

Merck & Co. Inc.  
Form 10-Q  
November 07, 2013

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, 2013

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.

One Merck Drive

Whitehouse Station, N.J. 08889-0100

(908) 423-1000

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, 2013: 2,921,928,875

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,	
	2013	2012	2013	2012
Sales	\$11,032	\$11,488	\$32,713	\$35,530
Costs, Expenses and Other				
Materials and production	4,104	4,137	12,347	12,286
Marketing and administrative	2,803	3,063	8,929	9,386
Research and development	1,660	1,918	5,668	5,944
Restructuring costs	870	110	1,144	473
Equity income from affiliates	(102	) (158	) (351	) (410
Other (income) expense, net	172	200	656	446
	9,507	9,270	28,393	28,125
Income Before Taxes	1,525	2,218	4,320	7,405
Taxes on Income	375	455	618	2,055
Net Income	1,150	1,763	3,702	5,350
Less: Net Income Attributable to Noncontrolling Interests	26	34	79	89
Net Income Attributable to Merck & Co., Inc.	\$1,124	\$1,729	\$3,623	\$5,261
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	\$0.38	\$0.57	\$1.22	\$1.73
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	\$0.38	\$0.56	\$1.20	\$1.71
Dividends Declared per Common Share	\$0.43	\$0.42	\$1.29	\$1.26

## 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,	
	2013	2012	2013	2012
Net Income Attributable to Merck & Co., Inc.	\$1,124	\$1,729	\$3,623	\$5,261
Other Comprehensive Income (Loss) Net of Taxes:				
Net unrealized (loss) gain on derivatives, net of reclassifications	(102	) (143	) 169	(99
Net unrealized gain (loss) on investments, net of reclassifications	43	32	(37	) 62
Benefit plan net gain and prior service cost, net of amortization	49	27	261	45
Cumulative translation adjustment	72	170	(409	) 84
	62	86	(16	) 92
Comprehensive Income Attributable to Merck & Co., Inc.	\$1,186	\$1,815	\$3,607	\$5,353

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, 2013	December 31, 2012
Assets		
Current Assets		
Cash and cash equivalents	\$14,090	\$13,451
Short-term investments	4,079	2,690
Accounts receivable (net of allowance for doubtful accounts of \$140 in 2013 and \$163 in 2012) (excludes accounts receivable of \$490 in 2013 and \$473 in 2012 classified in Other assets - see Note 4)	7,578	7,672
Inventories (excludes inventories of \$1,474 in 2013 and \$1,606 in 2012 classified in Other assets - see Note 5)	6,741	6,535
Deferred income taxes and other current assets	5,277	4,509
Total current assets	37,765	34,857
Investments	9,198	7,305
Property, Plant and Equipment, at cost, net of accumulated depreciation of \$17,805 in 2013 and \$17,385 in 2012	15,323	16,030
Goodwill	12,121	12,134
Other Intangibles, Net	25,002	29,083
Other Assets	7,010	6,723
	\$106,419	\$106,132
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	\$3,976	\$4,315
Trade accounts payable	2,469	1,753
Accrued and other current liabilities	9,183	9,737
Income taxes payable	1,298	1,200
Dividends payable	1,289	1,343
Total current liabilities	18,215	18,348
Long-Term Debt	22,647	16,254
Deferred Income Taxes and Noncurrent Liabilities	15,551	16,067
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 2013 and 2012		
Other paid-in capital	39,909	40,646
Retained earnings	39,773	39,985
Accumulated other comprehensive loss	(4,698)	(4,682)
	76,772	77,737
Less treasury stock, at cost:		
650,490,309 shares in 2013 and 550,468,221 shares in 2012	29,353	24,717
Total Merck & Co., Inc. stockholders' equity	47,419	53,020
Noncontrolling Interests	2,587	2,443
Total equity	50,006	55,463
	\$106,419	\$106,132

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,	
	2013	2012
Cash Flows from Operating Activities		
Net income	\$3,702	\$5,350
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	5,034	5,317
Intangible asset impairment charges	594	176
Equity income from affiliates	(351)	(410)
Dividends and distributions from equity affiliates	178	181
Deferred income taxes	(532)	(283)
Share-based compensation	210	257
Other	287	(34)
Net changes in assets and liabilities	(494)	(2,341)
Net Cash Provided by Operating Activities	8,628	8,213
Cash Flows from Investing Activities		
Capital expenditures	(1,119)	(1,176)
Purchases of securities and other investments	(13,077)	(6,891)
Proceeds from sales of securities and other investments	9,823	5,607
Other	48	53
Net Cash Used in Investing Activities	(4,325)	(2,407)
Cash Flows from Financing Activities		
Net change in short-term borrowings	151	(280)
Proceeds from issuance of debt	6,467	2,504
Payments on debt	(515)	(4)
Purchases of treasury stock	(6,320)	(1,439)
Dividends paid to stockholders	(3,897)	(3,836)
Proceeds from exercise of stock options	809	1,060
Other	(61)	(54)
Net Cash Used in Financing Activities	(3,366)	(2,049)
Effect of Exchange Rate Changes on Cash and Cash Equivalents	(298)	72
Net Increase in Cash and Cash Equivalents	639	3,829
Cash and Cash Equivalents at Beginning of Year	13,451	13,531
Cash and Cash Equivalents at End of Period	\$14,090	\$17,360

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 28, 2013.

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.

Recently Adopted Accounting Standards

In the first quarter of 2013, the Company adopted guidance issued by the Financial Accounting Standards Board (the “FASB”) that simplifies how an entity tests indefinite-lived intangibles for impairment. The amended guidance allows companies to first assess qualitative factors to determine whether it is more-likely-than-not that an indefinite-lived intangible asset is impaired as a basis for determining whether it is necessary to perform the quantitative impairment test. The adoption of this guidance had no impact on the Company’s financial position and results of operations.

2. Restructuring

2013 Restructuring Program

In October 2013, the Company announced a new global restructuring program (the “2013 Restructuring Program”) as part of a global initiative to sharpen its commercial and research and development focus. As part of the new 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 restructuring costs of \$544 million in the third quarter and first nine months of 2013 related to this 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 \$2.5 billion to \$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 February 2010, subsequent to the Merck and Schering-Plough Corporation (“Schering-Plough”) merger (the “Merger”), the Company commenced actions under a global restructuring program (the “Merger Restructuring Program”) in conjunction with the integration of the legacy Merck and legacy Schering-Plough businesses designed to optimize 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.

On October 1, 2013, the Company sold its active pharmaceutical ingredient (“API”) manufacturing business, including the related manufacturing facility, in the Netherlands to Aspen Holdings (“Aspen”) as part of planned manufacturing facility rationalizations under the Merger Restructuring Program. In conjunction with the sale, the parties entered into a strategic long-term supply agreement and approximately 960 employees who support the API business were transferred from Merck to Aspen. Also in connection with the sale, Aspen will acquire certain branded products from Merck, which will transfer to Aspen effective December 31, 2013. At September 30, 2013, the Company classified \$840 million of assets held for sale in Deferred income taxes and other current assets, which included property, plant

and equipment of \$210 million, inventory of \$430 million and other assets, primarily intangible assets, of \$200 million. The Company recognized a loss of \$42 million within Restructuring costs for the third quarter and first nine months of 2013 to reflect these assets at fair value less costs to sell based on the consideration to be received from Aspen.

- 5 -

---

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

The Company recorded total pretax restructuring costs of \$423 million and \$150 million in the third quarter of 2013 and 2012, respectively, and \$841 million and \$722 million in the first nine months of 2013 and 2012, respectively, related to this program. Since inception of the Merger Restructuring Program through September 30, 2013, Merck has recorded total pretax accumulated costs of approximately \$6.9 billion and eliminated approximately 24,880 positions comprised of employee separations, as well as the elimination of contractors and vacant positions. Approximately 8,300 position eliminations remain pending under this program as of September 30, 2013, which include the remaining actions under the 2008 Restructuring Program that are being reported as part of the Merger Restructuring Program commencing in the third quarter of 2013 as noted below. The restructuring actions under the Merger Restructuring Program are expected to be substantially completed by the end of 2013, with the exception of certain actions, principally manufacturing-related. Subsequent to the Merger, the Company has rationalized a number of manufacturing sites worldwide. The remaining actions under this program will result in additional manufacturing facility rationalizations, which are expected to be substantially completed by 2016. The Company expects the estimated total cumulative pretax costs for this program to be approximately \$7.4 billion to \$7.7 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.

## 2008 Global Restructuring Program

In October 2008, Merck announced a global restructuring program (the “2008 Restructuring Program”) to reduce its cost structure, increase efficiency, and enhance competitiveness. Pretax restructuring costs of \$13 million were recorded in the third quarter of 2012, and \$54 million and \$23 million were recorded in the first nine months of 2013 and 2012, respectively, related to the 2008 Restructuring Program. Since inception of the 2008 Restructuring Program through September 30, 2013, Merck has recorded total pretax accumulated costs of approximately \$1.7 billion and eliminated approximately 6,460 positions comprised of employee separations and the elimination of contractors and vacant positions. The 2008 Restructuring Program was substantially completed in 2011, with the exception of certain manufacturing-related actions, which are expected to be completed by the end of 2015. As of July 1, 2013, the remaining accrued liability for future separations under the 2008 Restructuring Program was transferred to the Merger Restructuring Program and any remaining activities under the 2008 Restructuring Program are being accounted for as part of the Merger Restructuring Program beginning in the third quarter of 2013.

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, 2013				Nine Months Ended September 30, 2013			
	Separation Costs	Accelerated Depreciation	Other	Total	Separation Costs	Accelerated Depreciation	Other	Total
<b>2013 Restructuring Program</b>								
Materials and production	\$—	\$ 20	\$—	\$20	\$—	\$ 20	\$—	\$20
Marketing and administrative	—	15	—	15	—	15	—	15
Research and development	—	8	—	8	—	8	—	8
Restructuring costs	501	—	—	501	501	—	—	501
	501	43	—	544	501	43	—	544
<b>Merger Restructuring Program</b>								
Materials and production	—	30	7	37	—	91	78	169
	—	20	(4	) 16	—	44	1	45



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

Marketing and administrative								
Research and development	—	1	—	1	—	30	—	30
Restructuring costs	241	—	128	369	435	—	162	597
	241	51	131	423	435	165	241	841
2008 Restructuring Program								
Materials and production	—	—	—	—	—	(2	) 6	4
Marketing and administrative	—	—	—	—	—	4	—	4
Restructuring costs	—	—	—	—	34	—	12	46
	—	—	—	—	34	2	18	54
	\$742	\$ 94	\$131	\$967	\$970	\$ 210	\$259	\$1,439

- 6 -

---

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

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

(\$ in millions)	Three Months Ended September 30, 2012				Nine Months Ended September 30, 2012				
	Separation Costs	Accelerated Depreciation	Other	Total	Separation Costs	Accelerated Depreciation	Other	Total	
Merger Restructuring Program									
Materials and production	\$—	\$ 42	\$ 13	\$ 55	\$—	\$ 79	\$ 50	\$ 129	
Marketing and administrative	—	16	3	19	—	59	5	64	
Research and development	—	(33	) <sup>(1)</sup> 1	(32	) —	49	5	54	
Restructuring costs	59	—	49	108	363	—	112	475	
	59	25	66	150	363	187	172	722	
2008 Restructuring Program									
Materials and production	—	1	4	5	—	4	15	19	
Marketing and administrative	—	6	—	6	—	6	—	6	
Restructuring costs	(1	) —	3	2	(12	) —	10	(2	)
	(1	) 7	7	13	(12	) 10	25	23	
	\$58	\$ 32	\$73	\$163	\$351	\$ 197	\$197	\$745	

<sup>(1)</sup> In the third quarter of 2012, the Company recorded an adjustment to accelerated depreciation costs included in research and development expenses revising previously recorded amounts for certain facilities.

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 2013 and 2012, approximately 1,070 positions and 525 positions, respectively, were eliminated under the Merger Restructuring Program. In addition, approximately 10 positions were eliminated in the third quarter of 2012 under the 2008 Restructuring Program. In the first nine months of 2013 and 2012, approximately 2,475 positions and 2,325 positions, respectively, were eliminated under the Merger Restructuring Program and approximately 55 positions and 150 positions, respectively, were eliminated under the 2008 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.

Other activity in 2013 and 2012 includes asset abandonment, shut-down and other related costs. Additionally, other activity includes employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans (see Note 12) and share-based compensation costs.

Adjustments to the recorded amounts were not material in any period.



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

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

The following table summarizes the charges and spending relating to restructuring activities by program for the nine months ended September 30, 2013:

(\$ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
<b>2013 Restructuring Program</b>				
Restructuring reserves January 1, 2013	\$—	\$—	\$—	\$—
Expense	501	43	—	544
(Payments) receipts, net	—	—	—	—
Non-cash activity	—	(43	) —	(43
Restructuring reserves September 30, 2013 <sup>(1)</sup>	\$501	\$—	\$—	\$501
<b>Merger Restructuring Program</b>				
Restructuring reserves January 1, 2013	\$699	\$—	\$19	\$718
Expense	435	165	241	841
(Payments) receipts, net	(374	) —	(90	) (464
Non-cash activity	62	(165	) (122	) (225
Restructuring reserves September 30, 2013 <sup>(1)</sup>	\$822	\$—	\$48	\$870
<b>2008 Restructuring Program</b>				
Restructuring reserves January 1, 2013	\$77	\$—	\$—	\$77
Expense	34	2	18	54
(Payments) receipts, net	(49	) —	(11	) (60
Non-cash activity	(62	) (2	) (7	) (71
Restructuring reserves September 30, 2013	\$—	\$—	\$—	\$—

The cash outlays associated with the 2013 Restructuring Program are expected to be substantially completed by the end of 2015. The cash outlays associated with the Merger Restructuring Program are expected to be substantially completed by the end of 2013 with the exception of certain actions, principally manufacturing-related, which are expected to be substantially completed by 2016.

### 3. Acquisitions, 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 and technology platforms 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 new technologies across a broad range of therapeutic areas. These arrangements often include upfront payments and royalty or profit share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development, as well as expense reimbursements or payments to the third party. In April 2013, Merck and Pfizer Inc. (“Pfizer”) announced that they had entered into a worldwide (except Japan) collaboration agreement for the development and commercialization of Pfizer’s ertugliflozin, an investigational oral sodium glucose cotransporter (“SGLT2”) inhibitor being evaluated for the treatment of type 2 diabetes. The Company is initiating Phase III clinical trials for ertugliflozin with Pfizer. Under the terms of the agreement, Merck and Pfizer will collaborate on the clinical development and commercialization of ertugliflozin and ertugliflozin-containing fixed-dose combinations with metformin and with Januvia (sitagliptin) tablets. Merck will continue to retain the rights to its existing portfolio of sitagliptin-containing products. Through the first nine months of 2013, Merck recorded as Research and development expenses \$60 million of upfront and milestone payments made to Pfizer. Pfizer will be eligible for additional payments associated with the achievement of pre-specified future clinical, regulatory and commercial milestones, including \$65 million for the initiation of Phase III clinical trials. The companies will share potential revenues and certain costs 60% to Merck and 40% to Pfizer. Each party will have certain manufacturing and supply obligations. The Company and Pfizer each have the right to terminate the agreement due to a material, uncured

breach by, or insolvency of, the other party, or in the event of a safety issue. Pfizer has the right to terminate the agreement upon 12 months notice at any time following the first anniversary of the first commercial sale of a collaboration product, but must assign all rights to ertugliflozin to Merck. Upon termination of the agreement, depending upon the circumstances, the parties have varying rights and obligations with respect to the continued development and commercialization of ertugliflozin and certain payment obligations.

In February 2013, Merck and Supera Farma Laboratorios S.A. (“Supera”), a Brazilian pharmaceutical company co-owned by Cristália and Eurofarma, established the previously announced joint venture that markets, distributes and sells a portfolio of pharmaceutical and branded generic products from Merck, Cristália and Eurofarma in Brazil. Merck owns 51% of the joint venture,

- 8 -

---

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

and Cristália and Eurofarma collectively own 49%. 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. This resulted in Merck recognizing intangible assets for currently marketed products of \$89 million, in-process research and development (“IPR&D”) of \$100 million, goodwill of \$103 million, and deferred tax liabilities of \$64 million. The Company also recorded increases to Noncontrolling interests and Other paid-in capital in the amounts of \$112 million and \$116 million, respectively. This transaction closed on February 1, 2013, and accordingly, the results of operations of the acquired business have been included in the Company’s results of operations beginning after that date.

#### 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, 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, a fully human monoclonal antibody. The Company has exclusive marketing rights to both products throughout Europe, Russia and Turkey. All profits derived from Merck’s exclusive distribution of the two products in these countries are equally divided between Merck and J&J. 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 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 (the “EU”) following the receipt of pricing and reimbursement approval within the EU.

## 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

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

puts through the collection of premium 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 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 and Japanese yen. For exposures in developing country currencies, the Company will enter into forward contracts to partially offset the effects of exchange on exposures when it is deemed economical to do so based on a cost-benefit analysis that considers the magnitude of the exposure, the volatility of the exchange rate and the cost of the hedging instrument. The Company will also minimize the effect of exchange on monetary assets and liabilities by managing operating activities and net asset positions at the local level.

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 (losses) gains of \$(33) million and \$35 million for the first nine months of 2013 and 2012, respectively, from the euro-denominated notes.

- 10 -

---

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

## 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. There were no interest rate swaps outstanding as of December 31, 2012.

