

Merck & Co. Inc.  
Form 10-Q  
May 09, 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 March 31, 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*

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

Identification No. 22-1918501

The number of shares of common stock outstanding as of the close of business on April 30, 2013: 3,019,611,844

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 InformationItem 1. Financial Statements**MERCK & CO., INC. AND SUBSIDIARIES****INTERIM CONSOLIDATED STATEMENT OF INCOME****(Unaudited, \$ in millions except per share amounts)**

	Three Months Ended March 31,	
	2013	2012
Sales	\$ 10,671	\$ 11,731
Costs, Expenses and Other		
Materials and production	3,959	4,037
Marketing and administrative	2,987	3,074
Research and development	1,907	1,862
Restructuring costs	119	219
Equity income from affiliates	(133)	(110)
Other (income) expense, net	282	142
	9,121	9,224
Income Before Taxes	1,550	2,507
Taxes on Income	(66)	740
Net Income	\$ 1,616	\$ 1,767
Less: Net Income Attributable to Noncontrolling Interests	23	29
Net Income Attributable to Merck & Co., Inc.	\$ 1,593	\$ 1,738
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	\$ 0.53	\$ 0.57
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	\$ 0.52	\$ 0.56
Dividends Declared per Common Share	\$ 0.43	\$ 0.42

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

	Three Months Ended March 31,	
	2013	2012
Net Income Attributable to Merck & Co., Inc.	\$ 1,593	\$ 1,738
Other Comprehensive Income (Loss) Net of Taxes:		
Net unrealized gain (loss) on derivatives, net of reclassifications	236	(58)
Net unrealized gain on investments, net of reclassifications	1	29
Benefit plan net gain and prior service cost, net of amortization	161	
Cumulative translation adjustment	(345)	(56)
	53	(85)

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

Comprehensive Income Attributable to Merck & Co., Inc.

\$ 1,646 \$ 1,653

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

- 2 -

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

## CONSOLIDATED BALANCE SHEET

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

	March 31, 2013	December 31, 2012
<b>Assets</b>		
Current Assets		
Cash and cash equivalents	\$ 13,024	\$ 13,451
Short-term investments	2,998	2,690
Accounts receivable (net of allowance for doubtful accounts of \$144 in 2013 and \$163 in 2012) (excludes accounts receivable of \$482 in 2013 and \$473 in 2012 classified in Other assets - see Note 4)	7,965	7,672
Inventories (excludes inventories of \$1,445 in 2013 and \$1,606 in 2012 classified in Other assets - see Note 5)	6,773	6,535
Deferred income taxes and other current assets	4,484	4,509
Total current assets	35,244	34,857
Investments	7,948	7,305
Property, Plant and Equipment, at cost, net of accumulated depreciation of \$17,622 in 2013 and \$17,385 in 2012	15,802	16,030
Goodwill	12,207	12,134
Other Intangibles, Net	28,108	29,083
Other Assets	6,891	6,723
	\$ 106,200	\$ 106,132
<b>Liabilities and Equity</b>		
Current Liabilities		
Loans payable and current portion of long-term debt	\$ 4,736	\$ 4,315
Trade accounts payable	2,084	1,753
Accrued and other current liabilities	9,569	9,737
Income taxes payable	1,075	1,200
Dividends payable	1,338	1,343
Total current liabilities	18,802	18,348
Long-Term Debt	16,089	16,254
Deferred Income Taxes and Noncurrent Liabilities	15,703	16,067
Merck & Co., Inc. Stockholders Equity		
Common stock, \$0.50 par value		
Authorized - 6,500,000,000 shares		
Issued - 3,577,103,522 shares in 2013 and 2012	1,788	1,788
Other paid-in capital	40,727	40,646
Retained earnings	40,272	39,985
Accumulated other comprehensive loss	(4,629)	(4,682)
	78,158	77,737
Less treasury stock, at cost:		
559,727,953 shares in 2013 and 550,468,221 shares in 2012	25,129	24,717
Total Merck & Co., Inc. stockholders equity	53,029	53,020
Noncontrolling Interests	2,577	2,443
Total equity	55,606	55,463
	\$ 106,200	\$ 106,132

