise price of \$91 million primarily represents a multiple of ten times Merck's average 1% annual profit allocation in the partnership for the three years prior to exercise. Merck recognized the \$91 million as a gain in the first nine months of 2014 within Other (income) expense, net. As a result of AstraZeneca's option exercise, the Company's remaining interest in AZLP was redeemed.

Accordingly, the Company also recognized a non-cash gain of approximately \$650 million in the first nine months of 2014 within Other (income) expense, net resulting from the retirement of \$2.4 billion of KBI preferred stock (see Note 10 to the interim consolidated financial statements), the elimination of the Company's \$1.4 billion investment in AZLP and a \$340 million reduction of goodwill. This transaction resulted in a net tax benefit of \$517 million in the first nine months of 2014 primarily reflecting the reversal of deferred taxes on the AZLP investment balance.

As a result of AstraZeneca exercising its option, as of July 1, 2014, the Company no longer records equity income from AZLP and supply sales to AZLP have terminated.

#### 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 \$318 million and \$397 million in the third quarter of 2015 and 2014, respectively, and were \$655 million and \$827 million for the first nine months of 2015 and 2014, respectively. SPMSD sales of Gardasil were \$46 million and \$73 million for the third quarter of 2015 and 2014, respectively, and were \$126 million and \$192 million for the first nine months of 2015 and 2014, respectively. The Company records the results from its interest in SPMSD and other equity method affiliates in Other (income) expense, net.

#### Simcere MSD Shanghai Pharmaceutical Co., Ltd.

In March 2015, Merck and Simcere Pharmaceutical Group (Simcere) executed a restructuring agreement in which Merck agreed to transfer its 51% ownership interest in the Simcere MSD Shanghai Pharmaceutical Co., Ltd. joint venture to Simcere. As a result, Merck deconsolidated the joint venture and recorded a net loss of \$7 million in Other (income) expense, net in the first nine months of 2015.

#### Liquidity and Capital Resources

(\$ in millions)	September 30, 2015	December 31, 2014	
Cash and investments	\$25,169	\$29,234	
Working capital	10,984	14,407	
Total debt to total liabilities and equity	26.3	% 21.8	%

Cash provided by operating activities was \$8.2 billion in the first nine months of 2015 compared with \$9.0 billion in the first nine months of 2014. Cash provided by operating activities in the first nine months of 2014 includes \$232 million received in connection with the sale of the U.S. marketing rights to Saphris. 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 used in investing activities was \$4.1 billion in the first nine months of 2015 compared with \$7.6 billion in the first nine months of 2014 primarily reflecting higher proceeds from the sales of securities and other investments and lower purchases of securities and other investments, as well as cash used in 2014 for the acquisition of Idenix Pharmaceuticals, Inc., partially offset by cash used for the acquisition of Cubist in 2015 and cash received in 2014 for the dispositions of businesses and in connection with AstraZeneca's option exercise. Cash used in financing activities was \$2.9 billion in the first nine months of 2015 compared with \$5.5 billion in the first nine months of 2014 driven primarily by higher proceeds from the issuance of debt and lower purchases of treasury stock, partially offset by a decrease in short-term borrowings, higher payments on debt and lower proceeds from the exercise of stock options. During the first nine months of 2015, the Company recorded a charge of \$715 million to revalue its net monetary assets in Venezuela, the large majority of which was cash (see Note 13 to the interim consolidated financial statements).

At September 30, 2015, the total of worldwide cash and investments was \$25.2 billion, including \$12.1 billion of cash, cash equivalents and short-term investments and \$13.1 billion of long-term investments. Generally 80%-90% of cash and investments are held by foreign subsidiaries that would be subject to significant tax payments if such cash and investments were repatriated in the form of dividends. The Company records U.S. deferred tax liabilities for certain unremitted earnings, but when amounts earned overseas are expected to be indefinitely reinvested outside of

the United States, no accrual for U.S. taxes is provided. The amount of cash and investments held by U.S. and foreign subsidiaries fluctuates due to a variety of factors including the timing and receipt of payments in the normal course of business. Cash provided by operating activities in the United States continues to be the Company's primary source of funds to finance domestic operating needs, capital expenditures, a portion of treasury stock purchases and dividends paid to shareholders.