During the third quarter of 2013, the Company entered into six interest rate swap contracts and is now a party to a total of 15 pay-floating, received-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. There are four swaps maturing in 2016 with notional amounts of \$250 million each that effectively convert the Company's 0.70% fixed-rate notes due 2016 to floating-rate instruments; four swaps maturing in 2018 with notional amounts of \$250 million each that effectively convert the Company's 1.30% fixed-rate notes due 2018 to floating-rate instruments; four swaps maturing in 2017, one with a notional amount of \$200 million, two with notional amounts of \$250 million each, and one with a notional amount of \$300 million, that effectively convert the Company's 6.00% fixed-rate notes due 2017 to floating-rate instruments; and three swaps maturing in 2019, two with notional amounts of \$200 million each, and one with a notional amount of \$150 million, that effectively convert a portion of the Company's 5.00% notes due 2019 to floating rate instruments. 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, 2013			December 31, 2012		
		Fair Value of Derivative		U.S. Dollar	Fair Value of Derivative		U.S. Dollar
		Asset	Liability	Notional	Asset	Liability	Notional
Derivatives Designated as Hedging Instruments							
Interest rate swap contracts (non-current)	Other assets	\$22	\$—	\$ 1,550	\$—	\$—	\$ —
Interest rate swap contracts (non-current)	Deferred income taxes and noncurrent liabilities	—	22	2,000	—	—	—
Foreign exchange contracts (current)	Deferred income taxes and other current assets	454	—	5,549	281	—	6,646
Foreign exchange contracts (non-current)	Other assets	460	—	6,071	387	—	5,989
Foreign exchange contracts (current)	Accrued and other current liabilities	—	1	303	—	13	938
Foreign exchange contracts (non-current)	Deferred income taxes and noncurrent liabilities	—	3	573	—	—	—
		\$936	\$26	\$ 16,046	\$668	\$13	\$ 13,573

Derivatives Not Designated as  
Hedging Instruments

Foreign exchange contracts (current)	Deferred income taxes and other current assets	\$ 15	\$—	\$ 2,237	\$55	\$—	\$ 4,548
Foreign exchange contracts (non-current)	Other assets	—	—	—	8	—	232
Foreign exchange contracts (current)	Accrued and other current liabilities	—	93	6,657	—	216	8,203
		\$ 15	\$ 93	\$ 8,894	\$ 63	\$ 216	\$ 12,983
		\$ 951	\$ 119	\$ 24,940	\$ 731	\$ 229	\$ 26,556

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:

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

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

(\$ in millions)	September 30, 2013		December 31, 2012	
	Asset	Liability	Asset	Liability
Gross amounts recognized in the consolidated balance sheet	\$951	\$119	\$731	\$229
Gross amount subject to offset in master netting arrangements not offset in the consolidated balance sheet	(113 )	(114 )	(195 )	(195 )
Cash collateral (received) posted	(566 )	—	(305 )	—
Net amounts	\$272	\$5	\$231	\$34

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 September 30, 2013		Nine Months Ended September 30, 2013	
	2013	2012	2013	2012
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>	\$(33 )	\$—	\$1	\$—
Amount of loss (gain) recognized in Other (income) expense, net on hedged item <sup>(1)</sup>	30	—	(2 )	—
Derivatives designated in foreign currency cash flow hedging relationships				
Foreign exchange contracts				
Amount of loss (gain) reclassified from AOCI to Sales	1	(4 )	36	49
Amount of loss (gain) recognized in OCI on derivatives	165	236	(219 )	202
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>	(5 )	(5 )	(7 )	(15 )
Amount of (gain) loss recognized in OCI on derivatives	(15 )	54	(259 )	(2 )
Derivatives not designated in a hedging relationship				
Foreign exchange contracts				
Amount of loss recognized in Other (income) expense, net on derivatives <sup>(3)</sup>	154	157	146	131
Amount of loss recognized in Sales on hedged item	8	17	5	17

<sup>(1)</sup> There was \$3 million of ineffectiveness on the hedged item during the third quarter and first nine months of 2013.

<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, 2013, the Company estimates \$16 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, 2013				December 31, 2012			
	Fair Value	Amortized Cost	Gross Gains	Unrealized Losses	Fair Value	Amortized Cost	Gross Gains	Unrealized Losses
Corporate notes and bonds	\$6,651	\$ 6,640	\$29	\$(18 )	\$5,063	\$ 5,013	\$52	\$(2 )
Commercial paper	2,532	2,532	—	—	2,150	2,150	—	—
U.S. government and agency securities	2,061	2,064	1	(4 )	1,206	1,204	2	—
Asset-backed securities	1,119	1,121	2	(4 )	837	835	3	(1 )
Mortgage-backed securities	608	611	2	(5 )	435	436	2	(3 )
Foreign government bonds	92	93	—	(1 )	108	107	1	—
Equity securities	453	400	53	—	403	370	33	—
	\$13,516	\$ 13,461	\$87	\$(32 )	\$10,202	\$ 10,115	\$93	\$(6 )

Available-for-sale debt securities included in Short-term investments totaled \$4.1 billion at September 30, 2013. Of the remaining debt securities, \$8.1 billion mature within five years. At September 30, 2013 and December 31, 2012, there were no debt securities pledged as collateral.

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

## Fair Value Measurements

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

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

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

Level 3 - Unobservable inputs that are supported by little or no market activity. Level 3 assets are those whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques with significant unobservable inputs, as well as instruments 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:

	Fair Value Measurements Using				Fair Value Measurements Using			
	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
(\$ in millions)	September 30, 2013				December 31, 2012			
Assets								
Investments								
Corporate notes and bonds	\$—	\$ 6,651	\$ —	\$6,651	\$—	\$ 5,063	\$ —	\$5,063
Commercial paper	—	2,532	—	2,532	—	2,150	—	2,150
U.S. government and agency securities	—	2,061	—	2,061	—	1,206	—	1,206
Asset-backed securities <sup>(1)</sup>	—	1,119	—	1,119	—	837	—	837
Mortgage-backed securities <sup>(1)</sup>	—	608	—	608	—	435	—	435
Foreign government bonds	—	92	—	92	—	108	—	108
Equity securities	214	—	—	214	196	—	—	196
	214	13,063	—	13,277	196	9,799	—	9,995
Other assets								
Securities held for employee compensation	195	44	—	239	169	38	—	207
Derivative assets <sup>(2)</sup>								
Purchased currency options	—	774	—	774	—	546	—	546
	—	155	—	155	—	185	—	185

Forward exchange contracts								
Interest rate swaps	—	22	—	22	—	—	—	—
	—	951	—	951	—	731	—	731
Total assets	\$409	\$ 14,058	\$ —	\$14,467	\$365	\$ 10,568	\$ —	\$10,933
Liabilities								
Derivative liabilities <sup>(2)</sup>								
Forward exchange contracts	\$—	\$ 96	\$ —	\$96	\$—	\$ 216	\$ —	\$216
Written currency options	—	1	—	1	—	13	—	13
Interest rate swaps	—	22	—	22	—	—	—	—
Total liabilities	\$—	\$ 119	\$ —	\$119	\$—	\$ 229	\$ —	\$229

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 2013. As of September 30, 2013, Cash and cash equivalents of \$14.1 billion included \$13.1 billion of cash equivalents (considered Level 2 in the fair value hierarchy).

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

### 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, 2013, was \$27.3 billion compared with a carrying value of \$26.6 billion and at December 31, 2012, was \$22.8 billion compared with a carrying value of \$20.6 billion. Fair value was estimated using recent observable market prices and would be considered Level 2 in the fair value hierarchy. At September 30, 2013, the Company classified assets held for sale of approximately \$840 million within Deferred income taxes and other current assets related to the sale of its API manufacturing business in the Netherlands (see Note 2). The fair value of these assets was based on the consideration to be received, which consists of cash (considered Level 1 in the fair value hierarchy) and notes receivable (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. Approximately one-third of the Company's cash and cash equivalents are invested in three highly rated money market funds.

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. The Company continues to monitor the credit and economic conditions within Greece, Italy, Spain, and Portugal, among other members of the EU. These economic conditions, as well as inherent variability of timing of cash receipts, have resulted in, and may continue to result in, an increase in the average length of time that it takes to collect accounts receivable outstanding. As such, time value of money discounts have been recorded for those customers for which collection of accounts receivable is expected to be in excess of one year. At September 30, 2013 and December 31, 2012, Other assets included \$490 million and \$473 million, respectively, of accounts receivable not expected to be collected within one year. 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.

At September 30, 2013, the Company's accounts receivable in Greece, Italy, Spain and Portugal totaled approximately \$1.2 billion. Of this amount, hospital and public sector receivables were approximately \$850 million in the aggregate, of which approximately 9%, 31%, 48% and 12% related to Greece, Italy, Spain and Portugal, respectively. At September 30, 2013, the Company's total accounts receivable outstanding for more than one year were approximately \$340 million, of which approximately 70% related to accounts receivable in Greece, Italy, Spain and Portugal, mostly comprised of hospital and public sector receivables.

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, 2013 and December 31, 2012, the Company had received cash collateral of \$566 million and \$305 million, respectively, from various counterparties and the obligation to return such collateral is recorded in Accrued and other current liabilities. The Company had not advanced any cash collateral to counterparties as of September 30,



2013 or December 31, 2012.

- 14 -

---

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

## 5. Inventories

Inventories consisted of:

(\$ in millions)	September 30, 2013	December 31, 2012
Finished goods	\$1,757	\$1,924
Raw materials and work in process	6,171	5,921
Supplies	235	244
Total (approximates current cost)	8,163	8,089
Increase to LIFO costs	52	52
	\$8,215	\$8,141
Recognized as:		
Inventories	\$6,741	\$6,535
Other assets	1,474	1,606

Amounts recognized as Other assets are comprised almost entirely of raw materials and work in process inventories. At September 30, 2013 and December 31, 2012, these amounts included \$1.3 billion and \$1.4 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included \$157 million and \$196 million at September 30, 2013 and December 31, 2012, respectively, of inventories produced in preparation for product launches.

## 6. Other Intangibles

In connection with mergers and acquisitions, the Company measures the fair value of marketed products and research and development pipeline programs and capitalizes these amounts. During the first nine months of 2013, the Company recorded an intangible asset impairment charge of \$330 million within Materials and production costs related to Saphris/Sycrest. During the second quarter, the Company reduced cash flow projections for Saphris/Sycrest as a result of reduced expectations in international markets and in the United States. These revisions to cash flows indicated that the Saphris/Sycrest intangible asset value was not recoverable on an undiscounted cash flows basis. Utilizing market participant assumptions, and considering several different scenarios, the Company concluded that its best estimate of the current fair value of the intangible asset related to Saphris/Sycrest was approximately \$170 million, which resulted in the recognition of an impairment charge.

In addition, during the third quarter of 2012, the Company recorded \$40 million, and during the first nine months of 2013 and 2012, recorded \$264 million and \$176 million, respectively, of IPR&D impairment charges within Research and development expenses. Of the IPR&D impairment charges recorded in the first nine months of 2013, \$181 million related to the write-off of the intangible asset associated with preladenant as a result of the discontinuation of the clinical development program for this compound. In addition, the Company recorded impairment charges resulting from changes in cash flow assumptions for certain compounds. The remaining impairment charges for the first nine months of 2013 and the charges in the third quarter and first nine months of 2012 reflect impairments primarily related to pipeline programs that had previously been deprioritized and were subsequently deemed to have no alternative use in the period. 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.

During the first quarter of 2013, the Company recorded goodwill and other intangible assets in connection with the formation of a joint venture with Supera (see Note 3).

## 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 and was comprised of the following:

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

(\$ in millions)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2013	2012	2013	2012
AstraZeneca LP	\$72	\$134	\$302	\$387
Other <sup>(1)</sup>	30	24	49	23
	\$102	\$158	\$351	\$410

<sup>(1)</sup> Includes results from Sanofi Pasteur MSD.

- 15 -

---

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

## AstraZeneca LP

In 1998, Merck and Astra completed the restructuring of the ownership and operations of their existing joint venture whereby Merck acquired Astra's interest in KBI Inc. ("KBI") and contributed KBI's operating assets to a new U.S. limited partnership, Astra Pharmaceuticals L.P. (the "Partnership"), 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.

In 2014, AstraZeneca has the option to purchase Merck's interest in KBI based in part on the value of Merck's interest in Nexium and Prilosec. AstraZeneca's option is exercisable between March 1, 2014 and April 30, 2014. If

AstraZeneca chooses to exercise this option, the closing date is expected to be June 30, 2014. Under the amended agreement, AstraZeneca will make a payment to Merck upon closing of \$327 million, reflecting an estimate of the fair value of Merck's interest in Nexium and Prilosec. This portion of the exercise price is subject to a true-up in 2018 based on actual sales from closing in 2014 to June 2018. The exercise price will also include an additional amount equal to a multiple of ten times Merck's average 1% annual profit allocation in the partnership for the three years prior to exercise. The Company believes that it is likely that AstraZeneca will exercise its option in 2014.

Summarized financial information for AZLP is as follows:

(\$ in millions)	Three Months Ended		Nine Months Ended	
	September 30, 2013	September 30, 2012	September 30, 2013	September 30, 2012
Sales	\$1,083	\$1,232	\$3,383	\$3,424
Materials and production costs	554	561	1,681	1,520
Other expense, net	398	204	1,198	936
Income before taxes <sup>(1)</sup>	\$131	\$467	\$504	\$968

<sup>(1)</sup> Merck's partnership returns from AZLP are generally contractually determined and are not based on a percentage of income from AZLP, other than with respect to Merck's 1% limited partnership interest.

## 8. Loans Payable, Long-Term Debt and Other Commitments

In May 2013, the Company completed an underwritten public offering of \$6.5 billion senior unsecured notes consisting of \$1.0 billion aggregate principal amount of 0.70% notes due 2016, \$500 million aggregate principal amount of floating rate notes due 2016, \$1.0 billion aggregate principal amount of 1.30% notes due 2018, \$1.0 billion aggregate principal amount of floating rate notes due 2018, \$1.75 billion aggregate principal amount of 2.80% notes due 2023 and \$1.25 billion aggregate principal amount of 4.15% notes due 2043. Interest on the notes is payable semi-annually. The notes of each series are redeemable in whole or in part at any time at the Company's option at varying redemption prices. A substantial portion of the net proceeds from the notes were used to repurchase the Company's common stock pursuant to an accelerated share repurchase agreement in May 2013 (see Note 10).

## 9. Contingencies and Environmental Liabilities

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 additional matters such as antitrust actions and 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

- 16 -

---

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

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 certain product liabilities effective August 1, 2004.

#### Vioxx Litigation

##### Product Liability Lawsuits

As previously disclosed, Merck is a defendant in approximately 90 federal and state lawsuits (the "Vioxx Product Liability Lawsuits") alleging personal injury or economic loss as a result of the purchase or use of Vioxx. Most of the remaining cases are coordinated in a multidistrict litigation in the U.S. District Court for the Eastern District of Louisiana (the "Vioxx MDL") before Judge Eldon E. Fallon.

There are pending in various U.S. courts putative class actions purportedly brought on behalf of individual purchasers or users of Vioxx seeking reimbursement for alleged economic loss. In the Vioxx MDL proceeding, approximately 30 such class actions remain. In June 2010, Merck moved to strike the class claims or for judgment on the pleadings regarding the master complaint, which includes the above-referenced cases, and briefing on that motion was completed in September 2010. The Vioxx MDL court heard oral argument on Merck's motion in October 2010 and took it under advisement.

In July 2013, Merck entered into a proposed settlement in the Vioxx MDL which would resolve Vioxx-related consumer economic loss claims asserted against the Company by all non-Missouri resident consumers who purchased Vioxx and seek to recover economic damages. Merck previously settled a similar Vioxx consumer class action in Missouri. Under the proposed settlement, Merck would pay up to \$23 million to pay all properly documented claims submitted by class members, approved attorneys' fees and expenses, and approved settlement notice costs and certain other administrative expenses. The settlement is subject to court approval, and the court has set a final fairness hearing on the settlement for December 2013.

In 2008, a Missouri state court certified a class of Missouri plaintiffs seeking reimbursement for out-of-pocket costs relating to Vioxx. In October 2012, the parties executed a settlement agreement to resolve the litigation. The Company established a reserve of \$39 million in the third quarter of 2012 in connection with that settlement agreement, which is the minimum amount that the Company is required to pay under the agreement. The court-approved program to notify class members about the settlement has been completed. The settlement was approved, and final judgment in the action has been entered. The court-approved process for class members to submit claims under the settlement closed on October 7, 2013.

In Indiana, plaintiffs filed a motion to certify a class of Indiana Vioxx purchasers in a case pending before the Circuit Court of Marion County, Indiana. That case has been dormant for several years. In April 2010, a Kentucky state court denied Merck's motion for summary judgment and certified a class of Kentucky plaintiffs seeking reimbursement for out-of-pocket costs relating to Vioxx. The trial court subsequently entered an amended class certification order in January 2011. Merck appealed that order to the Kentucky Court of Appeals and, in February 2012, the Kentucky Court of Appeals reversed the trial court's amended class certification order and remanded the case to the trial court with instructions that the trial court vacate its order certifying the class. The plaintiff petitioned the Kentucky Supreme Court to review the Court of Appeals' order and, in November 2012, the Kentucky Supreme Court granted review. Briefing before the Kentucky Supreme Court is now complete and the court heard oral argument on May 15, 2013. Merck has also been named as a defendant in lawsuits brought by state Attorneys General of five states — Alaska, Kentucky, Mississippi, Montana and Utah. All of these actions except for the Kentucky action are in the Vioxx MDL proceeding. These actions allege that Merck misrepresented the safety of Vioxx. These suits seek recovery for expenditures on Vioxx by government-funded health care programs, such as Medicaid, and/or penalties for alleged Consumer Fraud Act violations. The parties have tentatively reached an agreement to settle the Kentucky action. On January 10, 2013, Merck finalized a settlement in the action filed by the Pennsylvania Attorney General under which Merck agreed to pay Pennsylvania \$8.25 million in exchange for the dismissal of its lawsuit.

Shareholder Lawsuits

As previously disclosed, in addition to the Vioxx Product Liability Lawsuits, various putative class actions and individual lawsuits under federal securities laws and state laws have been filed against Merck and various current and former officers and directors (the “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 claims based on statements made on or after the voluntary withdrawal

- 17 -

---

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

of Vioxx on September 30, 2004, have been dismissed. In October 2011, defendants answered the Fifth Amended Class Action Complaint. In April 2012, plaintiffs filed a motion for class certification and, on January 30, 2013, Judge Chesler granted that motion. On March 15, 2013, plaintiffs filed a motion for leave to amend their complaint to add certain allegations to expand the class period. On May 29, 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. On June 30, 2013, plaintiffs filed their Sixth Amended Class Action Complaint. On July 1, 2013, defendants answered the Sixth Amended Class Action Complaint. Fact discovery is now closed; expert discovery is currently proceeding in accordance with the court's scheduling order.

As previously disclosed, several individual securities lawsuits filed by foreign institutional investors also are consolidated with the Vioxx Securities Lawsuits. In October 2011, plaintiffs filed amended complaints in each of the pending individual securities lawsuits. Also in October 2011, a new individual securities lawsuit (the "KBC Lawsuit") was filed in the District of New Jersey by several foreign institutional investors; that case is also consolidated with the Vioxx Securities Lawsuits. In January 2012, defendants filed motions to dismiss in one of the individual lawsuits (the "ABP Lawsuit"). Briefing on the motions to dismiss was completed in March 2012. In August 2012, Judge Chesler granted in part and denied in part the motions to dismiss the ABP Lawsuit. Among other things, certain alleged misstatements and omissions were dismissed as inactionable and all state law claims were dismissed in full. In September 2012, defendants answered the complaints in all individual actions other than the KBC Lawsuit; on the same day, defendants moved to dismiss the complaint in the KBC Lawsuit on statute of limitations grounds. In December 2012, Judge Chesler denied the motion to dismiss the KBC Lawsuit and, on January 4, 2013, defendants answered the complaint in the KBC Lawsuit. Fact discovery is now closed; expert discovery is currently proceeding in the individual securities lawsuits together with expert discovery in the class action.

#### Insurance

The Company has Directors and Officers insurance coverage applicable to the Vioxx Securities Lawsuits with remaining stated upper limits of approximately \$170 million, which is currently being used to partially fund the Company's legal fees. 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, Europe and Israel (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 Lawsuits") 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 Lawsuits. The Company has established a reserve with respect to the Canadian settlement, certain other Vioxx Product Liability Lawsuits and other immaterial settlements related to certain Vioxx International 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 (the "Fosamax Litigation"). As of September 30, 2013, approximately 5,255 cases, which include approximately 5,535 plaintiff groups, 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 1,140 of these actions, plaintiffs allege, among other things, that they have suffered osteonecrosis of the jaw ("ONJ"), generally subsequent to invasive dental procedures, such as tooth extraction or dental implants and/or delayed healing, in association with the use of Fosamax. In addition, plaintiffs in approximately

- 18 -

---

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

4,115 of these actions generally allege that they sustained femur fractures and/or other bone injuries (“Femur Fractures”) in association with the use of Fosamax.