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

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

## INTERIM CONSOLIDATED STATEMENT OF CASH FLOWS

(Unaudited, \$ in millions)

	Three Months Ended March 31,	
	2013	2012
<b>Cash Flows from Operating Activities</b>		
Net income	\$ 1,616	\$ 1,767
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	1,674	1,790
Intangible asset impairment charges	30	9
Equity income from affiliates	(133)	(110)
Dividends and distributions from equity affiliates	5	66
Deferred income taxes	(71)	(41)
Share-based compensation	67	76
Other	326	71
Net changes in assets and liabilities	(1,173)	(1,474)
Net Cash Provided by Operating Activities	2,341	2,154
<b>Cash Flows from Investing Activities</b>		
Capital expenditures	(351)	(331)
Purchases of securities and other investments	(4,010)	(2,725)
Proceeds from sales of securities and other investments	3,161	2,797
Other	47	(11)
Net Cash Used in Investing Activities	(1,153)	(270)
<b>Cash Flows from Financing Activities</b>		
Net change in short-term borrowings	880	634
Payments on debt	(506)	(2)
Purchases of treasury stock	(580)	(456)
Dividends paid to stockholders	(1,306)	(1,279)
Proceeds from exercise of stock options	92	379
Other	(1)	(1)
Net Cash Used in Financing Activities	(1,421)	(725)
Effect of Exchange Rate Changes on Cash and Cash Equivalents	(194)	(34)
Net (Decrease) Increase in Cash and Cash Equivalents	(427)	1,125
Cash and Cash Equivalents at Beginning of Year	13,451	13,531
Cash and Cash Equivalents at End of Period	\$ 13,024	\$ 14,656

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**

*Merger Restructuring Program*

In 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. These initial actions, which are expected to result in workforce reductions of approximately 17%, 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. In July 2011, the Company initiated further actions under the Merger Restructuring Program through which the Company expects to reduce its workforce measured at the time of the Merger by an additional 12% to 13% across the Company worldwide. A majority of the workforce reductions associated with these additional actions relate to manufacturing (including Animal Health), administrative and headquarters organizations. The Company will continue to hire employees in strategic growth areas of the business as necessary.

The Company recorded total pretax restructuring costs of \$153 million and \$279 million in the first quarter of 2013 and 2012, respectively, related to this program. Since inception of the Merger Restructuring Program through March 31, 2013, Merck has recorded total pretax accumulated costs of approximately \$6.2 billion and eliminated approximately 23,140 positions comprised of employee separations, as well as the elimination of contractors and vacant positions. 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 \$7.2 billion to \$7.5 billion. The Company estimates that approximately two-thirds of the cumulative pretax costs relate to cash outlays, primarily related to employee separation expense. Approximately one-third of the cumulative pretax costs are non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested.

*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. As part of the 2008 Restructuring Program, the Company expects to eliminate approximately 7,200 positions (6,800 active employees and 400 vacancies ) across the Company worldwide. Pretax restructuring costs of \$41 million and \$14 million were recorded in the first quarter of 2013 and 2012, respectively, related to the 2008 Restructuring Program. Since inception of the 2008 Restructuring Program through March 31, 2013, Merck has recorded total pretax accumulated costs of \$1.7 billion and eliminated approximately 6,450 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 2015,

with

-5-



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

the total cumulative pretax costs estimated to be up to \$2.0 billion. The Company estimates that two-thirds of the cumulative pretax costs relate to cash outlays, primarily from employee separation expense. Approximately one-third of the cumulative pretax costs are non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested.

For segment reporting, restructuring charges are unallocated expenses.