Capital expenditures totaled \$790 million and \$827 million for the first nine months of 2015 and 2014, respectively.

- 50 -

---



Dividends paid to stockholders were \$3.9 billion for both the first nine months of 2015 and 2014. In May 2015, the Board of Directors declared a quarterly dividend for the third quarter of \$0.45 per share on the Company's common stock that was paid in July 2015. In July 2015, the Board of Directors declared a quarterly dividend for the fourth quarter of \$0.45 per share on the Company's common stock that was paid in October 2015.

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 2015, the Company purchased \$3.0 billion (53 million shares) for its treasury. As of September 30, 2015, the Company's remaining share repurchase authorization was \$9.7 billion.

In February 2015, Merck issued \$8.0 billion aggregate principal amount of senior unsecured notes consisting of \$300 million principal amount of floating rate notes due 2017, \$700 million principal amount of floating rate notes due 2020, \$1.25 billion principal amount of 1.85% notes due 2020, \$1.25 billion aggregate principal amount of 2.35% notes due 2022, \$2.5 billion aggregate principal amount of 2.75% notes due 2025 and \$2.0 billion aggregate principal amount of 3.70% notes due 2045. The Company used a portion of the net proceeds of the offering of \$7.9 billion to repay commercial paper issued to substantially finance the Company's acquisition of Cubist. Any 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 3 to the interim consolidated financial statements).

The Company has a \$6.0 billion, five-year credit facility that matures in August 2019. The facility provides backup liquidity for the Company's commercial paper borrowing facility and is to be used for general corporate purposes. The Company has not drawn funding from this facility.

#### Critical Accounting Policies

The Company's significant accounting policies, which include management's best estimates and judgments, are included in Note 2 to the consolidated financial statements for the year ended December 31, 2014 included in Merck's Form 10-K filed on February 27, 2015. 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, 2014.

#### 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 annual and interim 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.

#### 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, 2015, 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.

- 51 -

---

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, 2014, as filed on February 27, 2015, 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 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, 2015 were as follows:

#### ISSUER PURCHASES OF EQUITY SECURITIES

Period	Total Number of Shares Purchased <sup>(1)</sup>	Average Price Paid Per Share	(\$ in millions)
			Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs <sup>(1)</sup>
July 1 - July 31	7,655,901	\$57.62	\$10,510
August 1 - August 31	5,827,454	\$56.02	\$10,184
September 1 - September 30	9,781,700	\$52.48	\$9,670
Total	23,265,055	\$55.06	\$9,670

Shares purchased during the period were made both as part of a plan approved by the Board of Directors in May

<sup>(1)</sup> 2013 to purchase up to \$15 billion in Merck shares and 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)
10	— Agreement Letter between Merck & Co., Inc. and Bruce N. Kuhlik, dated July 21, 2015
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, 2015, formatted in XBRL (Extensible Business Reporting Language): (i) the

Interim Consolidated Statement of Income, (ii) the Interim Consolidated Statement of Comprehensive Income, (iii) the Consolidated Balance Sheet, (iv) the Interim Consolidated Statement of Cash Flows, and (v) Notes to the Interim 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 5, 2015

/s/ Michael J. Holston  
MICHAEL J. HOLSTON  
Executive Vice President and General Counsel

Date: November 5, 2015

/s/ Rita A. Karachun  
RITA A. KARACHUN  
Senior Vice President Finance - Global  
Controller

- 53 -

---

EXHIBIT INDEX

Number	Description
3.1	— Restated Certificate of Incorporation of Merck & Co., Inc. (November 3, 2009) – Incorporated by reference to Current Report on Form 8-K filed on November 4, 2009 (No. 1-6571)
3.2	— By-Laws of Merck & Co., Inc. (effective July 22, 2015) - Incorporated by reference to Current Report on Form 8-K filed on July 28, 2015 (No. 1-6571)
10	— Agreement Letter between Merck & Co., Inc. and Bruce N. Kuhlik, dated July 21, 2015
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, 2015, formatted in XBRL (Extensible Business Reporting Language): (i) the Interim Consolidated Statement of Income, (ii) the Interim Consolidated Statement of Comprehensive Income, (iii) the Consolidated Balance Sheet, (iv) the Interim Consolidated Statement of Cash Flows, and (v) Notes to the Interim Consolidated Financial Statements.