Cases Alleging ONJ and/or Other Jaw Related Injuries

In August 2006, the Judicial Panel on Multidistrict Litigation (the “JPML”) ordered that certain Fosamax product liability cases pending in federal courts nationwide should be transferred and consolidated into one multidistrict litigation (the “Fosamax ONJ MDL”) for coordinated pre-trial proceedings. The Fosamax ONJ MDL has been transferred to Judge John Keenan in the U.S. District Court for the Southern District of New York. As a result of the JPML order, approximately 860 of the cases are before Judge Keenan. In the first Fosamax ONJ MDL trial, *Boles v. Merck*, the Fosamax ONJ MDL court declared a mistrial because the eight person jury could not reach a unanimous verdict. The *Boles* case was retried in June 2010 and resulted in a verdict in favor of the plaintiff in the amount of \$8 million. Merck filed post-trial motions seeking judgment as a matter of law or, in the alternative, a new trial. In October 2010, the court denied Merck’s post-trial motions but sua sponte ordered a remittitur reducing the verdict to \$1.5 million. Plaintiff rejected the remittitur ordered by the court and requested a new trial on damages. Plaintiff and Merck subsequently entered into a confidential stipulation as to the amount of plaintiff’s damages that enabled Merck to appeal the underlying judgment, and Merck filed its appeal in the *Boles* case in October 2012. Prior to 2013, three other cases were tried to verdict in the Fosamax ONJ MDL. Defense verdicts in favor of Merck were returned in each of those three cases. Plaintiffs have filed an appeal in two of the cases – *Graves v. Merck* and *Secrest v. Merck*. On January 30, 2013, the U.S. Court of Appeals for the Second Circuit affirmed the judgment in Merck’s favor in *Secrest*. Plaintiff in the *Secrest* case subsequently filed a petition for a writ of certiorari with the U.S. Supreme Court, but that petition was denied on June 3, 2013.

In February 2011, Judge Keenan ordered that two further bellwether trials be conducted in the Fosamax ONJ MDL. *Spano v. Merck* and *Jellema v. Merck* were selected by the court to be tried in 2012, but each case was dismissed by the plaintiffs. In March 2012, the court selected *Scheinberg v. Merck* as the next case to be tried. Trial in the *Scheinberg* case began on January 14, 2013 and, on February 5, 2013, the jury returned a mixed verdict, finding in favor of Merck on plaintiff’s design defect claim, and finding in favor of plaintiff on her failure to warn claim and awarding her \$285 thousand in compensatory damages. Merck’s post-trial motion for judgment as a matter of law in the *Scheinberg* case was denied on July 1, 2013, and the Company has filed an appeal with the U.S. Court of Appeals for the Second Circuit.

In November 2012, Judge Keenan issued an order requiring plaintiffs who do not allege certain types of specific injuries to provide expert reports in support of their claims. The deadlines for submission of these reports were staggered throughout the first half of 2013, and failure to comply with the order may result in dismissal of a plaintiff’s claim. To date, the claims of approximately 425 plaintiffs subject to the order have been dismissed with prejudice. In August 2013, Judge Keenan denied Merck’s request to extend his order to additional groups of plaintiffs and also decided to start winding down the Fosamax ONJ MDL by the remand/transfer of the remaining cases back to their proper venues at a rate of 200 cases per month beginning November 1, 2013. That date was subsequently changed at plaintiffs’ request to December 1, 2013.

In addition, in July 2008, an application was made by the Atlantic County Superior Court of New Jersey requesting that all of the Fosamax cases pending in New Jersey be considered for mass tort designation and centralized management before one judge in New Jersey. In October 2008, the New Jersey Supreme Court ordered that all pending and future actions filed in New Jersey arising out of the use of Fosamax and seeking damages for existing dental and jaw-related injuries, including ONJ, but not solely seeking medical monitoring, be designated as a mass tort for centralized management purposes before Judge Carol E. Higbee in Atlantic County Superior Court. As of September 30, 2013, approximately 280 ONJ cases were pending against Merck in Atlantic County, New Jersey. In July 2009, Judge Higbee entered a Case Management Order (and various amendments thereto) setting forth a schedule that contemplates completing fact and expert discovery in an initial group of cases to be reviewed for trial. In February 2011, the jury in *Rosenberg v. Merck*, the first trial in the New Jersey coordinated proceeding, returned a verdict in Merck’s favor. In April 2012, the jury in *Sessner v. Merck*, the second case tried in New Jersey, also returned a verdict in Merck’s favor. Plaintiffs have filed an appeal in both cases. On March 25, 2013, the New Jersey Appellate Division affirmed the judgment in Merck’s favor in the *Rosenberg* case.

Discovery is ongoing in the Fosamax ONJ MDL litigation, the New Jersey coordinated proceeding, and the remaining jurisdictions where Fosamax ONJ cases are pending. The Company intends to defend against these lawsuits.

Cases Alleging Femur Fractures

In March 2011, Merck submitted a Motion to Transfer to the JPML seeking to have all federal cases alleging Femur Fractures consolidated into one multidistrict litigation for coordinated pre-trial proceedings. The Motion to Transfer was granted in May 2011, and all federal cases involving allegations of Femur Fracture have been or will be transferred to a multidistrict litigation in the District of New Jersey (the "Fosamax Femur Fracture MDL"). As a result of the JPML order, approximately 1,085 cases were pending in the Fosamax Femur Fracture MDL as of September 30, 2013. A Case Management Order was entered requiring the parties to review 40 cases (later reduced to 33 cases). Judge Joel Pisano selected four cases from that group to be

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

tried as the initial bellwether cases in the Fosamax Femur Fracture MDL. The first bellwether case, *Glynn v. Merck*, began on April 8, 2013, and the jury returned a verdict in Merck's favor on April 29, 2013; in addition, on June 27, 2013, Judge Pisano 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. Plaintiff *Glynn* did not appeal that ruling and the *Glynn* judgment entered in Merck's favor is now final. The trial dates in the other three cases that were scheduled for bellwether trials (*Zessin v. Merck*, *Young v. Merck*, and *Johnson v. Merck*) were subsequently suspended and, instead, Judge Pisano set a May 5, 2014, trial date for the bellwether trial of a case where the alleged injury took place after January 31, 2011. The case to be tried on May 5, 2014, is expected to be identified in December 2013.

In addition, Judge Pisano entered an order in August 2013 requiring plaintiffs in the Fosamax 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. Plaintiffs filed their responses to the show cause order at the end of September 2013 and Merck filed its reply to those responses on October 30, 2013. As of September 30, 2013, approximately 2,520 cases alleging Femur Fractures have been filed in New Jersey state court and are pending before Judge Higbee in Atlantic County Superior Court. The parties have selected an initial group of 30 cases to be reviewed through fact discovery. The first trial of the New Jersey state Femur Fracture cases, *Su v. Merck*, began on March 11, 2013, but a mistrial was declared on March 28, 2013, after the plaintiff suffered a serious medical issue unrelated to her use of Fosamax that prevented her from proceeding with the trial. The next trial, *Unanski v. Merck*, was set to be tried beginning November 4, 2013, but was continued and is now set for trial, potentially along with one or two other cases (*Love v. Merck* and *Caravello v. Merck*), beginning on March 10, 2014. As of September 30, 2013, approximately 495 cases alleging Femur Fractures have been filed 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 Steven Perk is now presiding over the coordinated proceedings. No scheduling order has yet been entered.

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

Discovery is ongoing in the Fosamax 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, 2013, there were approximately 95 cases, which include approximately 100 plaintiff groups, filed and pending against Merck alleging that use of Januvia and/or Janumet caused the development of pancreatic cancer. These complaints were filed in several different state and federal courts, with the majority filed in the U.S. District Court for the Southern District of California. On April 5, 2013, a law firm representing certain plaintiffs filed a request with the JPML to create a federal MDL for lawsuits alleging pancreatic cancer due to use of the following medicines: Januvia, Janumet, and Byetta and Victoza, the latter two of which are products manufactured by other pharmaceutical companies. On August 26, 2013, the JPML granted the MDL request, created the "In re Incretin-Based Therapies Products Liability Litigation" MDL (the "Incretin MDL") in the U.S. District Court for the Southern District of California, and appointed Judge Anthony Battaglia to preside over the Incretin MDL. In addition to the cases noted above, the Company has agreed, as of September 30, 2013, to toll the statute of limitations until December 1, 2013, for an additional 54 claims. The Company intends to defend against these lawsuits.

#### NuvaRing

As previously disclosed, beginning in May 2007, a number of complaints were filed in various jurisdictions asserting claims against the Company's subsidiaries Organon USA, Inc., Organon Pharmaceuticals USA, Inc., Organon International (collectively, "Organon"), and the Company arising from Organon's marketing and sale of NuvaRing, a combined hormonal contraceptive vaginal ring. The plaintiffs contend that Organon and Schering-Plough, 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 are currently pending in a federal multidistrict litigation (the "NuvaRing MDL") venued in Missouri and in a coordinated proceeding in New Jersey state court.

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

As of September 30, 2013, there were approximately 1,715 NuvaRing cases. Of these cases, approximately 1,500 are or will be pending in the NuvaRing MDL in the U.S. District Court for the Eastern District of Missouri before Judge Rodney Sippel, and approximately 210 are pending in coordinated proceedings in the Bergen County Superior Court of New Jersey before Judge Brian R. Martinotti. Nine additional cases are pending in various other state courts, including three cases in a coordinated state

- 20 -

---

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

proceeding in the San Francisco Superior Court in California before Judge John E. Munter. Certain state court cases are scheduled for trial in 2014.

Pursuant to orders of Judge Sippel in the NuvaRing MDL, the parties originally selected a pool of more than 20 cases to prepare for trial and that pool was then narrowed to seven cases from which the first trials in the NuvaRing MDL will be selected. Judge Sippel recently denied the Company's motion for summary judgment in the first NuvaRing MDL trial which is expected to take place in the second quarter of 2014.

Pursuant to Judge Martinotti's order in the New Jersey proceeding, the parties selected nine trial pool cases to be prepared for trial. The plaintiffs voluntarily dismissed with prejudice two of the trial pool cases while the Company's summary judgment motions were pending. Judge Martinotti granted the Company's motions for summary judgment with respect to each of the remaining seven trial pool cases. Based on this ruling, there was no trial in New Jersey in June 2013 as previously expected. A further trial date has not been set in the remaining cases.

The Company has certain insurance coverage available to it, which is currently being used to partially fund the Company's legal fees. The Company intends to defend against these lawsuits.

**Propecia/Proscar**

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving Propecia and/or Proscar. As of September 30, 2013, approximately 1,130 lawsuits involving a total of approximately 1,380 plaintiffs (in some instances spouses are joined as plaintiffs in the suits) who allege that they have experienced persistent sexual side effects following cessation of treatment with Propecia and/or Proscar have been filed against Merck. Approximately 20 of the plaintiffs also allege that Propecia or Proscar has caused or can cause prostate 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 MDL 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. The Company intends to defend against these lawsuits.

**Vytorin/Zetia Litigation**

As previously disclosed, in April 2008, a Merck shareholder filed a putative class action lawsuit in federal court which was consolidated in the District of New Jersey with another federal securities lawsuit under the caption *In re Merck & Co., Inc. Vytorin Securities Litigation*. An amended consolidated complaint was filed in October 2008. A second amended consolidated complaint was filed in February 2012, and named as defendants Merck; Merck/Schering-Plough Pharmaceuticals; MSP Distribution Services (C) LLC; MSP Singapore Company LLC; and certain of the Company's current and former officers and directors. The complaint alleged that Merck delayed releasing unfavorable results of the ENHANCE clinical trial regarding the efficacy of Vytorin and that Merck made false and misleading statements about expected earnings, knowing that once the results of the ENHANCE study were released, sales of Vytorin would decline and Merck's earnings would suffer. On February 14, 2013, Merck announced that it had reached an agreement in principle with plaintiffs to settle this matter for \$215 million. On June 4, 2013, plaintiffs moved for preliminary approval of the settlement, which the court granted on June 7, 2013. On July 2, 2013, plaintiffs moved for final approval of the settlement. A final fairness hearing was held on October 1, 2013. Following the hearing, the court issued an opinion and order approving the settlement, and entered a final judgment dismissing the case with prejudice. The settlement was reflected in the Company's 2012 financial results as discussed below. There was a similar consolidated, putative class action securities lawsuit pending in the District of New Jersey, filed by a Schering-Plough shareholder against Schering-Plough and its former Chairman, President and Chief Executive Officer, Fred Hassan, under the caption *In re Schering-Plough Corporation/ENHANCE Securities Litigation*. The amended consolidated complaint was filed in September 2008 and named as defendants Schering-Plough; Merck/Schering-Plough Pharmaceuticals; certain of the Company's current and former officers and directors; and underwriters who participated in an August 2007 public offering of Schering-Plough's common and preferred stock. On February 14, 2013, Merck announced that it had reached an agreement in principle with plaintiffs to settle this matter for \$473 million. On June 4, 2013, plaintiffs moved for preliminary approval of the settlement, which the court granted on June 7, 2013. On July 2, 2013, plaintiffs moved for final approval of the settlement. A final fairness hearing was held on October 1, 2013. Following the hearing, the court issued an opinion and order approving the settlement, and entered a final judgment dismissing the case with prejudice. This settlement exhausted the remaining

Directors and Officers insurance coverage applicable to the Vytarin lawsuits brought by the legacy Schering-Plough shareholders. The settlement was reflected in the Company's 2012 financial results and, together with the settlement described in the preceding paragraph, resulted in an aggregate charge of \$493 million after taking into account anticipated insurance recoveries of \$195 million. In the second quarter of 2013, the Company paid \$480 million into a settlement fund. The Company's insurers subsequently paid the remaining \$208 million, which reflects an additional \$13 million of insurance recoveries not previously recognized.

- 21 -

---

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

Governmental Proceedings

The Company has received a subpoena from the Office of Inspector General of the U.S. Department of Health and Human Services on behalf of the U.S. Attorney's Office for the District of Maryland and the Civil Division of the U.S. Department of Justice which requests information relating to the Company's marketing of Singulair and Dulera and certain of its other marketing activities from January 1, 2006 to the present. The Company is cooperating with the government.

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

Commercial Litigation

AWP Litigation

As previously disclosed, the Company and/or certain of its subsidiaries have been named as defendants in cases brought by various states alleging manipulation by pharmaceutical manufacturers of Average Wholesale Prices ("AWP"), which are sometimes used by public and private payors in calculating provider reimbursement levels. The outcome of these lawsuits could include substantial damages, the imposition of substantial fines and penalties and injunctive or administrative remedies.

Since the start of 2012, the Company has settled AWP cases brought by the states of Alabama, Alaska, Kansas, Illinois, Kentucky, Louisiana, Oklahoma, and Mississippi. The Company and/or certain of its subsidiaries continue to be defendants in cases brought by two states, Utah and Wisconsin.

The Company has also been reinstated as a defendant in a putative class action in New Jersey Superior Court which alleges on behalf of third-party payers and individuals that manufacturers inflated drug prices by manipulation of AWP's and other means. This case was originally dismissed against the Company without prejudice in 2007. The Company intends to defend against this lawsuit.

K-DUR Antitrust Litigation

As previously disclosed, in June 1997 and January 1998, Schering-Plough settled patent litigation with Upsher-Smith, Inc. ("Upsher-Smith") and ESI Lederle, Inc. ("Lederle"), respectively, relating to generic versions of K-DUR, Schering-Plough's long-acting potassium chloride product supplement used by cardiac patients, for which Lederle and Upsher-Smith had filed Abbreviated New Drug Applications ("ANDAs"). Following the commencement of an administrative proceeding by the U.S. Federal Trade Commission (the "FTC") in 2001 alleging anti-competitive effects from those settlements (which has been resolved in Schering-Plough's favor), putative class and non-class action suits were filed on behalf of direct and indirect purchasers of K-DUR against Schering-Plough, Upsher-Smith and Lederle and were consolidated in a multi-district litigation in the U.S. District Court for the District of New Jersey. These suits claimed violations of federal and state antitrust laws, as well as other state statutory and common law causes of action, and sought unspecified damages. In April 2008, the indirect purchasers voluntarily dismissed their case. In March 2010, the District Court granted summary judgment to the defendants on the remaining lawsuits and dismissed the matter in its entirety. In July 2012, the Third Circuit Court of Appeals reversed the District Court's grant of summary judgment and remanded the case for further proceedings. At the same time, the Third Circuit upheld a December 2008 decision by the District Court to certify certain direct purchaser plaintiffs' claims as a class action.

In August 2012, the Company filed a petition for certiorari with the U.S. Supreme Court seeking review of the Third Circuit's decision. In June 2013, the Supreme Court granted that petition, vacated the judgment of the Third Circuit, and remanded the case for further consideration in light of its recent decision in *FTC v. Actavis, Inc.* That decision held that whether a so-called "reverse payment" — i.e., a payment from the holder of a pharmaceutical patent to a party challenging the patent made in connection with a settlement of their dispute — violates the antitrust laws should be determined on the basis of a "rule of reason" analysis. In September 2013, the Third Circuit returned the case to the District Court for further proceedings in accordance with the Actavis standard.

Coupon Litigation



In 2012, as previously disclosed, a number of private health plans filed separate putative class action lawsuits against the Company alleging that Merck's coupon programs injured health insurers by reducing beneficiary co-payment amounts and, thereby, allegedly causing beneficiaries to purchase higher-priced drugs than they otherwise would have purchased and increasing the insurers' reimbursement costs. The actions, which were assigned to a District Judge in the U.S. District Court for the District of New Jersey, sought damages and injunctive relief barring the Company from issuing coupons that would reduce beneficiary co-pays on behalf of putative nationwide classes of health insurers. Similar actions relating to manufacturer coupon programs have been filed against several other pharmaceutical manufacturers in a variety of federal courts. On April 29, 2013, the District Court

- 22 -

---

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

dismissed all the actions against Merck without prejudice on the grounds that plaintiffs had failed to demonstrate their standing to sue. Plaintiffs subsequently filed a consolidated amended complaint, and Merck has filed a motion to dismiss that complaint.

**Patent Litigation**

From time to time, generic manufacturers of pharmaceutical products file ANDAs with the U.S. Food and Drug Administration (the “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: AzaSite, Emend for Injection, Integrilin, Nexium, and Zetia. 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.

**AzaSite** — In May 2011, 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 AzaSite. A trial in the case commenced in July 2013 and was completed in August 2013. In October 2013, the District Court issued a decision stating that the patents in suit were valid and would be infringed by the product described in Sandoz’s application for its generic azithromycin eye drop formulation. The court also issued an order blocking the FDA from approving Sandoz’s application until after the last of the patents expires on March 31, 2019. Sandoz can appeal this decision.