The following tables summarize the charges related to Merger Restructuring Program and 2008 Restructuring Program activities by type of cost:

(\$ in millions)	Three Months Ended March 31, 2013			
	Separation Costs	Accelerated Depreciation	Other	Total
<i>Merger Restructuring Program</i>				
Materials and production	\$	\$ 31	\$ 9	\$ 40
Marketing and administrative		15		15
Research and development		15		15
Restructuring costs	65		18	83
	65	61	27	153
<i>2008 Restructuring Program</i>				
Materials and production			3	3
Marketing and administrative		2		2
Restructuring costs	32		4	36
	32	2	7	41
	\$ 97	\$ 63	\$ 34	\$ 194

(\$ in millions)	Three Months Ended March 31, 2012			
	Separation Costs	Accelerated Depreciation	Other	Total
<i>Merger Restructuring Program</i>				
Materials and production	\$	\$ (21)	\$ 17	\$ (4)
Marketing and administrative		23	1	24
Research and development		41	4	45
Restructuring costs	180		34	214
	180	43	56	279
<i>2008 Restructuring Program</i>				
Materials and production		2	7	9
Restructuring costs	2		3	5
	2	2	10	14
	\$ 182	\$ 45	\$ 66	\$ 293

Separation costs are associated with actual headcount reductions, as well as those headcount reductions which were probable and could be reasonably estimated. In the first quarter of 2013 and 2012, approximately 740 positions and 1,020 positions, respectively, were eliminated under the Merger Restructuring Program and approximately 50 positions and 140 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 cash flows were sufficient to recover the respective book values, Merck was required to accelerate depreciation of the site assets rather than write them off immediately. Anticipated site closure dates, particularly related to manufacturing locations, have been and may continue to

be adjusted to reflect changes resulting from regulatory or other factors.

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

Other activity in 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 11) and share-based compensation costs.

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

The following table summarizes the charges and spending relating to Merger Restructuring Program and 2008 Restructuring Program activities for the three months ended March 31, 2013:

(\$ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
<b>Merger Restructuring Program</b>				
Restructuring reserves January 1, 2013	\$ 699	\$	\$ 19	\$ 718
Expense	65	61	27	153
(Payments) receipts, net	(108)		(27)	(135)
Non-cash activity		(61)	(4)	(65)
Restructuring reserves March 31, 2013 <sup>(1)</sup>	\$ 656	\$	\$ 15	\$ 671
<b>2008 Restructuring Program</b>				
Restructuring reserves January 1, 2013	\$ 77	\$	\$	\$ 77
Expense	32	2	7	41
(Payments) receipts, net	(46)		(4)	(50)
Non-cash activity		(2)	(3)	(5)
Restructuring reserves March 31, 2013 <sup>(1)</sup>	\$ 63	\$	\$	\$ 63

<sup>(1)</sup> 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. The cash outlays associated with the remaining restructuring reserves for the 2008 Restructuring Program are primarily manufacturing-related and are expected to be completed by the end of 2015.

### 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. Ertugliflozin is Phase III ready, with trials expected to begin later in 2013. 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 Januvia (sitagliptin) tablets. Merck will continue to retain the rights to its existing portfolio of sitagliptin-containing products. Through the first quarter 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. 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 has the right to terminate the agreement at any time up to the commencement of the first Phase III clinical trial. 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

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

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 will market, distribute and sell a portfolio of innovative pharmaceutical and branded generic products from Merck, Cristália and Eurofarma in Brazil. Merck owns 51% of the joint venture, 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

---

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

*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 puts through the collection of premium by

writing call options. If the

- 8 -

---

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

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 gains (losses) of \$78 million and \$(44) million for the first three months of 2013 and 2012, respectively, from the euro-denominated notes.

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 March 31, 2013 or December 31, 2012.

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	March 31, 2013			December 31, 2012		
		Asset	Liability	U.S. Dollar Notional	Asset	Liability	U.S. Dollar Notional
<b>Derivatives Designated as Hedging Instruments</b>							
Foreign exchange contracts (current)	Deferred income taxes and other current assets	\$ 580	\$	\$ 6,370	\$ 281	\$	\$ 6,646
Foreign exchange contracts (non-current)	Other assets	596		6,101	387		5,989
Foreign exchange contracts (current)	Accrued and other current liabilities		3	748		13	938
		\$ 1,176	\$ 3	\$ 13,219	\$ 668	\$ 13	\$ 13,573
<b>Derivatives Not Designated as Hedging Instruments</b>							
Foreign exchange contracts (current)	Deferred income taxes and other current assets	\$ 132	\$	\$ 6,237	\$ 55	\$	\$ 4,548
Foreign exchange contracts (non-current)	Other assets	6		113	8		232
Foreign exchange contracts (current)	Accrued and other current liabilities		142	3,893		216	8,203
		\$ 138	\$ 142	\$ 10,243	\$ 63	\$ 216	\$ 12,983
		\$ 1,314	\$ 145	\$ 23,462	\$ 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:

(\$ in millions)	March 31, 2013		December 31, 2012	
	Asset	Liability	Asset	Liability
Gross amounts recognized in the consolidated balance sheet	\$ 1,314	\$ 145	\$ 731	\$ 229
Gross amount subject to offset in master netting arrangements not offset in the consolidated balance sheet	(115)	(115)	(195)	(195)
Gross amount not subject to master netting arrangements	(3)	(1)	(3)	(3)
Cash collateral (received) posted	(841)		(305)	
Net amounts	\$ 355	\$ 29	\$ 228	\$ 31

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



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

Three Months Ended  
March 31,

(\$ in millions)

2013            2012

<i>Derivatives designated in foreign currency cash flow hedging relationships</i>		
Foreign exchange contracts		
Amount of loss reclassified from AOCI to Sales	\$     32	\$     27
Amount of (gain) loss recognized in OCI on derivatives	(349)	120
<i>Derivatives designated in foreign currency net investment hedging relationships</i>		
Foreign exchange contracts		
Amount of gain recognized in Other (income) expense, net on derivatives <sup>(1)</sup>	(2)	(9)
Amount of gain recognized in OCI on derivatives	(180)	(142)
<i>Derivatives not designated in a hedging relationship</i>		
Foreign exchange contracts		
Amount of loss recognized in Other (income) expense, net on derivatives <sup>(2)</sup>	24	253
Amount of gain recognized in Sales on hedged item	(10)	

<sup>(1)</sup> There was no ineffectiveness on the hedge. Represents the amount excluded from hedge effectiveness testing.

<sup>(2)</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.

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

At March 31, 2013, the Company estimates \$42 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:

	March 31, 2013				December 31, 2012			
	Fair Value	Amortized Cost	Gross Unrealized		Fair Value	Amortized Cost	Gross Unrealized	
(\$ in millions)			Gains	Losses			Gains	Losses
Corporate notes and bonds	\$ 5,807	\$ 5,769	\$ 41	\$ (3)	\$ 5,063	\$ 5,013	\$ 52	\$ (2)
Commercial paper	2,229	2,229			2,150	2,150		
U.S. government and agency securities	1,205	1,203	2		1,206	1,204	2	
Asset-backed securities	878	876	3	(1)	837	835	3	(1)
Mortgage-backed securities	491	491	2	(2)	435	436	2	(3)
Foreign government bonds	121	120	1		108	107	1	
Equity securities	429	376	53		403	370	33	
	\$ 11,160	\$ 11,064	\$ 102	\$ (6)	\$ 10,202	\$ 10,115	\$ 93	\$ (6)

Available-for-sale debt securities included in *Short-term investments* totaled \$3.0 billion at March 31, 2013. Of the remaining debt securities, \$6.9 billion mature within five years. At March 31, 2013 and December 31, 2012, there were no debt securities pledged as collateral.

**Fair Value Measurements**

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

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

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

*Level 3* - Unobservable inputs that are supported by little or no market activity. Level 3 assets 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.

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

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

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

	Fair Value Measurements Using				Fair Value Measurements Using			
	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
	March 31, 2013				December 31, 2012			
<b>Assets</b>								
<i>Investments</i>								
Corporate notes and bonds	\$	\$ 5,807	\$	\$ 5,807	\$	\$ 5,063	\$	\$ 5,063
Commercial paper		2,229		2,229		2,150		2,150
U.S. government and agency securities		1,205		1,205		1,206		1,206
Asset-backed securities <sup>(1)</sup>		878		878		837		837
Mortgage-backed securities <sup>(1)</sup>		491		491		435		435
Foreign government bonds		121		121		108		108
Equity securities	215			215	196			196
	215	10,731		10,946	196	9,799		9,995
<i>Other assets</i>								
Securities held for employee compensation	183	31		214	169	38		207
<i>Derivative assets <sup>(2)</sup></i>								
Purchased currency options		934		934		546		546
Forward exchange contracts		380		380		185		185
		1,314		1,314		731		731
<b>Total assets</b>	<b>\$ 398</b>	<b>\$ 12,076</b>	<b>\$</b>	<b>\$ 12,474</b>	<b>\$ 365</b>	<b>\$ 10,568</b>	<b>\$</b>	<b>\$ 10,933</b>
<b>Liabilities</b>								
<i>Derivative liabilities <sup>(2)</sup></i>								
Forward exchange contracts	\$	\$ 142	\$	\$ 142	\$	\$ 216	\$	\$ 216
Written currency options		3		3		13		13
<b>Total liabilities</b>	<b>\$</b>	<b>\$ 145</b>	<b>\$</b>	<b>\$ 145</b>	<b>\$</b>	<b>\$ 229</b>	<b>\$</b>	<b>\$ 229</b>