In June 2013, a patent infringement lawsuit was filed in the United States against Mylan Pharmaceuticals, Inc. and Mylan Inc. (collectively, “Mylan”) in respect of Mylan’s application to the FDA seeking pre-patent expiry approval to market a generic version of AzaSite. The lawsuit automatically stays FDA approval of Mylan’s application until October 2015 or until an adverse court decision, if any, whichever may occur earlier.

**Emend for Injection** — In May 2012, a patent infringement lawsuit was filed in the United States against 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. 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 has agreed with Intas to stay the lawsuit pending the outcome of the lawsuit with Sandoz.

**Integrilin** — In February 2009, a patent infringement lawsuit was filed (jointly with Millennium Pharmaceuticals, Inc.) in the United States against Teva Parenteral Medicines, Inc. (“TPM”) in respect of TPM’s application to the FDA seeking pre-patent expiry approval to sell a generic version of Integrilin. In October 2011, the parties entered a settlement agreement allowing TPM to sell a generic version of Integrilin beginning June 2, 2015. In November 2012, a patent infringement lawsuit was filed against APP Pharmaceuticals, Inc. and Fresenius Kabi USA Inc. (collectively, “APP”) in respect of APP’s application to the FDA seeking pre-patent expiry approval to sell a generic version of Integrilin. In March 2013, the parties entered into a settlement agreement allowing APP to sell a generic version of Integrilin beginning June 2, 2015. In September 2013, a patent infringement lawsuit was filed against Ben Venue Laboratories d/b/a/ Bedford Laboratories (“Bedford”) in respect of Bedford’s application to the FDA seeking pre-patent expiry approval to sell a generic version of Integrilin. The lawsuit automatically stays FDA approval of Bedford’s application until February 2016 or until an adverse court decision, if any, whichever may occur earlier.

**Nexium** — Patent infringement lawsuits were brought (jointly with AstraZeneca) in the United States against the following generic companies: Ranbaxy Laboratories Ltd., IVAX Pharmaceuticals, Inc. (later acquired by Teva Pharmaceuticals, Inc. (“Teva”)), Dr. Reddy’s Laboratories, Sandoz, Lupin Ltd., Hetero Drugs Limited Unit III and Torrent Pharmaceuticals Ltd. in response to each generic company’s application seeking pre-patent expiry approval to

sell a generic version of Nexium. Settlements have been reached in each of these lawsuits, the terms of which provide that the respective generic company may bring a generic version of esomeprazole product to market on May 27, 2014. In addition, a patent infringement lawsuit was also filed (jointly with AstraZeneca) in February 2010 in the United States against Sun Pharma Global Fze (“Sun Pharma”) in respect of its application to the FDA seeking pre-patent expiry approval to sell a generic version of Nexium IV, which lawsuit was settled with an agreement which provides that Sun Pharma will be entitled to bring its generic esomeprazole IV product to market in the United States on January 1, 2014. A patent infringement lawsuit was also filed (jointly with AstraZeneca) in the United States against Hanmi USA, Inc. (“Hanmi”) related to its application to the FDA seeking pre-patent expiry approval to sell a different salt of esomeprazole than is found in Nexium (the “Hanmi Product”). In a May 2013 agreement, Hanmi conceded the validity and enforceability of the patents in the lawsuit. The parties also agreed that the Hanmi Product would not infringe those patents under the District Court’s

- 23 -

---

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

December 2012 claim interpretation order, which AstraZeneca and KBI have appealed. Hanmi may decide to launch its esomeprazole product at risk as it has received final FDA approval. Finally, additional patent infringement lawsuits have been filed (jointly with AstraZeneca) in the United States against Mylan Laboratories Limited (“Mylan Labs”) and Actavis, Inc./Watson Pharma Company (collectively, “Actavis/Watson”) related to their applications to the FDA seeking pre-patent expiry approval to sell generic versions of Nexium. The Mylan Labs and Actavis/Watson applications to the FDA remain stayed until August 2014 and October 2015, respectively, or until earlier adverse court decisions, if any, whichever may occur earlier.

Zetia — In March 2007, a patent infringement lawsuit was filed in the United States against Glenmark Pharmaceuticals Inc., USA and its parent corporation (collectively, “Glenmark”) in respect of Glenmark’s application to the FDA seeking pre-patent expiry approval to sell a generic version of Zetia. In May 2010, Glenmark agreed to a settlement by virtue of which Glenmark will be permitted to launch its generic product in the United States on December 12, 2016, subject to receiving final FDA approval. In June 2010, a patent infringement lawsuit was filed in the United States against Mylan in respect of Mylan’s application to the FDA seeking pre-patent expiry approval to sell a generic version of Zetia. A trial against Mylan jointly in respect of Zetia and Vytorin was conducted in December 2011. In April 2012, the court issued a decision finding the patent valid and enforceable. Accordingly, Mylan’s application will not be approvable until April 25, 2017. On February 7, 2013, the Court of Appeals for the Federal Circuit affirmed the lower court decision. In April 2013, the Federal Circuit denied Mylan’s motion for rehearing en banc. Mylan has exhausted all appeals and the decision is now final. In September 2010, a patent infringement lawsuit was filed in the United States against Teva in respect of Teva’s application to the FDA seeking pre-patent expiry approval to sell a generic version of Zetia. In July 2011, the patent infringement lawsuit was dismissed without any rights granted to Teva. In September 2012, a patent infringement suit was filed in the United States against Sandoz in respect of Sandoz’s application to the FDA seeking pre-patent expiry approval to market a generic version of Zetia. In August 2013, an agreement was reached with Sandoz by virtue of which Sandoz is prohibited from selling its generic product in the United States before April 2017, except as permitted under the agreement.

#### Environmental Litigation

As previously disclosed, approximately 2,200 plaintiffs filed an amended complaint against Merck and 12 other defendants in U.S. District Court, Eastern District of California asserting claims under the Clean Water Act, the Resource Conservation and Recovery Act, as well as negligence and nuisance. The suit seeks damages for personal injury, diminution of property value, medical monitoring and other alleged real and personal property damage associated with groundwater, surface water and soil contamination found at the site of a former Merck subsidiary in Merced, California. Certain of the other defendants in this suit have settled with plaintiffs regarding some or all aspects of plaintiffs’ claims. This lawsuit is proceeding in a phased manner. A jury trial commenced in February 2011 during which a jury was asked to make certain factual findings regarding whether contamination moved off-site to any areas where plaintiffs could have been exposed to such contamination and, if so, when, where and in what amounts. Defendants in this “Phase 1” trial included Merck and three of the other original 12 defendants. In March 2011, the Phase 1 jury returned a mixed verdict, finding in favor of Merck and the other defendants as to some, but not all, of plaintiffs’ claims. Specifically, the jury found that contamination from the site did not enter or affect plaintiffs’ municipal water supply wells or any private domestic wells. The jury found, however, that plaintiffs could have been exposed to contamination via air emissions prior to 1994, as well as via surface water in the form of storm drainage channeled into an adjacent irrigation canal, including during a flood in April 2006. In response to post-trial motions by Merck and other defendants, on September 7, 2011, the court entered an order setting aside a part of the Phase 1 jury’s findings that had been in favor of plaintiffs. Specifically, the court held that plaintiffs could not have been exposed to any contamination in surface or flood water during the April 2006 flood or, in fact, at any time later than 1991. Merck’s motion for reconsideration of the remainder of the jury’s Phase I verdict that was adverse to Merck was denied. The court has dismissed the claims of 1,083 of the plaintiffs in this action whose claims were precluded by aspects of the Phase I jury findings and the court’s subsequent orders. The parties have reached an agreement intended to resolve the remainder of this litigation, which is subject to sufficient plaintiff participation.

#### 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

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

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, 2013 and December 31, 2012 of approximately \$190 million and \$260 million, respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

## 10. Equity

(\$ and shares in millions)	Common Stock Shares	Par Value	Other Paid-In Capital	Retained Earnings	Accumulated		Treasury Stock Shares	Non- Controlling Interests	Total
					Other Comprehensive Loss	Cost			
Balance January 1, 2012	3,577	\$ 1,788	\$ 40,663	\$ 38,990	\$ (3,132)	) 536	\$(23,792)	\$ 2,426	\$ 56,943
Net income attributable to Merck & Co., Inc.	—	—	—	5,261	—	—	—	—	5,261
Cash dividends declared on common stock	—	—	—	(3,861)	—	—	—	—	(3,861)
Treasury stock shares purchased	—	—	—	—	—	36	(1,439)	—	(1,439)
Share-based compensation plans and other	—	—	(192)	—	—	(39)	1,369	—	1,177
Other comprehensive income	—	—	—	—	92	—	—	—	92
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	89	89
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(50)	(50)
Balance at September 30, 2012	3,577	\$ 1,788	\$ 40,471	\$ 40,390	\$ (3,040)	) 533	\$(23,862)	\$ 2,465	\$ 58,212
Balance January 1, 2013	3,577	\$ 1,788	\$ 40,646	\$ 39,985	\$ (4,682)	) 550	\$(24,717)	\$ 2,443	\$ 55,463
Net income attributable to Merck & Co., Inc.	—	—	—	3,623	—	—	—	—	3,623
Cash dividends declared on common stock	—	—	—	(3,835)	—	—	—	—	(3,835)
Treasury stock shares purchased	—	—	(500)	—	—	129	(5,820)	—	(6,320)
Share-based compensation plans and other	—	—	(353)	—	—	(29)	1,184	14	845
Other comprehensive loss	—	—	—	—	(16)	—	—	—	(16)
Supera joint venture	—	—	116	—	—	—	—	112	228
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	79	79
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(61)	(61)
Balance at September 30, 2013	3,577	\$ 1,788	\$ 39,909	\$ 39,773	\$ (4,698)	) 650	\$(29,353)	\$ 2,587	\$ 50,006

On May 20, 2013, Merck entered into an accelerated share repurchase ("ASR") agreement with Goldman, Sachs & Co. ("Goldman Sachs"). Under the ASR, Merck agreed to purchase approximately \$5 billion of Merck's common stock, in total, with an initial delivery of approximately 99.5 million shares of Merck's common stock, based on current market price, made by Goldman Sachs to Merck, and payment of \$5 billion made by Merck to Goldman Sachs, on May 21,

2013. The payment to Goldman Sachs was recorded as a reduction to shareholders' equity, consisting of a \$4.5 billion increase in treasury stock, which reflected the value of the initial 99.5 million shares received upon execution, and a \$500 million decrease in other-paid-in capital, which reflected the value of the stock held back by Goldman Sachs pending final settlement. Upon settlement of the ASR on October 31, 2013, Merck received an additional 5.5 million shares as determined by the average daily volume weighted-average price of Merck's common stock during the term of the ASR program bringing the total shares received by Merck under this program to 105 million. The receipt of the additional shares will be reflected as an increase to treasury stock and an increase to other-paid-in capital in the fourth quarter of 2013. The ASR was entered into pursuant to a share repurchase program announced on May 1, 2013. 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 is carried by KBI and included in Noncontrolling interests on the Consolidated Balance Sheet. If AstraZeneca exercises its option to acquire Merck's interest in AZLP (see Note 7), this preferred stock obligation will be retired.

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

## 11. Share-Based Compensation Plans

The Company has share-based compensation plans under which the Company grants restricted stock units (“RSUs”) and performance share units (“PSUs”) to certain management level employees. 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 amounts of share-based compensation cost recorded in the Consolidated Statement of Income:

(\$ in millions)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2013	2012	2013	2012
Pretax share-based compensation expense	\$68	\$88	\$210	\$257
Income tax benefit	(21 )	(28 )	(64 )	(81 )
Total share-based compensation expense, net of taxes	\$47	\$60	\$146	\$176

During the first nine months of 2013 and 2012, the Company granted 6 million RSUs with a weighted-average grant date fair value of \$45.04 per RSU and 7 million RSUs with a weighted-average grant date fair value of \$39.38 per RSU, respectively.

During the first nine months of 2013 and 2012, the Company granted 6 million options with a weighted-average exercise price of \$45.00 per option and 7 million options with a weighted-average exercise price of \$39.39 per option, respectively. The weighted-average fair value of options granted for the first nine months of 2013 and 2012 was \$6.21 and \$5.47 per option, respectively, and was determined using the following assumptions:

	Nine Months Ended			
	September 30,			
	2013	2012		
Expected dividend yield	4.2	% 4.4		%
Risk-free interest rate	1.2	% 1.3		%
Expected volatility	25.0	% 25.3		%
Expected life (years)	7.0	7.0		

At September 30, 2013, there was \$458 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 cost of such plans consisted of the following components:

(\$ in millions)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2013	2012	2013	2012
Service cost	\$167	\$133	\$512	\$416
Interest cost	166	162	497	494
Expected return on plan assets	(270 )	(239 )	(817 )	(727 )
Net amortization	86	48	252	144
Termination benefits	5	4	10	13
Curtailments	(4 )	(4 )	(6 )	(5 )
	\$150	\$104	\$448	\$335



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

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

The Company provides medical benefits, principally to its eligible U.S. retirees and similar benefits to their dependents, through its other postretirement benefit plans. The net cost of such plans consisted of the following components:

(\$ in millions)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2013	2012	2013	2012
Service cost	\$28	\$22	\$76	\$64
Interest cost	25	31	79	93
Expected return on plan assets	(31 )	(34 )	(94 )	(102 )
Net amortization	(13 )	(9 )	(37 )	(25 )
Termination benefits	4	5	6	10
Curtailments	(5 )	(2 )	(7 )	(6 )
	\$8	\$13	\$23	\$34

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

13. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

(\$ in millions)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2013	2012	2013	2012
Interest income	\$(67 )	\$(47 )	\$(189 )	\$(177 )
Interest expense	215	178	600	524
Exchange losses	11	50	278	130
Other, net	13	19	(33 )	(31 )
	\$172	\$200	\$656	\$446

The increases in interest expense in the third quarter and first nine months of 2013 as compared with the same periods in 2012 are driven in part by the issuances of debt in September 2012 and May 2013. The higher exchange losses in the first nine months of 2013 as compared with the same period in 2012 are due primarily to a Venezuelan currency devaluation. In February 2013, the Venezuelan government devalued its currency (Bolívar Fuertes) from 4.30 VEF per U.S. dollar to 6.30 VEF per U.S. dollar. The Company recognized losses due to exchange of approximately \$140 million in the first nine months of 2013 resulting from the remeasurement of the local monetary assets and liabilities at the new rate. Since January 2010, Venezuela has been designated hyperinflationary and, as a result, local foreign operations are remeasured in U.S. dollars with the impact recorded in results of operations.

Interest paid for the nine months ended September 30, 2013 and 2012 was \$591 million and \$533 million, respectively.

14. Taxes on Income

The effective income tax rates of 24.6% and 14.3% for the third quarter and first nine months of 2013, respectively, and 20.5% and 27.8% for the third quarter and first nine months of 2012, respectively, reflect the impacts of acquisition-related costs and restructuring costs, partially offset by the beneficial impact of foreign earnings. In addition, the effective income tax rates for the third quarter and first nine months of 2013 reflect net benefits of \$165 million from the settlements of certain federal income tax issues. The effective income tax rate for the first nine months of 2013 also reflects reductions in tax reserves upon expiration of applicable statute of limitations, the favorable impact of tax legislation enacted in the first quarter of 2013 that extended the R&D tax credit for both 2012 and 2013, as well as a benefit of approximately \$160 million associated with the resolution of a previously disclosed legacy Schering-Plough federal income tax issue as discussed below. The effective tax rates for the third quarter and

first nine months of 2012 also reflect the favorable impacts of a tax settlement with the Canada Revenue Agency (the “CRA”) as discussed below and the realization of foreign tax credits.

In the third quarter of 2013, the Internal Revenue Service (“IRS”) finalized its examination of Schering-Plough’s 2007-2009 tax years. The Company’s unrecognized tax benefits for the years under examination exceed the adjustments related

- 27 -

---

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

to this examination period and therefore the Company recorded a net \$165 million tax provision benefit for the third quarter and first nine months of 2013.

In 2010, the IRS finalized its examination of Schering-Plough's 2003-2006 tax years. In this audit cycle, the Company reached an agreement with the IRS on an adjustment to income related to intercompany pricing matters. This income adjustment mostly reduced net operating loss carryforwards and other tax credit carryforwards. The Company's reserves for uncertain tax positions were adequate to cover all adjustments related to this examination period.

Additionally, as previously disclosed, the Company was seeking resolution of one issue raised during this examination through the IRS administrative appeals process. In the first quarter of 2013, the Company recorded an out-of-period net tax benefit of \$160 million related to this issue, which was settled in the fourth quarter of 2012, with final resolution relating to interest owed being reached in the first quarter of 2013. The Company's unrecognized tax benefits related to this issue exceeded the settlement amount. Management has concluded that the exclusion of this benefit is not material to prior period financial statements or projected current year financial results.

As previously disclosed, the CRA had proposed adjustments for 1999 and 2000 relating to intercompany pricing matters and, in July 2011, the CRA issued assessments for other miscellaneous audit issues for tax years 2001-2004. In the third quarter of 2012, Merck and the CRA reached a settlement for these years that calls for Merck to pay additional Canadian tax of approximately \$65 million. The Company's unrecognized tax benefits related to these matters exceeded the settlement amount and, therefore, the Company recorded a net \$112 million tax provision benefit in the third quarter of 2012. A portion of the taxes paid is expected to be creditable for U.S. tax purposes. The Company had previously established reserves for these matters. The resolution of these matters did not have a material effect on the Company's results of operations, financial position or liquidity.

#### 15. Earnings Per Share

Prior to 2013, the Company calculated earnings per share pursuant to the two-class method under which all earnings (distributed and undistributed) are allocated to common shares and participating securities based on their respective rights to receive dividends. RSUs and certain PSUs granted before December 31, 2009 (which generally have a three year vesting period) to certain management level employees met the definition of participating securities. RSUs and PSUs issued on or after January 1, 2010, do not meet the definition of participating securities; therefore, beginning in 2013 the Company no longer applies the two-class method.

The calculations of earnings per share are as follows:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2013	2012	2013	2012
(\$ and shares in millions except per share amounts)				
Basic Earnings per Common Share				
Net income attributable to Merck & Co., Inc.	\$1,124	\$1,729	\$3,623	\$5,261
Less: Income allocated to participating securities	—	—	—	4
Net income allocated to common shareholders	\$1,124	\$1,729	\$3,623	\$5,257
Average common shares outstanding	2,927	3,045	2,975	3,043
	\$0.38	\$0.57	\$1.22	\$1.73
Earnings per Common Share Assuming Dilution				
Net income attributable to Merck & Co., Inc.	\$1,124	\$1,729	\$3,623	\$5,261
Less: Income allocated to participating securities	—	—	—	4
Net income allocated to common shareholders	\$1,124	\$1,729	\$3,623	\$5,257
Average common shares outstanding	2,927	3,045	2,975	3,043
Common shares issuable <sup>(1)</sup>	33	34	32	34
Average common shares outstanding assuming dilution	2,960	3,079	3,007	3,077
	\$0.38	\$0.56	\$1.20	\$1.71

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

For the three months ended September 30, 2013 and 2012, 23 million and 97 million, respectively, and for the first nine months of 2013 and 2012, 29 million and 111 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.