<sup>(1)</sup> Primarily all of the asset-backed securities are highly-rated (Standard & Poor's rating of AAA and Moody's Investors Service rating of Aaa), secured primarily by credit card, auto loan, and home equity receivables, with weighted-average lives of primarily 5 years or less. Mortgage-backed securities represent AAA-rated securities issued or unconditionally guaranteed as to payment of principal and interest by U.S. government agencies.

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

There were no transfers between Level 1 and Level 2 during the first three months of 2013. As of March 31, 2013, Cash and cash equivalents of \$13.0 billion included \$12.0 billion of cash equivalents (which would be considered Level 2 in the fair value hierarchy).

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.

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

The estimated fair value of loans payable and long-term debt (including current portion) at March 31, 2013 was \$22.8 billion compared with a carrying value of \$20.8 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.

### *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 two 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

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

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 the global economic downturn and the 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 March 31, 2013 and December 31, 2012, *Other assets* included \$482 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 March 31, 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 \$800 million in the aggregate, of which approximately 18%, 38%, 36% and 9% related to Greece, Italy, Spain and Portugal, respectively. At March 31, 2013, the Company's total accounts receivable outstanding for more than one year were approximately \$245 million, of which approximately 50% 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 March 31, 2013 and December 31, 2012, the Company had received cash collateral of \$841 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 March 31, 2013 or December 31, 2012.

## 5. Inventories

Inventories consisted of:

<i>(\$ in millions)</i>	March 31, 2013	December 31, 2012
Finished goods	\$ 2,055	\$ 1,924
Raw materials and work in process	5,876	5,921
Supplies	240	244
Total (approximates current cost)	8,171	8,089
Increase to LIFO costs	47	52
	\$ 8,218	\$ 8,141
Recognized as:		
Inventories	\$ 6,773	\$ 6,535
Other assets	1,445	1,606

Amounts recognized as *Other assets* are comprised almost entirely of raw materials and work in process inventories. At March 31, 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 \$173 million and \$196 million at March 31, 2013 and December 31, 2012, respectively, of inventories produced in preparation for product launches.

Notes to Interim Consolidated Financial Statements (unaudited) (continued)**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 quarter of 2013 and 2012, the Company recorded \$30 million and \$9 million, respectively, of IPR&D impairment charges within *Research and development* expenses primarily for 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:

(\$ in millions)	Three Months Ended March 31,	
	2013	2012
AstraZeneca LP	\$ 125	\$ 113
Other <sup>(1)</sup>	8	(3)
	\$ 133	\$ 110

<sup>(1)</sup> Includes results from Sanofi Pasteur MSD.  
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 March 31	
	2013	2012
Sales	\$ 1,158	\$ 1,042
Materials and production costs	552	478
Other expense, net	381	381

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

Income before taxes <sup>(1)</sup>	\$ 225	\$ 183
------------------------------------	--------	--------

*(1) 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.*

- 14 -

---

Notes to Interim Consolidated Financial Statements (unaudited) (continued)**8. 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 preliminary nature of the litigation discussed below, including the *Vioxx* Litigation, and the complexities involved in these matters, the Company is unable to reasonably estimate a possible loss or range of possible loss for such matters until the Company knows, among other factors, (i) what claims, if any, will survive dispositive motion practice, (ii) the extent of the claims, including the size of any potential class, particularly when damages are not specified or are indeterminate, (iii) how the discovery process will affect the litigation, (iv) the settlement posture of the other parties to the litigation and (v) any other factors that may have a material effect on the litigation.