- 28 -

---

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

## 16. Other Comprehensive Income (Loss)

In the first quarter of 2013, the Company prospectively adopted guidance issued by the FASB that requires additional disclosure related to the impact of reclassification adjustments out of AOCI on net income. Changes in AOCI by component are as follows:

(\$ in millions)	Three Months Ended September 30,				
	Derivatives	Investments	Employee Benefit Plans	Cumulative Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
Balance July 1, 2012, net of taxes	\$48	\$ 51	\$(2,328 )	\$( 897 )	\$( 3,126 )
Other comprehensive income (loss), net of taxes	(143 )	32	27	170	86
Balance September 30, 2012, net of taxes	\$(95 )	\$ 83	\$(2,301 )	\$( 727 )	\$( 3,040 )
Balance July 1, 2013, net of taxes	\$174	\$( 7 )	\$(3,455 )	\$(1,472 )	\$( 4,760 )
Other comprehensive income (loss) before reclassification adjustments, pretax	(165 )	55	( 7 )	74	(43 )
Tax	63	( 8 )	—	( 2 )	53
Other comprehensive income (loss) before reclassification adjustments, net of taxes	(102 )	47	( 7 )	72	10
Reclassification adjustments, pretax	—	( 9 )	73	—	64
Tax	—	5	(17 )	—	(12 )
Reclassification adjustments, net of taxes	—	(1) (4 )	(2) 56	(3) —	52
Other comprehensive income (loss), net of taxes	(102 )	43	49	72	62
Balance September 30, 2013, net of taxes	\$72	\$ 36	\$(3,406 )	\$(1,400 )	\$( 4,698 )
(\$ in millions)	Nine Months Ended September 30,				
	Derivatives	Investments	Employee Benefit Plans	Cumulative Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
Balance January 1, 2012, net of taxes	\$4	\$ 21	\$(2,346 )	\$( 811 )	\$( 3,132 )
Other comprehensive income (loss), net of taxes	(99 )	62	45	84	92
Balance September 30, 2012, net of taxes	\$(95 )	\$ 83	\$(2,301 )	\$( 727 )	\$( 3,040 )
Balance January 1, 2013, net of taxes	\$(97 )	\$ 73	\$(3,667 )	\$( 991 )	\$( 4,682 )
Other comprehensive income (loss) before reclassification adjustments, pretax	248	11	137	(304 )	92
Tax	(100 )	(16 )	(30 )	(105 )	(251 )
Other comprehensive income (loss) before reclassification adjustments, net of taxes	148	( 5 )	107	(409 )	(159 )
Reclassification adjustments, pretax	33	(43 )	215	—	205
Tax	(12 )	11	(61 )	—	(62 )
Reclassification adjustments, net of taxes	21	(1) (32 )	(2) 154	(3) —	143
Other comprehensive income (loss), net of taxes	169	(37 )	261	(409 )	(16 )

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

Balance September 30, 2013, net of taxes    \$72            \$ 36            \$(3,406 )    \$(1,400 )    \$ (4,698 )

- (1) Relates to foreign currency cash flow hedges that were reclassified from AOCI to Sales.
- (2) Represents net realized gains on the sales of available-for-sale investments that were reclassified from AOCI to Other (income) expense, net.
- (3) Includes net amortization of prior service cost and actuarial gains and losses included in net periodic benefit cost (see note 12).

- 29 -

---

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

17. Segment Reporting

The Company's operations are principally managed on a products basis and are comprised of four operating segments – Pharmaceutical, Animal Health, Consumer Care and Alliances (which includes revenue and equity income from the Company's relationship with AZLP). The Animal Health, Consumer Care 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. Additionally, the Company has consumer care operations that develop, manufacture and market over-the-counter, foot care and sun care products, which are sold through wholesale and retail drug, food chain and mass merchandiser outlets, as well as club stores and specialty channels.

- 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, 2013	September 30, 2012	September 30, 2013	September 30, 2012
Primary Care and Women's Health				
Cardiovascular				
Zetia	\$662	\$645	\$1,941	\$1,891
Vytorin	396	423	1,207	1,312
Diabetes and Obesity				
Januvia	927	975	2,883	2,952
Janumet	442	405	1,325	1,207
Respiratory				
Nasonex	297	292	1,008	960
Singulair	280	602	898	3,373
Dulera	82	52	229	140
Asmanex	43	42	133	141
Women's Health and Endocrine				
NuvaRing	170	156	492	459
Fosamax	140	152	421	522
Follistim AQ	124	111	380	352
Implanon	96	93	282	254
Cerazette	51	64	159	202
Other				
Arcoxia	112	109	354	338
Avelox	38	30	102	146
Hospital and Specialty				
Immunology				
Remicade	574	490	1,651	1,527
Simponi	126	86	354	236
Infectious Disease				
Isentress	427	399	1,201	1,133
Cancidas	151	163	477	474
PegIntron	104	165	372	510
Invanz	130	118	360	329
Victrelis	121	149	347	387
Noxafil	75	66	212	191
Oncology				
Temodar	162	227	596	688
Emend	123	111	373	358
Other				
Cosopt/Trusopt	104	102	313	331
Bridion	75	68	206	186
Integrilin	45	48	140	160
Diversified Brands				
Cozaar/Hyzaar	238	295	760	969
Primaxin	88	109	256	301
Zocor	65	86	221	285
Propecia	71	104	206	312



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

Clarinet	54	64	180	337
Claritin Rx	36	47	151	181
Remeron	44	52	150	175
Proscar	38	55	136	160
Maxalt	40	166	124	476
Vaccines <sup>(1)</sup>				
Gardasil	665	581	1,438	1,189
ProQuad/M-M-R II/Varivax	421	396	1,032	967
RotaTeq	201	150	507	433
Zostavax	185	202	494	426
Pneumovax 23	193	160	412	372
Other pharmaceutical <sup>(2)</sup>	1,059	1,065	3,194	3,175
Total Pharmaceutical segment sales	9,475	9,875	27,677	30,517
Other segment sales <sup>(3)</sup>	1,501	1,556	4,844	4,830
Total segment sales	10,976	11,431	32,521	35,347
Other <sup>(4)</sup>	56	57	192	183
	\$11,032	\$11,488	\$32,713	\$35,530

These amounts do not reflect sales of vaccines sold in most major European markets through the Company's joint

(1) venture, Sanofi Pasteur MSD, the results of which are reflected in Equity income from affiliates. These amounts do, however, reflect supply sales to Sanofi Pasteur MSD.

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

(3) Represents the non-reportable segments of Animal Health, Consumer Care and Alliances. The Alliances segment includes revenue from the Company's relationship with AZLP.

(4) Other revenues are primarily comprised of miscellaneous corporate revenues, third-party manufacturing sales, sales related to divested products or businesses and supply sales not included in segment results.

## 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,	
	2013	2012	2013	2012
Segment profits:				
Pharmaceutical segment	\$5,983	\$6,265	\$17,022	\$19,767
Other segments	750	819	2,445	2,397
Total segment profits	6,733	7,084	19,467	22,164
Other profits (losses)	(6	) (4	) (24	) (32
Unallocated:				
Interest income	67	47	189	177
Interest expense	(215	) (178	) (600	) (524
Equity income from affiliates	(67	) (5	) (82	) (14
Depreciation and amortization	(512	) (477	) (1,449	) (1,593
Research and development	(1,437	) (1,689	) (5,004	) (5,263
Amortization of purchase accounting adjustments	(1,176	) (1,232	) (3,545	) (3,687
Restructuring costs	(870	) (110	) (1,144	) (473
Other unallocated, net	(992	) (1,218	) (3,488	) (3,350
	\$1,525	\$2,218	\$4,320	\$7,405

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, divested products or businesses and other supply sales.

Other unallocated, net includes expenses from corporate and manufacturing cost centers, 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

### Loss of Market Exclusivity

The patents that provided market exclusivity for Singulair (montelukast sodium) in a number of major European markets expired in February 2013. The patent that provided U.S. market exclusivity for Singulair expired in August 2012. In addition, the patent that provided U.S. market exclusivity for Maxalt (rizatriptan benzoate) expired in December 2012 and the Company lost U.S. market exclusivity for Propecia (finasteride) in January 2013 and Temodar (temozolomide) in August 2013. The Company experienced a significant and rapid decline in sales of these products in those markets following loss of market exclusivity.

### Share Repurchase Program

On May 1, 2013, Merck announced that its board of directors had authorized additional purchases of up to \$15 billion of Merck's common stock for its treasury. The Company expects to repurchase approximately \$7.5 billion of common stock within 12 months following the date of the announcement, financed through a combination of debt issuance and operating cash flows, with the remainder to be repurchased over time with no time limit. Purchases may be made in open-market transactions, block transactions on or off an exchange, or in privately negotiated transactions. On May 20, 2013, Merck entered into an accelerated share repurchase ("ASR") agreement with Goldman, Sachs & Co. ("Goldman Sachs"). Under the ASR, Merck agreed to purchase approximately \$5 billion of Merck's common stock, in total, with an initial delivery of approximately 99.5 million shares of Merck's common stock made by Goldman Sachs to Merck, and payment of \$5 billion made by Merck to Goldman Sachs, on May 21, 2013. Merck received an additional 5.5 million shares from Goldman Sachs upon closing of the transaction on October 31, 2013 bringing the total shares received by Merck under this program to 105 million (see "Liquidity and Capital Resources" below).

### 2013 Restructuring Program

In October 2013, the Company announced a new global restructuring program (the "2013 Restructuring Program") as part of a global initiative to sharpen its commercial and research and development focus. As part of the new 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 recorded total pretax restructuring costs of \$544 million in the third quarter and first nine months of 2013 related to this 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 \$2.5 billion to \$3.0 billion. The Company expects the actions under the 2013 Restructuring Program to result in annual net cost savings of approximately \$2.0 billion by the end of 2015. The Company anticipates that the actions under the 2013 Restructuring Program, combined with remaining actions under the Merger Restructuring Program (discussed below), will result in annual net cost savings of \$2.5 billion by the end of 2015 compared with full-year 2012 expense levels.

## Operating Results

### Sales

Worldwide sales were \$11.0 billion for the third quarter of 2013, a decline of 4% compared with the third quarter of 2012. The third quarter sales decline was driven primarily by lower sales of Singulair. As noted above, the patents that provided U.S. market exclusivity and market exclusivity in a number of major European markets for Singulair expired in August 2012 and February 2013, respectively, and the Company experienced a significant and rapid decline in Singulair sales in those markets thereafter. Foreign exchange unfavorably affected global sales performance by 2% in the third quarter of 2013. The revenue decline in the third quarter of 2013 also reflects lower sales of Maxalt, Varivax (Varicella Virus Vaccine Live), Temodar, PegIntron (peginterferon alpha-2b), Cozaar (losartan potassium)/Hyzaar (losartan potassium and hydrochlorothiazide), and Januvia (sitagliptin). These declines were partially offset by growth in ProQuad (Measles, Mumps, Rubella and Varicella Virus Vaccine Live), Remicade (infliximab), Gardasil [human papillomavirus quadrivalent (types 6, 11, 16 and 18) vaccine, recombinant], RotaTeq (Rotavirus Vaccine, Live Oral, Pentavalent) and Simponi (golimumab).

Global sales for the first nine months of 2013 were \$32.7 billion, a decrease of 8% compared with the same period in 2012. Foreign exchange unfavorably affected global sales performance by 2% in the first nine months of 2013. The sales decline in the first nine months of 2013 was driven primarily by lower sales of Singulair, Maxalt, Cozaar/Hyzaar, Clarinex (desloratadine), PegIntron, Varivax, Propecia, Vytorin (ezetimibe/simvastatin), Fosamax (alendronate sodium) and Temodar. These declines were partially offset by higher sales of Gardasil, ProQuad, Remicade, Simponi, Janumet (sitagliptin metformin HCl), Dulera (mometasone furoate/formoterol fumarate dihydrate) Inhalation Aerosol and RotaTeq.

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access worldwide. In many international markets, government-mandated pricing actions have reduced prices of generic and patented drugs. These and other austerity measures negatively affected the Company's revenue performance in the first nine months of 2013 and the Company anticipates these measures will continue to negatively affect revenue performance for the remainder of 2013.

As discussed in Note 2 to the interim consolidated financial statements, on October 1, 2013, the Company sold its active pharmaceutical ingredient ("API") manufacturing business, including the related manufacturing facility, in the Netherlands to Aspen Holdings ("Aspen"). The annual sales associated with the API business were approximately \$200 million. In connection with this sale, Aspen will also acquire certain products within Diversified Brands, which will transfer to Aspen effective December 31, 2013. The annual sales associated with the branded products to be divested are approximately \$230 million.

Sales of the Company's products were as follows:

(\$ in millions)	Three Months Ended		Nine Months Ended	
	September 30, 2013	September 30, 2012	September 30, 2013	September 30, 2012
Primary Care and Women's Health				
Cardiovascular				
Zetia	\$662	\$645	\$1,941	\$1,891
Vytorin	396	423	1,207	1,312
Diabetes and Obesity				
Januvia	927	975	2,883	2,952
Janumet	442	405	1,325	1,207
Respiratory				
Nasonex	297	292	1,008	960
Singulair	280	602	898	3,373
Dulera	82	52	229	140
Asmanex	43	42	133	141
Women's Health and Endocrine				
NuvaRing	170	156	492	459
Fosamax	140	152	421	522
Follistim AQ	124	111	380	352
Implanon	96	93	282	254
Cerazette	51	64	159	202
Other				
Arcoxia	112	109	354	338
Avelox	38	30	102	146
Hospital and Specialty				
Immunology				
Remicade	574	490	1,651	1,527
Simponi	126	86	354	236
Infectious Disease				
Isentress	427	399	1,201	1,133
Cancidas	151	163	477	474
PegIntron	104	165	372	510
Invanz	130	118	360	329
Victrelis	121	149	347	387
Noxafil	75	66	212	191
Oncology				
Temodar	162	227	596	688
Emend	123	111	373	358
Other				
Cosopt/Trusopt	104	102	313	331
Bridion	75	68	206	186
Integrilin	45	48	140	160
Diversified Brands				
Cozaar/Hyzaar	238	295	760	969
Primaxin	88	109	256	301
Zocor	65	86	221	285
Propecia	71	104	206	312

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

Clarinet	54	64	180	337
Claritin Rx	36	47	151	181
Remeron	44	52	150	175
Proscar	38	55	136	160
Maxalt	40	166	124	476
Vaccines <sup>(1)</sup>				
Gardasil	665	581	1,438	1,189
ProQuad/M-M-R II/Varivax	421	396	1,032	967
RotaTeq	201	150	507	433
Zostavax	185	202	494	426
Pneumovax 23	193	160	412	372
Other pharmaceutical <sup>(2)</sup>	1,059	1,065	3,194	3,175
Total Pharmaceutical segment sales	9,475	9,875	27,677	30,517
Other segment sales <sup>(3)</sup>	1,501	1,556	4,844	4,830
Total segment sales	10,976	11,431	32,521	35,347
Other <sup>(4)</sup>	56	57	192	183
	\$11,032	\$11,488	\$32,713	\$35,530

These amounts do not reflect sales of vaccines sold in most major European markets through the Company's joint

(1) venture, Sanofi Pasteur MSD, the results of which are reflected in Equity income from affiliates. These amounts do, however, reflect supply sales to Sanofi Pasteur MSD.

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

(3) Represents the non-reportable segments of Animal Health, Consumer Care and Alliances. The Alliances segment includes revenue from the Company's relationship with AZLP.

(4) Other revenues are primarily comprised of miscellaneous corporate revenues, third-party manufacturing sales, sales related to divested products or businesses and supply sales not included in segment results.

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 \$1.3 billion for both the three months ended September 30, 2013 and 2012, and by \$3.9 billion and \$4.3 billion for the nine months ended September 30, 2013 and 2012, 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

Worldwide sales of Zetia (ezetimibe) (marketed as Ezetrol outside the United States), a cholesterol absorption inhibitor, were \$662 million in the third quarter of 2013 and \$1.9 billion for the first nine months of 2013, representing increases of 3% compared with the same periods of 2012. Foreign exchange unfavorably affected global sales performance by 2% in both the third quarter and first nine months of 2013. The sales increases primarily reflects volume growth in the United States and Japan, partially offset by the unfavorable effect of foreign exchange particularly in Japan. In the first nine months of 2013, volume growth in the emerging markets also contributed to the sales increase.

Global sales of Vytorin (marketed outside the United States as Inegy), a combination product containing the active ingredients of both Zetia and Zocor (simvastatin), were \$396 million and \$1.2 billion in the third quarter and first nine months of 2013, respectively, representing declines of 6% and 8%, respectively, compared with the same periods in 2012. The sales declines primarily reflect lower volumes in the United States and Latin America, partially offset by volume growth in the Asia Pacific region.

##### Diabetes and Obesity

Global sales of Januvia, Merck's dipeptidyl peptidase-4 ("DPP-4") inhibitor for the treatment of type 2 diabetes, were \$927 million in the third quarter of 2013, a decrease of 5% compared with the third quarter of 2012 including a 4% unfavorable effect from foreign exchange. Excluding the negative effect from foreign exchange, sales performance in the third quarter of 2013 as compared with the third quarter of 2012 reflects lower sales in the United States driven primarily by lower customer inventory levels, as well as lower demand, partially offset by volume growth in Japan, Europe and the emerging markets. Worldwide sales of Januvia were \$2.9 billion in the first nine months of 2013, a decline of 2% compared with the same period of 2012 including a 4% unfavorable effect from foreign exchange. Excluding the negative effect from foreign exchange, sales in the first nine months of 2013 as compared with the first nine months of 2012 reflect volume growth in Japan, certain emerging markets and Europe, partially offset by volume declines in the United States.

Worldwide sales of Janumet, Merck's oral antihyperglycemic agent that combines sitagliptin (Januvia) with metformin in a single tablet to target all three key defects of type 2 diabetes, were \$442 million for the third quarter of 2013 and \$1.3 billion for the first nine months of 2013, representing increases of 9% and 10%, respectively, compared with the same periods of 2012, reflecting volume growth internationally and, for the first nine months of 2013, also in the United States.

##### Respiratory

Global sales of Nasonex (mometasone furoate monohydrate), an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, increased 2% in the third quarter of 2013 to \$297 million and 5% in the first nine months of 2013 to \$1.0 billion driven primarily by increases in the United States, reflecting net favorable adjustments to indirect customer discounts, as well as volume growth in Japan for the year-to-date period, partially offset by declines in Latin America. Foreign exchange unfavorably affected global sales performance by 2% and 3% in the third quarter and first nine months of 2013, respectively. In 2009, Apotex Inc. and Apotex Corp. (collectively, "Apotex") filed an application with the U.S. Food and Drug Administration (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. If generic versions become available, significant losses of Nasonex sales could occur and the Company may take a non-cash impairment charge with respect to the value of the Nasonex intangible asset, which had a carrying value of approximately \$1.4 billion at September 30, 2013. If the Nasonex intangible asset is determined to be impaired, the impairment charge could be material. U.S. sales of Nasonex were \$597 million for the full year of 2012.

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, declined 53% in the third quarter of 2013 to \$280 million and fell 73% in the first nine months of 2013 to \$898 million compared with the same periods of 2012, driven primarily by lower sales in United States, as well as in Europe. The patent

- 36 -

---



that provided U.S. market exclusivity for Singulair expired in August 2012 and the Company has lost nearly all sales of Singulair in the United States. In addition, the patents that provided market exclusivity for Singulair expired in a number of major European markets in February 2013 and the Company is experiencing a significant and rapid decline in Singulair sales in those markets following the patent expiries and expects the decline to continue.

Global sales of Dulera Inhalation Aerosol, a combination medicine for the treatment of asthma, were \$82 million in the third quarter of 2013 compared with \$52 million in the third quarter of 2012 and were \$229 million in the first nine months of 2013 compared with \$140 million for the first nine months of 2012. The sales increases reflect higher demand in the United States. In January 2012, Merck received a Complete Response Letter (“CRL”) from the FDA on the Company’s supplemental New Drug Application for Dulera Inhalation Aerosol for the treatment of chronic obstructive pulmonary disease. The Company has determined not to conduct an additional clinical study and will no longer pursue an update to the application in the future.

#### Women’s Health and Endocrine

Worldwide sales of NuvaRing (etonogestrel/ethinyl estradiol vaginal ring), a vaginal contraceptive product, increased 9% in the third quarter of 2013 to \$170 million and grew 7% in the first nine months of 2013 to \$492 million compared with the same periods in 2012 primarily reflecting volume growth in the United States.

Worldwide sales of Fosamax (marketed as Fosamac in Japan) and Fosamax Plus D (alendronate sodium/cholecalciferol) (marketed as Fosavance throughout the European Union (the “EU”)) for the treatment and, in the case of Fosamax, prevention of osteoporosis declined 8% in the third quarter of 2013 to \$140 million compared with the third quarter of 2012 driven primarily by lower sales in the emerging markets. Global sales of Fosamax decreased 19% in the first nine months of 2013 to \$421 million compared with the same period of 2012 driven by declines in all regions. These medicines have lost market exclusivity in the United States and in most major international markets. The Company expects the sales declines within the Fosamax product franchise to continue. Global sales of Follistim AQ (follitropin beta injection) (marketed in most countries outside the United States as Puregon), a biological fertility treatment, grew 12% in the third quarter of 2013 to \$124 million and increased 8% in the first nine months of 2013 to \$380 million compared with the same periods in 2012 driven largely by positive performance in the United States. Puregon lost market exclusivity in the EU in August 2009.

The Company continues to experience difficulty manufacturing certain women’s health products. The Company is working to resolve these issues, which were not material to the Company’s results of operations.

#### Other

Other products included in Primary Care and Women’s Health include among others, Asmanex Twisthaler (mometasone furoate inhalation powder), an inhaled corticosteroid for asthma; Implanon (etonogestrel implant), a single-rod subdermal contraceptive implant; Cerazette (desogestrol), a progestin only oral contraceptive; Arcoxia (etoricoxib) for the treatment of arthritis and pain; and Avelox (moxifloxacin hydrochloride), a broad-spectrum fluoroquinolone antibiotic for the treatment of certain respiratory and skin infections marketed by the Company in the United States. The patent that provides U.S. market exclusivity for Avelox expires in March 2014; however, by agreement, a generic manufacturer may launch a generic version of Avelox in February 2014.

#### Hospital and Specialty

##### Immunology

Sales of Remicade, a treatment for inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), grew 17% to \$574 million for the third quarter of 2013 compared with the third quarter of 2012 and increased 8% to \$1.7 billion for the first nine months of 2013 compared with the same period in 2012. Foreign exchange favorably affected sales performance by 5% and 1% in the third quarter and first nine months of 2013, respectively. Sales growth in both periods reflects volume growth in Europe, as well as Russia.

Sales of Simponi, a once-monthly subcutaneous treatment for certain inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were \$126 million in the third quarter of 2013 compared with \$86 million in the third quarter of 2012 and were \$354 million in the first nine months of 2013 compared with \$236 million in the first nine months of 2012. Sales growth was driven by continued uptake since launch. Simponi was approved by the European Commission (the “EC”) in October 2009. In September 2013, the EC approved Simponi for the treatment of

adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy or who are intolerant to or have medical contraindications for such therapies.

- 37 -

---

### Infectious Disease

Global sales of Isentress (raltegravir), an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection, grew 7% in the third quarter of 2013 to \$427 million and increased 6% in the first nine months of 2013 to \$1.2 billion compared with the same periods in 2012 primarily reflecting volume growth in Europe and the United States.

Global sales of Cancidas (caspofungin acetate), an anti-fungal product, decreased 7% in the third quarter of 2013 to \$151 million reflecting declines in the emerging markets, particularly China. Sales of Cancidas grew 1% in the first nine months of 2013 to \$477 million compared with the same period in 2012 primarily reflecting volume growth in Europe, Japan and Latin America, largely offset by declines in China.

Worldwide sales of PegIntron, a treatment for chronic hepatitis C, were \$104 million and \$372 million in the third quarter and first nine months of 2013, respectively, representing declines of 37% and 27%, respectively, compared with the same periods in 2012. The Company believes that the sales declines are attributable in part to patient treatment being delayed by health care providers in anticipation of new therapeutic options becoming available. Foreign exchange unfavorably affected global sales performance by 3% in both the third quarter and first nine months of 2013.

Worldwide sales of Victrelis (boceprevir), an oral medicine for the treatment of chronic hepatitis C, were \$121 million and \$347 million in the third quarter and first nine months of 2013, respectively, representing declines of 19% and 10%, respectively, compared with the same periods of 2012. Foreign exchange unfavorably affected global sales performance by 1% in both the third quarter and first nine months of 2013. Sales declines in the United States were partially offset by growth in the emerging markets. The Company believes that the sales declines in the United States are attributable in part to patient treatment being delayed by health care providers in anticipation of new therapeutic options becoming available.

### Oncology

Sales of Temodar (marketed as Temodal outside the United States), a treatment for certain types of brain tumors, were \$162 million for the third quarter of 2013, a decline of 28% compared with the third quarter of 2012, and were \$596 million for the first nine months of 2013, a decline of 13% compared with the same period in 2012. Foreign exchange unfavorably affected global sales performance by 3% and 2% in the third quarter and first nine months of 2013, respectively. Sales performance primarily reflects generic competition in the United States and Europe. As previously disclosed, by agreement, a generic manufacturer launched a generic version of Temodar in the United States in August 2013. Temodar lost patent exclusivity in the EU in 2009. Accordingly, the Company is experiencing significant sales declines due the loss of exclusivity in these markets and the Company expects these declines to continue.

Global sales of Emend (aprepitant), for the prevention of chemotherapy-induced and post-operative nausea and vomiting, were \$123 million in the third quarter of 2013, an increase of 11% compared with the third quarter of 2012, largely reflecting volume growth in the United States and the emerging markets. Sales of Emend were \$373 million for the first nine months of 2013, an increase of 4% compared with the same period in 2012, reflecting volume growth in the emerging markets and the United States, partially offset by a decline in Japan. Foreign exchange unfavorably affected global sales performance by 2% for the first nine months of 2013.

### Other

Worldwide sales of ophthalmic products Cosopt (dorzolamide hydrochloride-timolol maleate ophthalmic solution) and Trusopt (dorzolamide hydrochloride ophthalmic solution) increased 3% in the third quarter of 2013 to \$104 million. Global sales of Cosopt and Trusopt decreased 5% in the first nine months of 2013 to \$313 million. Foreign exchange unfavorably affected global sales performance by 8% and 7% in the third quarter and first nine months of 2013, respectively. Excluding the unfavorable effect of foreign exchange, sales performance in the first nine months of 2013 reflects volume growth in Japan, partially offset by declines in Europe and Canada. The patent for Cosopt expired in a number of major European markets in March 2013 and the Company is experiencing sales declines in those markets and expects the declines to continue. The patents that provided market exclusivity for Cosopt and Trusopt in the United States and for Trusopt in a number of major European markets had previously expired.

Bridion (sugammadex sodium injection), for the reversal of certain muscle relaxants used during surgery, is approved and has been launched in many countries outside of the United States. Sales of Bridion grew 10% to \$75 million in the third quarter of 2013 and increased 11% to \$206 million for the first nine months of 2013 compared with the same periods of 2012. The sales increases were driven by volume growth in Europe, the emerging markets and Japan, partially offset by the unfavorable effect of foreign exchange particularly in Japan. Foreign exchange unfavorably affected global sales performance by 16% and 12% in the third quarter and first nine months of 2013, respectively. In September 2013, the Company received a CRL from the FDA for the resubmission of the New Drug Application (“NDA”) for sugammadex sodium injection (see “Research and Development Update” below).

- 38 -

---

In 2009, the FDA approved Saphris (asenapine), an antipsychotic indicated for the treatment of schizophrenia and bipolar I disorder in adults. In 2010, asenapine, sold under the brand name Sycrest, received marketing approval in the EU for the treatment of bipolar I disorder in adults. In 2010, Merck and H. Lundbeck A/S (“Lundbeck”) announced a worldwide commercialization agreement for Sycrest sublingual tablets (5 mg, 10 mg). Under the terms of the agreement, Lundbeck paid a fee and makes product supply payments in exchange for exclusive commercial rights to Sycrest in all markets outside the United States, China and Japan. Merck’s sales of Saphris were \$44 million and \$39 million in the third quarter of 2013 and 2012, respectively, and were \$117 million and \$123 million in the first nine months of 2013 and 2012, respectively. During the second quarter of 2013, the Company reduced cash flow projections for Saphris/Sycrest as a result of reduced expectations in international markets and in the United States. These revisions to cash flows indicated that the Saphris/Sycrest intangible asset value was not recoverable on an undiscounted cash flows basis. Utilizing market participant assumptions, and considering several different scenarios, the Company concluded that its best estimate of the current fair value of the intangible asset related to Saphris/Sycrest was approximately \$170 million, which resulted in the recognition of an impairment charge of \$330 million reflected within Materials and production costs for the first nine months of 2013.

Other products contained in Hospital and Specialty include among others, Invanz (ertapenem sodium) for the treatment of certain infections; Noxafil (posaconazole) for the prevention of certain invasive fungal infections; and Integrilin (eptifibatide), a treatment for patients with acute coronary syndrome, which is sold by the Company in the United States and Canada.

#### 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.

Global sales of Cozaar and its companion agent Hyzaar (a combination of Cozaar and hydrochlorothiazide), treatments for hypertension, were \$238 million in the third quarter of 2013 and \$760 million for the first nine months of 2013, representing declines of 19% and 22%, respectively, compared with the same periods of 2012. The declines were driven largely by lower sales in Japan, reflecting lower volumes and the unfavorable effect of foreign exchange, and lower volumes in Europe. Foreign exchange unfavorably affected global sales performance by 9% and 8% for the third quarter and first nine months of 2013, respectively. The patents that provided market exclusivity for Cozaar and Hyzaar in the United States and in a number of major international markets have expired. Accordingly, the Company expects the declines in Cozaar and Hyzaar sales to continue.

Worldwide sales of Propecia, a product for the treatment of male pattern hair loss, were \$71 million and \$206 million in the third quarter and first nine months of 2013, respectively, representing declines of 32% and 34%, respectively, compared with the same periods in 2012. Foreign exchange unfavorably affected global sales performance by 8% and 6% in the third quarter and first nine months of 2013, respectively. The sales declines in both periods were driven primarily by volume declines in the United States, as well as declines in Japan due largely to the unfavorable effect of foreign exchange. The Company lost U.S. market exclusivity for Propecia in 2013 and multiple generics have entered the market. Accordingly, the Company is experiencing a significant decline in U.S. sales of Propecia and expects the decline to continue.

Global sales of Clarinex (marketed as Aerius in many countries outside the United States), a non-sedating antihistamine, were \$54 million for the third quarter of 2013, a decline of 15% compared with the third quarter of 2012, and were \$180 million for the first nine months of 2013, a decline of 47% compared with the same period of 2012, reflecting lower volumes in the United States, and for the year-to-date period also in Europe, as a result of generic competition. As previously disclosed, by virtue of litigation settlements, certain generic manufacturers were given the right to enter the U.S. market in 2012 and several generic versions have been launched. The Company anticipates that sales of Clarinex will continue to decline.

Global sales of Maxalt, a product for the acute treatment of migraine, were \$40 million and \$124 million in the third quarter and first nine months of 2013, respectively, representing declines of 76% and 74%, respectively, compared

with the same periods in 2012, driven primarily by lower volumes in the United States, as well as in Europe. The patent that provided U.S. market exclusivity for Maxalt expired in December 2012 and the Company experienced a significant and rapid decline in U.S. Maxalt sales thereafter. In addition, the patent that provided market exclusivity for Maxalt expired in a number of major European markets in August 2013 and the Company is experiencing sales declines in those markets. The Company anticipates the sales declines in the United States and Europe will continue. Other products contained in Diversified Brands include among others, Primaxin (imipenem and cilastatin sodium), an anti-bacterial product; Zocor, a statin for modifying cholesterol; prescription Claritin (loratadine), a treatment for seasonal outdoor allergies and year-round indoor allergies; Remeron (mirtazapine), an antidepressant; and Proscar (finasteride), a urology product for the treatment of symptomatic benign prostate enlargement.

- 39 -

---

## 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 (see “Selected Joint Venture and Affiliate Information” below). Supply sales to SPMSD, however, are included.

Merck’s sales of Gardasil, a vaccine to help prevent certain diseases caused by human papillomavirus (“HPV”) types 6, 11, 16 and 18, grew 15% in the third quarter of 2013 to \$665 million and increased 21% in the first nine months of 2013 to \$1.4 billion as compared with the same periods in 2012. The sales increases were driven primarily by volume growth in the United States, reflecting continued uptake in males and higher public sector purchases, and for the year-to-date period volume growth in certain emerging markets, partially offset by lower sales volumes in Japan. Sales in the third quarter and first nine months of 2013 include \$23 million and \$37 million, respectively, of purchases for the U.S. Centers for Disease Control and Prevention Pediatric Vaccine Stockpile. On June 14, 2013, the Japanese Health Ministry issued an advisory to suspend active promotion of HPV vaccines. Accordingly, the Company recorded almost no sales of Gardasil in Japan in the third quarter of 2013. Sales of Gardasil in Japan were approximately \$140 million for the full year of 2012.

ProQuad, a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, which experienced supply constraints in recent years, became available again in the United States for ordering in October 2012. Merck’s sales of ProQuad were \$101 million in the third quarter of 2013 and \$245 million in the first nine months of 2013.

Merck’s sales of Varivax, a vaccine to help prevent chickenpox (varicella), were \$213 million for the third quarter of 2013 compared with \$283 million for the third quarter of 2012 and were \$540 million for the first nine months of 2013 compared with \$675 million for the first nine months of 2012. Merck’s sales of M-M-R II [Measles, Mumps and Rubella Virus Vaccine Live], a vaccine to help protect against measles, mumps and rubella, were \$107 million for the third quarter of 2013 compared with \$111 million for the third quarter of 2012 and were \$247 million for the first nine months of 2013 compared with \$292 million for the first nine months of 2012. The Varivax and M-M-R II sales declines are largely attributable to the availability of ProQuad discussed above.

Global sales of RotaTeq, a vaccine to help protect against rotavirus gastroenteritis in infants and children, recorded by Merck were \$201 million in the third quarter of 2013, an increase of 34% compared with the third quarter of 2012, and were \$507 million in the first nine months of 2013, an increase of 17% compared with the same period in 2012, reflecting higher public sector purchases in the United States and higher sales in Japan. In the first nine months of 2013, these increases were partially offset by declines in Latin America.

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 \$185 million in the third quarter of 2013 compared with \$202 million in the third quarter of 2012 driven by lower demand in the United States. Zostavax sales were \$494 million in the first nine months of 2013 compared with \$426 million in the first nine months of 2012 primarily reflecting higher demand in the United States, as well as in Canada. The Company is launching Zostavax on a limited basis outside of the United States.

## Other Segments

### 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 intense competition and the frequent introduction of generic products. Global sales of Animal Health products totaled \$800 million for the third quarter of 2013, a decline of 2% compared with the third quarter of 2012, and were \$2.5 billion for the first nine months of 2013, essentially flat when compared with the same period in 2012. Foreign exchange unfavorably affected global sales performance by 2% in both the third quarter and first nine months of 2013. Sales performance in the quarter and

year-to-date period reflects lower sales of ruminant products, primarily Zilmax, partially offset by growth in companion animal products. During the third quarter of 2013, Merck Animal Health voluntarily suspended sales of Zilmax (zilpaterol hydrochloride), a feed supplement for beef cattle, in the United States and Canada. Zilmax sales in the United States and Canada were \$159 million for the full year of 2012.

Consumer Care

Consumer Care products include over-the-counter, foot care and sun care products such as Claritin non-drowsy antihistamines; Dr. Scholl's foot care products; and Coppertone sun care products. Global sales of Consumer Care products were \$443 million for the third quarter of 2013, a decrease of 2% compared with the third quarter of 2012, including a 2% unfavorable effect from foreign exchange. The sales decline largely reflects lower sales of Dr. Scholl's foot care products, partially offset by the launch of Oxytrol for Women, the first and only over-the-counter treatment for overactive bladder in women. Consumer Care product sales were \$1.5 billion for the first nine months of 2013, a decline of 3% compared with the first nine months of 2012



including a 1% unfavorable effect from foreign exchange. The sales decline in the year-to-date period resulted from the termination in China of certain Consumer Care distribution arrangements and a reversal of sales previously made to those distributors, together with associated termination costs. Excluding those actions, Consumer Care global sales would have increased by 1% for the first nine months of 2013 compared with the same period in 2012 including a 1% unfavorable impact due to foreign exchange.

#### Alliances

The alliances segment includes results from the Company's relationship with AstraZeneca ("AZLP"). Revenue from AZLP, primarily relating to sales of Nexium and Prilosec, was \$220 million and \$255 million in the third quarter of 2013 and 2012, respectively, and was \$727 million and \$664 million in the first nine months of 2013 and 2012, respectively. AstraZeneca has an option to buy Merck's interest in a subsidiary and, through it, Merck's interest in Nexium and Prilosec, exercisable in 2014, and the Company believes that it is likely that AstraZeneca will exercise that option (see "Selected Joint Venture and Affiliate Information" below). If AstraZeneca exercises its option, the Company will no longer record equity income from AZLP and supply sales to AZLP are expected to terminate.

#### Costs, Expenses and Other

In October 2013, the Company announced the 2013 Restructuring Program as part of a global initiative to sharpen its commercial and research and development focus. The actions under the new program 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 restructuring costs of \$544 million in the third quarter and first nine months of 2013 related to this 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 \$2.5 billion to \$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 expects the actions under the 2013 Restructuring Program to result in annual net cost savings of approximately \$2.0 billion by the end of 2015. The Company anticipates that the actions under the 2013 Restructuring Program, combined with remaining actions under the Merger Restructuring Program (discussed below), will result in annual net cost savings of \$2.5 billion by the end of 2015 compared with full-year 2012 expense levels.