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

The Company's decision to obtain insurance coverage is dependent on market conditions, including cost and availability, existing at the time such decisions are made. The Company has evaluated its risks and has determined that the cost of obtaining product liability insurance outweighs the likely benefits of the coverage that is available and, as such, has no insurance for 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 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 is ongoing and will continue until 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



---

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

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 has set oral argument for May 15, 2013.

Merck has also been named as a defendant in lawsuits brought by state Attorneys General in five states. 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 Kentucky action is currently scheduled to proceed to trial in Kentucky state court in October 2013. 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 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, which motion has been fully briefed. 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. Discovery is currently proceeding in the individual securities lawsuits together with 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



---

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

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 and with respect to certain other *Vioxx* Product Liability Lawsuits, including the Missouri matter discussed above. 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 March 31, 2013, approximately 4,990 cases, which include approximately 5,585 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 1,210 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 3,780 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 940 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*. On April 30, 2013, plaintiff in the *Secrest* case filed a petition for writ of certiorari with the U.S. Supreme Court.

In February 2011, Judge Keenan ordered that there will be two further bellwether trials 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. On March 5, 2013, Merck filed a post-trial motion for judgment as a matter of law in the *Scheinberg* case and that motion is still pending.

In November 2011, 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 are staggered throughout the first half of 2013, and failure to comply with the order may result in dismissal of a plaintiff's claim. The first deadline passed on February 20, 2013, and Merck submitted to the court on February 27, 2013 a list of several hundred plaintiffs who failed to comply with that first deadline. On March 13, 2013, Judge Keenan ordered that those plaintiffs who failed to provide reports by the February 20, 2013 deadline had 30 days to provide the required reports or, upon motion, the case may be dismissed with prejudice and/or the court may impose sanctions for failure to comply. To date, more than 225 plaintiffs subject to the order have dismissed their claims with prejudice.



---

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

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 March 31, 2013, approximately 265 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.

In California, the parties are reviewing the claims of two plaintiffs in the *Carrie Smith, et al. v. Merck* case and the claims in *Pedrojetti v. Merck*. The cases of one or more of these plaintiffs may be tried in 2013.

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 1,015 cases were pending in the *Fosamax* Femur Fracture MDL as of March 31, 2013. A Case Management Order has been entered that requires the parties to review 40 cases (later reduced to 33 cases). Judge Joel Pisano has selected four cases from that group to be 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. The *Zessin v. Merck* case was set to be tried in September 2013 but has been rescheduled for January 2014; the *Young v. Merck* and *Johnson v. Merck* cases are expected to be tried later in 2014.

As of March 31, 2013, approximately 2,305 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*, is currently set to be tried beginning November 4, 2013.

As of March 31, 2013, approximately 440 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. A trial date has been set for August 12, 2013 for the *Barnes v. Merck* case pending in Alabama state court.

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 of March 31, 2013, there were 43 filed complaints against Merck alleging that plaintiffs' use of *Januvia* and/or *Janumet* caused them to develop pancreatic cancer. These complaints were filed in several different state and federal courts, with the majority filed in the United States 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



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

Victoza, the latter two of which are products manufactured by other pharmaceutical companies. In its MDL request, the law firm asked the JPML to appoint Judge Anthony Battaglia of the United States District Court for the Southern District of California as the MDL Judge. On April 29, 2013, Merck and the other defendant manufacturers individually filed responses, all of which agreed that Judge Battaglia should preside if the JPML determines that an MDL is warranted. 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.

As of March 31, 2013, there were approximately 1,410 *NuvaRing* cases. Of these cases, approximately 1,190 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. In addition, there are several cases pending in various other state courts. 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.

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 eight cases from which the first trials in the *NuvaRing* MDL will be selected. The first *NuvaRing* MDL trial is expected to take place in October of 2013. The Company has filed motions related to the admissibility of expert testimony and motions for summary judgment. Judge Sippel recently denied the majority of the Company's expert challenges. In one of the eight trial pool cases in which the Company moved for summary judgment, the plaintiff dismissed her case with prejudice. No date is set yet for any hearings on the Company's remaining summary judgment motions in the *NuvaRing* MDL.