In February 2010, subsequent to the Merck and Schering-Plough Corporation ("Schering-Plough") merger (the "Merger"), the Company commenced actions under a global restructuring program (the "Merger Restructuring Program") in conjunction with the integration of the legacy Merck and legacy Schering-Plough businesses designed to optimize 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 restructuring costs of \$423 million and \$150 million in the third quarter of 2013 and 2012, respectively, and \$841 million and \$722 million in the first nine months of 2013 and 2012, respectively, related to this program. The restructuring actions under the Merger Restructuring Program are expected to be substantially completed by the end of 2013, with the exception of certain actions, principally manufacturing-related. Subsequent to the Merger, the Company has rationalized a number of manufacturing sites worldwide. The remaining actions under this program will result in additional manufacturing facility rationalizations, which are expected to be substantially completed by 2016. The Company expects the estimated total cumulative pretax costs for this program to be approximately \$7.4 billion to \$7.7 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 by the end of 2013 of approximately \$3.5 billion to \$4.0 billion and annual savings upon completion of the program of approximately \$4.0 billion to \$4.6 billion.

In October 2008, Merck announced a global restructuring program (the “2008 Restructuring Program”) to reduce its cost structure, increase efficiency, and enhance competitiveness. Pretax restructuring costs of \$13 million were recorded in the third quarter of 2012, and \$54 million and \$23 million were recorded in the first nine months of 2013 and 2012, respectively, related to the 2008 Restructuring Program. The 2008 Restructuring Program was substantially completed in 2011, with the exception of certain manufacturing-related actions, which are expected to be completed by the end of 2015. Merck expects the 2008 Restructuring Program to yield cumulative pretax savings of \$3.8 billion to \$4.2 billion from 2008 to 2013. As of July 1, 2013, the remaining accrued liability for future separations under the 2008 Restructuring Program was transferred to the Merger Restructuring Program

and any remaining activities under the 2008 Restructuring Program are being accounted for as part of the Merger Restructuring Program beginning in the third quarter of 2013.

The Company anticipates that total costs associated with restructuring activities in 2013 for the 2013 Restructuring Program, the Merger Restructuring Program and the 2008 Restructuring Program will be in the range of \$1.6 billion to \$1.9 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 \$4.1 billion for the third quarter of 2013, a decrease of 1% compared with the third quarter of 2012, and were \$12.3 billion for the first nine months of 2013, comparable with the first nine months of 2012. Costs in the third quarter and first nine months of 2013 include \$1.2 billion and \$3.5 billion, respectively, and for the third quarter and first nine months of 2012 include \$1.2 billion and \$3.7 billion, respectively, of expenses for the amortization of intangible assets recognized in connection with mergers and acquisitions. In addition, expenses in the third quarter and first nine months of 2013 include a \$41 million intangible asset impairment charge related to a licensing agreement and for the first nine months of 2013 also include a product intangible asset impairment charge of \$330 million. Included in materials and production costs are costs associated with restructuring activities which amounted to \$57 million and \$60 million in the third quarter of 2013 and 2012, respectively, and \$193 million and \$148 million in the first nine months of 2013 and 2012, 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 62.8% in the third quarter of 2013 compared with 64.0% in the third quarter of 2012 and was 62.3% in the first nine months of 2013 compared with 65.4% for the first nine months of 2012. The amortization of intangible assets, as well as the restructuring and impairment charges noted above reduced gross margin by 11.2 percentage points for both the third quarter of 2013 and 2012, and by 12.4 and 10.8 percentage points for the first nine months of 2013 and 2012, respectively. The gross margin declines were driven in part by the loss of Singulair sales as a result of patent expiries in the United States in August 2012 and in major European markets in February 2013. In addition, generic competition in the United States for Maxalt, Temodar and Propecia also negatively affected gross margin in the third quarter and first nine months of 2013. These declines were partially offset by improvements resulting from lower costs due to manufacturing efficiencies. The Company anticipates that gross margin will continue to be negatively affected by the loss of market exclusivity for Singulair, Maxalt, Temodar and Propecia for the remainder of 2013.

#### Marketing and Administrative

Marketing and administrative expenses were \$2.8 billion in the third quarter of 2013 and were \$8.9 billion for the first nine months of 2013, representing declines of 8% and 5%, respectively, compared with the same periods of 2012. The declines were largely due to lower promotional spending and selling costs, as well as the favorable effect of foreign exchange. Expenses for the third quarter of 2013 and 2012 include \$31 million and \$25 million, respectively, and for the first nine months of 2013 and 2012 include \$64 million and \$70 million, respectively, of restructuring costs, related primarily to accelerated depreciation for facilities to be closed or divested. Separation costs associated with sales force reductions have been incurred and are reflected in Restructuring costs as discussed below. Marketing and administrative expenses also include \$20 million and \$68 million of acquisition-related costs in the third quarter of 2013 and 2012, respectively, and \$62 million and \$183 million for the first nine months of 2013 and 2012, respectively, consisting of incremental, third-party integration costs related to the Merger, including costs related to legal entity and systems integration.

#### Research and Development

Research and development expenses were \$1.7 billion for the third quarter of 2013, a decline of 13% compared with the third quarter of 2012, and were \$5.7 billion for the first nine months of 2013, a decrease of 5% compared with the first nine months of 2012. Research and development expenses are comprised of the costs directly incurred by Merck Research Laboratories (“MRL”), the Company’s research and development division that focuses on human health-related activities, which were approximately \$1.0 billion and \$1.1 billion in the third quarter of 2013 and 2012, respectively, and were \$3.2 billion and \$3.3 billion in the first nine months of 2013 and 2012, 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, certain costs from operating segments, including the Pharmaceutical, Animal Health and Consumer Care segments, which in the aggregate were \$661 million and \$798 million for the third quarter of 2013 and 2012, respectively, and \$2.1 billion and \$2.4 billion for the first nine months of 2013 and 2012, respectively. Research and development costs for the third quarter and first nine months of 2013 declined in part due to targeted productivity improvements and the timing of clinical development programs. Research and development expenses in the first nine months of 2013 also reflect lower costs for upfront

and milestone payments for in-licensed programs as compared with the same period in the prior year, largely due to the payment of \$120 million in 2012 related to an agreement with Endocyte, Inc.

Research and development expenses also include in-process research and development (“IPR&D”) impairment charges and research and development-related restructuring charges. During the third quarter of 2012, the Company recorded \$40 million, and for the first nine months of 2013 and 2012 recognized \$264 million and \$176 million, respectively, of IPR&D impairment charges. Of the IPR&D impairment charges recorded in the first nine months of 2013, \$181 million related to the write-off of the intangible asset associated with preladenant as a result of the discontinuation of the clinical development program for this compound (see “Research and Development Update” below). In addition, the Company recorded impairment charges resulting from changes in cash flow assumptions for certain compounds. The remaining impairment charges for the first nine months of 2013 and the charges in the third quarter and first nine months of 2012 reflect impairments primarily related to pipeline programs that had previously been deprioritized and were subsequently deemed to have no alternative use during the period. The Company may recognize additional non-cash impairment charges in the future for the cancellation or delay of other pipeline programs that were measured at fair value and capitalized in connection with mergers and acquisitions and such charges could be material. Research and development expenses also reflect accelerated depreciation and asset abandonment costs associated with restructuring activities of \$9 million and \$(32) million in the third quarter of 2013 and 2012, respectively, and \$38 million and \$54 million in the first nine months of 2013 and 2012, respectively. In the third quarter of 2012, the Company recorded an adjustment to accelerated depreciation costs included in research and development expenses revising previously recorded amounts for certain facilities.

#### Restructuring Costs

Restructuring costs, primarily representing separation and other related costs associated with restructuring activities, were \$870 million and \$110 million for the third quarter of 2013 and 2012, respectively, and were \$1.1 billion and \$473 million for the first nine months of 2013 and 2012, respectively. Costs in the third quarter and first nine months of 2013 include \$501 million of costs related to the 2013 Restructuring Program. Nearly all of the remaining costs in 2013 and the costs in 2012 related to the Merger Restructuring Program. Separation costs were incurred associated with actual headcount reductions, as well as estimated expenses under existing severance programs for headcount reductions that were probable and could be reasonably estimated. Merck eliminated approximately 1,070 positions in the third quarter of 2013 which related to the Merger Restructuring Program. During the first nine months of 2013, Merck eliminated approximately 2,530 positions of which 2,475 related to the Merger Restructuring Program and 55 related to the 2008 Restructuring Program. Merck eliminated approximately 535 positions in the third quarter of 2012, nearly all of which related to the Merger Restructuring Program. During the first nine months of 2012, Merck eliminated approximately 2,475 positions of which 2,325 related to the Merger Restructuring Program and 150 related to the 2008 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.

#### Equity Income from Affiliates

Equity income from affiliates, which reflects the performance of the Company’s joint ventures and other equity method affiliates, primarily AZLP, was \$102 million in the third quarter of 2013 compared with \$158 million in the third quarter of 2012 and was \$351 million in the first nine months of 2013 compared with \$410 million in the first nine months of 2012. The declines were driven primarily by lower equity from AZLP. (See “Selected Joint Venture and Affiliate Information” below.)

#### Other (Income) Expense, Net

Other (income) expense, net was \$172 million of expense in the third quarter of 2013 compared with \$200 million of expense in the third quarter of 2012 and was \$656 million of expense in the first nine months of 2013 compared with \$446 million of expense in the first nine months of 2012. The higher net expenses in the first nine months of 2013

include losses from a Venezuelan currency devaluation, as well as increased interest expense resulting in part from issuances of debt in September 2012 and May 2013. In February 2013, the Venezuelan government devalued its currency (Bolívar Fuertes) from 4.30 VEF per U.S. dollar to 6.30 VEF per U.S. dollar. The Company recognized losses due to exchange of approximately \$140 million in the first quarter of 2013 resulting from the remeasurement of the local monetary assets and liabilities at the new rate. Since January 2010, Venezuela has been designated hyperinflationary and, as a result, local foreign operations are remeasured in U.S. dollars with the impact recorded in results of operations. Given the economic and political environment in Venezuela, future devaluations of its currency may occur.

## Segment Profits

(\$ in millions)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2013	2012	2013	2012
Pharmaceutical segment profits	\$5,983	\$6,265	\$17,022	\$19,767
Other non-reportable segment profits	750	819	2,445	2,397
Other	(5,208 )	(4,866 )	(15,147 )	(14,759 )
Income before income taxes	\$1,525	\$2,218	\$4,320	\$7,405

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 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-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, divested products or businesses, and other supply sales.

Pharmaceutical segment profits declined 5% in the third quarter and 14% in first nine months of 2013 as compared with the same periods in 2012, driven primarily by the effects of the loss of market exclusivity for certain products, particularly Singulair.

## Taxes on Income

The effective income tax rates of 24.6% and 20.5% for the third quarter of 2013 and 2012, respectively, and 14.3% and 27.8% for the first nine months of 2013 and 2012, respectively, reflect the impacts of acquisition-related costs and restructuring costs, partially offset by the beneficial impact of foreign earnings. In addition, the effective tax rates for the third quarter and first nine months of 2013 reflect a net benefit of \$165 million from the settlements of certain federal income tax issues. The effective income tax rate for the first nine months of 2013 also reflects net benefits from reductions in tax reserves upon expiration of applicable statute of limitations, the favorable impact of tax legislation enacted in the first quarter of 2013 that extended the R&D tax credit for both 2012 and 2013, as well as an out-of-period net tax benefit of approximately \$160 million associated with the resolution of a previously disclosed legacy Schering-Plough federal income tax issue (see note 14 to the interim consolidated financial statements). The effective tax rates for the third quarter and first nine months of 2012 also reflect the favorable impacts of a tax settlement with the Canada Revenue Agency and the realization of foreign tax credits.

## Net Income and Earnings per Common Share

Net income attributable to Merck & Co., Inc. was \$1.1 billion for the third quarter of 2013 compared with \$1.7 billion for the third quarter of 2012 and \$3.6 billion for the first nine months of 2013 compared with \$5.3 billion for the first nine months of 2012. Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders ("EPS") for the third quarter of 2013 were \$0.38 compared with \$0.56 in the third quarter of 2012 and \$1.20 for the first nine months of 2013 compared with \$1.71 for the first nine months of 2012. The declines in net income and EPS were due primarily to lower sales reflecting the loss of market exclusivity for certain products, particularly Singulair, as well as higher restructuring costs and, for the year-to-date period, higher intangible asset impairment charges and exchange losses, partially offset by the favorable impact of certain tax items and lower operating expenses. Earnings per share for the third quarter and first nine months of 2013 benefited from lower average shares outstanding due to the ASR program (see Note 10 to the interim consolidated financial statements).

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-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

- 44 -

---



standardized meaning prescribed by GAAP and, therefore, may not be comparable to the calculation of similar measures of other companies.

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

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

(\$ in millions except per share amounts)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2013	2012	2013	2012
Pretax income as reported under GAAP	\$1,525	\$2,218	\$4,320	\$7,405
Increase (decrease) for excluded items:				
Acquisition-related costs	1,196	1,340	4,201	4,046
Restructuring costs	967	163	1,439	745
Certain other items	—	—	(13	) —
	3,688	3,721	9,947	12,196
Taxes on income as reported under GAAP	375	455	618	2,055
Estimated tax benefit on excluded items	393	300	1,081	848
Net tax benefits from settlements of federal income tax issues	165	—	325	—
	933	755	2,024	2,903
Non-GAAP net income	2,755	2,966	7,923	9,293
Less: Net income attributable to noncontrolling interests	26	34	79	89
Non-GAAP net income attributable to Merck & Co., Inc.	\$2,729	\$2,932	\$7,844	\$9,204
EPS assuming dilution as reported under GAAP	\$0.38	\$0.56	\$1.20	\$1.71
EPS difference <sup>(1)</sup>	0.54	0.39	1.41	1.28
Non-GAAP EPS assuming dilution	\$0.92	\$0.95	\$2.61	\$2.99

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

#### Acquisition-Related Costs

Non-GAAP income and non-GAAP EPS exclude the impact of certain amounts recorded in connection with mergers and acquisitions. These amounts include the amortization of intangible assets and inventory step-up, as well as intangible asset impairment charges. Also excluded are incremental, third-party integration costs associated with the Merger, such as costs related to legal entity and system integration, as well as other costs associated with mergers and acquisitions, such as severance costs which are not part of the Company's formal restructuring programs. These costs are excluded because management believes that these costs are not representative of ongoing normal business activities.

#### Restructuring Costs

Non-GAAP income and non-GAAP EPS exclude costs related to restructuring actions, including restructuring activities related to the Merger (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; 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

- 45 -

---

they would occur as part of the Company's normal business on a regular basis. Excluded from non-GAAP income and non-GAAP EPS are tax benefits from the resolution of certain federal income tax issues (see Note 14 to the interim consolidated financial statements).

#### Research and Development Update

In September 2013, the Company announced that the NDA for its investigational fertility treatment, corifollitropin alfa, has been accepted for standard review by the FDA. Merck is seeking FDA approval of corifollitropin alfa for controlled ovarian stimulation in women participating in assisted reproductive technology. If approved, corifollitropin alfa would be the first sustained follicular stimulant for use in a fertility treatment regimen. Merck's corifollitropin alfa is currently approved in more than 50 markets outside the United States, including the EU.

In July 2013, Merck announced that the NDA for its investigational anti-thrombotic medicine, vorapaxar, has been accepted for standard review by the FDA. Merck is seeking FDA approval of vorapaxar for the secondary prevention of cardiovascular events in patients with a history of heart attack and no history of stroke or transient ischemic attack. In March 2013, Merck announced that the Biologics License Application ("BLA") for MK-7243, an investigational Timothy grass pollen (*Phleum pratense*) allergy immunotherapy tablet ("AIT"), was accepted for review by the FDA. The BLA for MK-7243 is supported by Phase III trials that evaluated the safety and efficacy of the investigational product, including a long-term, multi-season trial. In addition, in May 2013, Merck announced that the BLA for MK-3641, an investigational ragweed pollen (*Ambrosia artemisiifolia*) AIT, was accepted for review by the FDA. The BLA for MK-3641 is supported by five studies evaluating the efficacy and safety of the tablet in adults, 18 years of age or older, with ragweed induced allergic rhinitis (with or without conjunctivitis). MK-7243 and MK-3641 are investigational sublingual dissolvable tablets designed to help treat the underlying cause of allergic rhinitis by generating an immune response to help protect against the targeted allergens. Merck has partnered with ALK-Abello to develop its investigational sublingual allergy immunotherapy tablets for ragweed pollen, Timothy grass pollen and house dust mites in North America. Merck expects the FDA's review for both MK-7243 and MK-3641 to be completed in the first half of 2014.

In April 2013, Merck announced that the FDA has granted MK-3475 Breakthrough Therapy designation for the treatment of patients with advanced melanoma. MK-3475 is Merck's investigational antibody therapy targeting Programmed Death receptor ("PD-1") that is currently being evaluated for the treatment of patients with advanced melanoma, and other tumor types. The designation of an investigational drug as a Breakthrough Therapy is intended to expedite the development and review of a candidate that is planned for use, alone or in combination, to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. The MK-3475 program also includes studies in patients with non-small cell lung cancer, squamous cell carcinoma of the head and neck, triple-negative breast cancer, uroepithelial tumors, colorectal cancer and hematologic malignancies. A new nonproprietary generic name for MK-3475 is under review by the United States Adopted Names Council.

In October 2013, Merck announced that the FDA has granted MK-5172/MK-8742 Breakthrough Therapy designation for treatment of chronic hepatitis C virus ("HCV") infection. MK-5172/MK-8742 is an all-oral combination regimen consisting of MK-5172, an investigational HCV NS3/4A protease inhibitor, and MK-8742, an investigational HCV NS5A replication complex inhibitor. MK-5172 and MK-8742 are being investigated in a broad clinical program that includes studies in patients with multiple HCV genotypes who are treatment-naïve, treatment failures as well as other important HCV subpopulations such as patients with cirrhosis and those co-infected with HIV.

In October 2013, Merck announced that V503, the Company's investigational 9-valent HPV vaccine, has completed its pivotal Phase III clinical trial and has met all primary study endpoints. The study evaluated the efficacy, immunogenicity and safety of V503 in females 16-26 years of age. The Company expects to submit a BLA for V503

to the FDA in 2013.

In September 2013, Merck announced that it had received a CRL from the FDA for the resubmission of the NDA for sugammadex sodium injection (MK-8616), Merck's investigational medicine for the reversal of neuromuscular blockade induced by rocuronium or vecuronium. The FDA's letter raised concerns about operational aspects of a hypersensitivity study that the agency had requested in 2008. To address the CRL, the Company intends to conduct a confirmatory hypersensitivity study as soon as practicable, following discussion about the study with the FDA. Sugammadex sodium injection is currently marketed in more than 50 countries outside of the United States as Bridion.

In July 2013, the Company announced that it had received a CRL from the FDA regarding the NDA for suvorexant, Merck's investigational medicine for the treatment of insomnia. In the CRL, the FDA advised Merck that: (1) the efficacy of

- 46 -

---

suvorexant has been established at doses of 10 mg to 40 mg in elderly and non-elderly adult patients; (2) 10 mg should be the starting dose for most patients, and must be available before suvorexant can be approved; (3) 15 mg and 20 mg doses would be appropriate in patients in whom the 10 mg dose is well-tolerated but not effective; and, (4) for patients taking concomitant moderate CYP3A4 inhibitors, a 5 mg dose would be necessary. In addition, the FDA determined that the safety data do not support the approval of suvorexant 30 mg and 40 mg. Based on initial review of the letter, Merck has determined that additional clinical efficacy studies of suvorexant 10 mg will not be necessary. However, further work to support manufacture of the 5 and 10 mg dosages is required to advance these dosage forms. Merck is in discussions with the FDA to confirm whether any new clinical data will be required to support the 5 mg dose. The Company is evaluating the requests outlined in the CRL and plans to submit definitive data in its NDA resubmission to the FDA in the first half of 2014. As previously disclosed, both FDA approval and a separate scheduling determination by the U.S. Drug Enforcement Administration are required before Merck can introduce suvorexant in the United States. Insomnia is a condition characterized by difficulty falling asleep and/or staying asleep. If approved, suvorexant would be the first in a new class of medicines, called orexin receptor antagonists, for use in patients with insomnia. The Company has submitted a new drug application for suvorexant to the health authorities in Japan and is continuing with plans to seek approval for suvorexant in other countries around the world.

In April 2013, Merck and Pfizer Inc. (“Pfizer”) announced that they had entered into a worldwide (except Japan) collaboration agreement for the development and commercialization of Pfizer’s ertugliflozin, an investigational oral sodium glucose cotransporter (“SGLT2”) inhibitor being evaluated for the treatment of type 2 diabetes. The Company is initiating Phase III clinical trials for ertugliflozin with Pfizer. Under the terms of the agreement, Merck and Pfizer will collaborate on the clinical development and commercialization of ertugliflozin and ertugliflozin-containing fixed-dose combinations with metformin and with Januvia (sitagliptin) tablets. Merck will continue to retain the rights to its existing portfolio of sitagliptin-containing products. Through the first nine months of 2013, Merck recorded as Research and development expenses \$60 million of upfront and milestone payments made to Pfizer. Pfizer will be eligible for additional payments associated with the achievement of pre-specified future clinical, regulatory and commercial milestones, including \$65 million for the initiation of Phase III clinical trials. The companies will share potential revenues and certain costs 60% to Merck and 40% to Pfizer. Each party will have certain manufacturing and supply obligations. The Company and Pfizer each have the right to terminate the agreement due to a material, uncured breach by, or insolvency of, the other party, or in the event of a safety issue. Pfizer has the right to terminate the agreement upon 12 months notice at any time following the first anniversary of the first commercial sale of a collaboration product, but must assign all rights to ertugliflozin to Merck. Upon termination of the agreement, depending upon the circumstances, the parties have varying rights and obligations with respect to the continued development and commercialization of ertugliflozin and certain payment obligations.

In September 2013, Merck and AstraZeneca announced a worldwide licensing agreement for Merck’s oral small molecule inhibitor of WEE1 kinase (MK-1775). MK-1775 is currently being evaluated in Phase IIa clinical studies in combination with standard-of-care therapies for the treatment of patients with certain types of ovarian cancer. Under the terms of the agreement, which closed in October 2013, AstraZeneca paid Merck a \$50 million upfront fee. In addition Merck will be eligible to receive future payments tied to development and regulatory milestones, plus sales-related payments and tiered royalties. AstraZeneca will be responsible for all future clinical development, manufacturing and marketing.

Merck has made the decision to discontinue the Phase III clinical trial for NOMAC/E2 (MK-8175A ), an oral combined hormonal contraceptive, being conducted in the United States. This decision is not based on any new safety or efficacy findings.

In May 2013, the Company provided an update on the clinical program for preladenant, Merck’s investigational adenosine A2A receptor antagonist for the treatment of Parkinson’s disease. An initial review of data from three separate Phase III trials did not provide evidence of efficacy for preladenant compared with placebo. Based on these results, Merck has taken steps to discontinue the extension phases of these studies and no longer plans to pursue

regulatory filings for preladenant. The decision to discontinue these studies is not based on any safety finding. The Company recorded an impairment charge of \$181 million in the first nine months of 2013 related to the discontinuation of the clinical development program for preladenant.

- 47 -

---

The chart below reflects the Company's research pipeline as of October 31, 2013. Candidates shown in Phase III include specific products and the date such candidate entered into Phase III development. Candidates shown in Phase II 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. Candidates in Phase I, additional indications in the same therapeutic area and additional claims, line extensions or formulations for in-line products are not shown.

Phase II	Phase III (Phase III entry date)	Under Review
Allergy	Atherosclerosis	Allergy
MK-8237, Immunotherapy <sup>(1)</sup>	MK-0859 (anacetrapib) (May 2008)	MK-7243, Grass pollen (U.S.) <sup>(1)</sup>
Alzheimer's Disease	Clostridium difficile Infection	MK-3641, Ragweed (U.S.) <sup>(1)</sup>
MK-8931 <sup>(2)</sup>	MK-3415A (actoxumab/bezlotoxumab) (November 2011)	Fertility
MK-7622	Contraception	MK-8962 (corifollitropin alfa injection) (U.S.)
Asthma	MK-8175A (NOMAC/E2) (U.S.) (June 2006) <sup>(3)</sup>	Insomnia
MK-1029	Diabetes Mellitus	MK-4305 (suvorexant) (U.S.) <sup>(6)</sup>
Bacterial Infection	MK-3102 (omarigliptin) (September 2012)	Neuromuscular Blockade Reversal
MK-7655	Hepatitis C	MK-8616 (sugammadex sodium injection) (U.S.) <sup>(7)</sup>
Cancer	MK-7009 (vaniprevir) (June 2011) <sup>(4)</sup>	Platinum-Resistant Ovarian Cancer
MK-0646 (dalotuzumab)	Herpes Zoster	MK-8109 (vintafolide) (EU)
MK-2206	V212 (inactivated VZV vaccine) (December 2010)	Thrombosis
MK-8669 (ridaforolimus)	HPV-Related Cancers	MK-5348 (vorapaxar) (U.S.)
CMV Prophylaxis in Transplant Patients	V503 (HPV vaccine (9 valent)) (September 2008)	
MK-8228 (letermovir)	Melanoma	
Contraception, Medicated IUS	MK-3475 (August 2013) <sup>(5)</sup>	
MK-8342	Osteoporosis	Footnotes:
Contraception, Next Generation Ring	MK-0822 (odanacatib) (September 2007)	<sup>(1)</sup> North American rights only.
MK-8175A	Pediatric Hexavalent Combination Vaccine	<sup>(2)</sup> Phase II/III adaptive design.
MK-8342B	V419 (April 2011)	<sup>(3)</sup> In November 2011, Merck received a CRL from the FDA for NOMAC/E2 (MK-8175A). Merck has made the decision to discontinue the Phase III clinical trial for NOMAC/E2 being conducted in the United States.
Diabetes	Platinum-Resistant Ovarian Cancer	<sup>(4)</sup> For development in Japan only.
MK-8835 (ertugliflozin)	MK-8109 (vintafolide) (U.S.) (April 2011)	<sup>(5)</sup> A new nonproprietary generic name for MK-3475 is under review by the United States Adopted Names Council.
Hepatitis C	Psoriasis	<sup>(6)</sup> In June 2013, Merck received a CRL from the FDA for suvorexant (MK-4305). The Company is
MK-5172	MK-3222 (tildrakizumab) (December 2012)	
MK-8742	Thrombosis	
HIV	MK-5348 (vorapaxar) (EU) (September 2007)	
MK-1439		
Migraine		
MK-1602		
Overactive Bladder		

MK-4618

evaluating the requests in the CRL and plans to submit definitive data in its NDA resubmission to the FDA in the first half of 2014.

Pneumoconjugate Vaccine  
V114  
Rheumatoid Arthritis  
MK-8457

<sup>(7)</sup> In September 2013, Merck received a CRL from the FDA for the resubmission of the NDA for sugammadex sodium injection (MK-8616). To address the CRL, the Company intends to conduct a confirmatory hypersensitivity study as soon as practicable, following discussion about the study with the FDA.

#### Selected Joint Venture and Affiliate Information

##### AstraZeneca LP

In 1998, Merck and Astra completed the restructuring of the ownership and operations of their existing joint venture whereby Merck acquired Astra's interest in KBI Inc. ("KBI") and contributed KBI's operating assets to a new U.S. limited partnership, Astra Pharmaceuticals L.P. (the "Partnership"), 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.

In 2014, AstraZeneca has the option to purchase Merck's interest in KBI based in part on the value of Merck's interest in Nexium and Prilosec. AstraZeneca's option is exercisable between March 1, 2014 and April 30, 2014. If AstraZeneca chooses to exercise this option, the closing date is expected to be June 30, 2014. Under the amended agreement, AstraZeneca will make a payment to Merck upon closing of \$327 million, reflecting an estimate of the fair value of Merck's interest in Nexium and Prilosec. This portion of the exercise price is subject to a true-up in 2018 based on actual sales from closing in 2014 to June 2018. The exercise price will also include an additional amount equal to a multiple of ten times Merck's average 1% annual profit allocation in the partnership for the three years prior to exercise. The Company believes that it is likely that AstraZeneca will exercise its



option in 2014. If AstraZeneca exercises its option, the Company will no longer record equity income from AZLP and supply sales to AZLP are expected to terminate.

#### 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 \$392 million and \$336 million in the third quarter of 2013 and 2012, respectively, and were \$829 million and \$771 million for the first nine months of 2013 and 2012, respectively. The increase in both periods was largely attributable to \$41 million of higher Zostavax sales due to the launch in the United Kingdom in the third quarter of 2013. Higher sales of Gardasil also contributed to the increase in SPMSD sales in the first nine months of 2013. SPMSD sales of Gardasil were \$87 million and \$82 million for the third quarter of 2013 and 2012, respectively, and were \$221 million and \$197 million for the first nine months of 2013 and 2012, respectively.

The Company records the results from its interest in AZLP and SPMSD in Equity income from affiliates.

#### Liquidity and Capital Resources

(\$ in millions)	September 30, 2013	December 31, 2012		
Cash and investments	\$27,367	\$23,446		
Working capital	19,550	16,509		
Total debt to total liabilities and equity	25.0	% 19.4	%	

During the first nine months of 2013, cash provided by operating activities was \$8.6 billion compared with \$8.2 billion in the first nine months of 2012. Cash provided by operating activities in the first nine months of 2013 includes a payment of \$480 million in connection with the previously disclosed settlement of the ENHANCE Litigation (see Note 9 to the interim consolidated financial statements). Cash provided by operating activities in the first nine months of 2012 includes a payment of \$960 million related to the resolution of certain Vioxx litigation. Cash provided by operating activities continues to be the Company's primary source of funds to finance operating needs, capital expenditures, treasury stock purchases and dividends paid to shareholders. Global economic conditions and ongoing sovereign debt issues, among other factors, have adversely affected foreign receivables in certain European countries (see Note 4 to the interim consolidated financial statements). Additionally, the Company continues to expand in the emerging markets where payment terms tend to be longer. While the Company continues to receive payment on these receivables, these conditions have resulted in an increase in the average length of time it takes to collect accounts receivable outstanding thereby adversely affecting cash provided by operating activities.

Cash used in investing activities was \$4.3 billion in the first nine months of 2013 compared with \$2.4 billion in the first nine months of 2012 primarily reflecting higher purchases of securities and other investments, partially offset by higher proceeds from the sales of securities and other investments. Cash used in financing activities was \$3.4 billion in the first nine months of 2013 compared with \$2.0 billion in the first nine months of 2012. The higher use of cash in financing activities was driven primarily by higher purchases of treasury stock (largely under an accelerated share repurchase agreement as discussed below), as well as higher payments on debt and lower proceeds from the exercise of stock options, partially offset by higher proceeds from the issuance of debt and an increase in short-term borrowings.

At September 30, 2013, the total of worldwide cash and investments was \$27.4 billion, including \$18.2 billion of cash, cash equivalents and short-term investments and \$9.2 billion of long-term investments. Generally 80%-90% of these cash and investments are held by foreign subsidiaries and 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, treasury stock purchases and dividends paid to shareholders.

Capital expenditures totaled \$1.1 billion and \$1.2 billion for the first nine months of 2013 and 2012, respectively. Dividends paid to stockholders were \$3.9 billion and \$3.8 billion for the first nine months of 2013 and 2012, respectively. In May 2013, the Board of Directors declared a quarterly dividend for the third quarter of \$0.43 per share on the Company's common stock that was paid in July 2013. In July 2013, the Board of Directors declared a quarterly dividend for the fourth quarter of \$0.43 per share on the Company's common stock that was paid in October 2013.

- 49 -

---

In May 2013, the Company completed an underwritten public offering of \$6.5 billion senior unsecured notes consisting of \$1.0 billion aggregate principal amount of 0.70% notes due 2016, \$500 million aggregate principal amount of floating rate notes due 2016, \$1.0 billion aggregate principal amount of 1.30% notes due 2018, \$1.0 billion aggregate principal amount of floating rate notes due 2018, \$1.75 billion aggregate principal amount of 2.80% notes due 2023 and \$1.25 billion aggregate principal amount of 4.15% notes due 2043. Interest on the notes is payable semi-annually. The notes of each series are redeemable in whole or in part at any time at the Company's option at varying redemption prices. A substantial portion of the net proceeds from the notes were used to repurchase the Company's common stock pursuant to an accelerated share repurchase agreement in May 2013 discussed below. On May 20, 2013, Merck entered into an accelerated share repurchase ("ASR") agreement with Goldman Sachs. Under the ASR, Merck agreed to purchase approximately \$5 billion of Merck's common stock, in total, with an initial delivery of approximately 99.5 million shares of Merck's common stock, based on current market price, made by Goldman Sachs to Merck, and payment of \$5 billion made by Merck to Goldman Sachs, on May 21, 2013. The payment to Goldman Sachs was recorded as a reduction to shareholders' equity, consisting of a \$4.5 billion increase in treasury stock, which reflected the value of the initial 99.5 million shares received upon execution, and a \$500 million decrease in other-paid-in capital, which reflected the value of the stock held back by Goldman Sachs pending final settlement. Upon settlement of the ASR on October 31, 2013, Merck received an additional 5.5 million shares as determined by the average daily volume weighted-average price of Merck's common stock during the term of the ASR program bringing the total shares received by Merck under this program to 105 million. The receipt of the additional shares will be reflected as an increase to treasury stock and an increase to other-paid-in capital in the fourth quarter of 2013. The ASR was entered into pursuant to the share repurchase program announced on May 1, 2013 as discussed below.

On May 1, 2013, the Company announced that its board of directors authorized additional purchases of up to \$15 billion of Merck's common stock for its treasury. The Company expects to repurchase approximately \$7.5 billion of common stock within 12 months following the date of the announcement, financed through a combination of debt issuance and operating cash flows, with the remainder to be repurchased over time with no time limit. Purchases may be made in open-market transactions, block transactions on or off an exchange, or in privately negotiated transactions. During the first nine months of 2013, the Company purchased 129 million shares for its treasury, which includes 99.5 million shares under the ASR discussed above. The Company spent \$6.3 billion purchasing these shares, including \$5.0 billion related to the ASR. As of September 30, 2013, the Company had approximately \$10.6 billion remaining under the May share repurchase program.

The Company has a \$4.0 billion, five-year credit facility that matures in May 2017. 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, 2012 included in Merck's Form 10-K filed on February 28, 2013. 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, 2012 other than with respect to the guidance on testing indefinite-lived intangible assets for impairment adopted in the first quarter of 2013 as discussed in Note 1 to the interim 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

Officers have concluded that as of September 30, 2013, the Company's disclosure controls and procedures are effective. The Company implemented a new financial reporting consolidation system in the third quarter of 2013. The Company completed testing of this financial reporting system prior to its launch, continues to monitor impacted financial and business processes and believes that an effective control environment has been maintained post-implementation.

- 50 -

---

**CAUTIONARY FACTORS THAT MAY AFFECT FUTURE RESULTS**

This report and other written reports and oral statements made from time to time by the Company may contain so-called “forward-looking statements,” all of which are based on management’s current expectations and are subject to risks and uncertainties which may cause results to differ materially from those set forth in the statements. One can identify these forward-looking statements by their use of words such as “anticipates,” “expects,” “plans,” “will,” “estimates,” “forecasts,” “projects” and other words of similar meaning. One can also identify them by the fact that they do not relate strictly to historical or current facts. These statements are likely to address the Company’s growth strategy, financial results, product development, product approvals, product potential and development programs. One must carefully consider any such statement and should understand that many factors could cause actual results to differ materially from the Company’s forward-looking statements. These factors include inaccurate assumptions and a broad variety of other risks and uncertainties, including some that are known and some that are not. No forward-looking statement can be guaranteed and actual future results may vary materially.

The Company does not assume the obligation to update any forward-looking statement. One should carefully evaluate such statements in light of factors, including risk factors, described in the Company’s filings with the Securities and Exchange Commission, especially on Forms 10-K, 10-Q and 8-K. In Item 1A. “Risk Factors” of the Company’s Annual Report on Form 10-K for the year ended December 31, 2012, as filed on February 28, 2013, 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 months ended September 30, 2013 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	1,855,733	\$47.40	\$10,702
August 1 - August 31	1,369,853	\$48.12	\$10,636
September 1 - September 30	1,277,728	\$47.77	\$10,575
Total	4,503,314	\$47.73	\$10,575

<sup>(1)</sup> All shares purchased during the period were made as part of a plan approved by the Board of Directors in May 2013 to purchase up to \$15 billion in Merck shares.

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
3.2	By-Laws of Merck & Co., Inc. (effective January 1, 2012) – Incorporated by reference to Current Report on Form 8-K filed December 21, 2011
10	Merck & Co., Inc. U.S. Separation Benefits Plan (effective as of January 1, 2013) (amended and restated as of October 1, 2013)
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, 2013, formatted in XBRL (Extensible Business Reporting Language): (i) the Interim Consolidated Statement of Income, (ii) the Interim Consolidated Statement of Comprehensive Income, (iii) the Interim Consolidated Balance Sheet, (iv) the Consolidated Statement of Cash Flows, and (v) Notes to 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 7, 2013

/s/ Bruce N. Kuhlik  
BRUCE N. KUHLIK  
Executive Vice President and General Counsel

Date: November 7, 2013

/s/ John Canan  
JOHN CANAN  
Senior Vice President Finance - Global  
Controller

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
3.2	By-Laws of Merck & Co., Inc. (effective January 1, 2012) – Incorporated by reference to Current Report on Form 8-K filed December 21, 2011
10	Merck & Co., Inc. U.S. Separation Benefits Plan (effective as of January 1, 2013) (amended and restated as of October 1, 2013)
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, 2013, formatted in XBRL (Extensible Business Reporting Language): (i) the Interim Consolidated Statement of Income, (ii) the Interim Consolidated Statement of Comprehensive Income, (iii) the Interim Consolidated Balance Sheet, (iv) the Interim Consolidated Statement of Cash Flows, and (v) Notes to Interim Consolidated Financial Statements.