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. While this ruling means there will not be a trial in New Jersey in June 2013 as previously expected, it is not yet known how this decision will impact the remaining cases.

*Propecia/Proscar*

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving *Propecia* and/or *Proscar*. As of March 31, 2013, approximately 540 lawsuits involving a total of approximately 760 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. 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 has been 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 alleges 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. In December 2008, Merck and the





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

other defendants moved to dismiss this lawsuit on the grounds that the plaintiffs failed to state a claim for which relief can be granted. In September 2009, the court denied defendants' motion to dismiss. In March 2012, defendants filed a motion for summary judgment. In September 2012, the court denied defendants' motion for summary judgment and granted lead plaintiffs' amended motion for class certification. On February 13, 2013, Merck announced that it had reached an agreement in principle with plaintiffs to settle this matter for \$215 million. On March 11, 2013, the court stayed all proceedings pending submission of the agreement for court approval. The proposed settlement was reflected in the Company's 2012 financial results as discussed below.

There is 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 names 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. In December 2008, Schering-Plough and the other defendants filed motions to dismiss this lawsuit on the grounds that the plaintiffs failed to state a claim for which relief can be granted. In September 2009, the court denied defendants' motions to dismiss. In March 2012, the Schering-Plough defendants filed a motion for partial summary judgment and the underwriter defendants filed a motion for summary judgment. In September 2012, the court denied defendants' motions for summary judgment and granted lead plaintiffs' amended motion for class certification. On February 13, 2013, Merck announced that it had reached an agreement in principle with plaintiffs to settle this matter for \$473 million. On March 11, 2013, the court stayed all proceedings pending submission of the settlement agreement for court approval. If approved, this settlement will exhaust the remaining Directors and Officers insurance coverage applicable to the *Vytorin* lawsuits brought by the legacy Schering-Plough shareholders. The proposed 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.

## **Commercial Litigation**

### *AWP Litigation*

As previously disclosed, the Company and/or certain of its subsidiaries remain 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 certain AWP cases brought by the states of Alabama, Alaska, Kansas, Kentucky, Louisiana, Oklahoma, and Mississippi. The Company and/or certain of its subsidiaries continue to be defendants in cases brought by five states.

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.

### *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, 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 dismissed all the actions against Merck without prejudice on the ground that plaintiffs had failed to demonstrate their standing to sue. Plaintiffs were given until June 3, 2013 to file amended complaints.

---

Notes to Interim Consolidated Financial Statements (unaudited) (continued)**Patent Litigation**

From time to time, generic manufacturers of pharmaceutical products file Abbreviated New Drug Applications ( 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, *Nasonex*, Nexium, *Vytorin* 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. The lawsuit automatically stays FDA approval of Sandoz's ANDA until October 2013 or until an adverse court decision, if any, whichever may occur earlier. A trial in the case is scheduled for July 2013.

**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 ANDA 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'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 Intas's ANDA until July 2015 or until an adverse court decision, if any, whichever may occur earlier.

**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.

**Nasonex** In December 2009, a patent infringement lawsuit was filed in the United States against Apotex Corp. ( Apotex ) in respect of Apotex's application to the FDA seeking pre-patent expiry approval to market a generic version of *Nasonex*. A trial in this matter was held in April 2012. A decision was issued in June 2012, holding that the Merck patent covering mometasone furoate monohydrate was valid, but that it was not infringed by Apotex's proposed product. An appeal hearing is scheduled for June 2013.

**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. Finally, additional patent infringement lawsuits have been filed (jointly with AstraZeneca) in the United States against Hanmi USA, Inc. ( Hanmi ) and Mylan Laboratories Limited ( Mylan Labs ) related to their applications to the FDA seeking pre-patent expiry approval to sell generic versions

---

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

of Nexium. The Hanmi and Mylan Labs applications to the FDA remain stayed until May 2013 and August 2014, respectively, or until earlier adverse court decisions, if any, whichever may occur earlier. A trial in the Hanmi case is scheduled for May 2013. In March 2013, a patent infringement lawsuit was filed (jointly with AstraZeneca) in the United States against Actavis, Inc./Watson Pharma Company (collectively, Actavis/Watson ) in respect of Actavis/Watson s application to the FDA seeking pre-patent expiry approval to market a generic version of Nexium. The lawsuit automatically stays FDA approval of Actavis/Watson s ANDA until October 2015 or until an adverse court decision, if any, whichever may occur earlier.

*Vytorin* In December 2009, a patent infringement lawsuit was filed in the United States against Mylan Pharmaceuticals, Inc. ( Mylan ) in respect of Mylan s application to the FDA seeking pre-patent expiry approval to sell a generic version of *Vytorin*. 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 ANDA 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. In February 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 *Vytorin*. In July 2011, the patent infringement lawsuit was dismissed and Teva agreed not to sell generic versions of *Zetia* or *Vytorin* until the Company s exclusivity rights expire on April 25, 2017, except in certain circumstances. In August 2010, a patent infringement lawsuit was filed in the United States against Impax Laboratories Inc. ( Impax ) in respect of Impax s application to the FDA seeking pre-patent expiry approval to sell a generic version of *Vytorin*. An agreement was reached with Impax to stay the lawsuit pending the outcome of the lawsuit with Mylan. In October 2011, a patent infringement lawsuit was filed in the United States against Actavis, Inc. ( Actavis ) in respect to Actavis application to the FDA seeking pre-patent expiry approval to sell a generic version of *Vytorin*. An agreement was reached with Actavis to stay the lawsuit pending the outcome of the lawsuit with Mylan.

*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 ANDA 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. 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*. The lawsuit automatically stays FDA approval of Sandoz s ANDA until February 2015 or until an adverse court decision, if any, whichever may occur earlier.

---

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

### **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 I trial included Merck and three of the other original 12 defendants. In March 2011, the Phase I 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 I 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. Subject to the court's anticipated rulings on defendants' potentially dispositive summary judgment and other pre-trial motions, trial of nine selected trial plaintiffs' claims currently is anticipated to begin near the end of June 2013.

### **Other Litigation**

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

### **Legal Defense Reserves**

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of March 31, 2013 and December 31, 2012 of approximately \$230 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.

Notes to Interim Consolidated Financial Statements (unaudited) (continued)**9. Equity**

(\$ and shares in millions)	Common Stock		Other	Retained	Accumulated	Treasury Stock		Non-	Total
	Shares	Par Value	Paid-In Capital	Earnings	Other Comprehensive Loss	Shares	Cost	Controlling Interests	
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.				1,738					1,738
Cash dividends declared on common stock				(1,287)					(1,287)
Treasury stock shares purchased						12	(456)		(456)
Share-based compensation plans and other			(11)			(13)	444		433
Other comprehensive loss					(85)				(85)
Net income attributable to noncontrolling interests								29	29
Distributions attributable to noncontrolling interests								(1)	(1)
Balance March 31, 2012	3,577	\$ 1,788	\$ 40,652	\$ 39,441	\$ (3,217)	535	\$ (23,804)	\$ 2,454	\$ 57,314
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.				1,593					1,593
Cash dividends declared on common stock				(1,306)					(1,306)
Treasury stock shares purchased						14	(580)		(580)
Share-based compensation plans and other			(35)			(4)	168		133
Other comprehensive income					53				53
Supera joint venture			116					112	228
Net income attributable to noncontrolling interests								23	23
Distributions attributable to noncontrolling interests								(1)	(1)
Balance March 31, 2013	3,577	\$ 1,788	\$ 40,727	\$ 40,272	\$ (4,629)	560	\$ (25,129)	\$ 2,577	\$ 55,606

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.

**10. Share-Based Compensation Plans**

The Company has share-based compensation plans under which the Company grants restricted stock units ( RSUs ) and performance share units ( PSUs ) to certain management level employees. 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:

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

(\$ in millions)	Three Months Ended	
	March 31	
	2013	2012
Pretax share-based compensation expense	\$ 67	\$ 76
Income tax benefit	(20)	(24)
Total share-based compensation expense, net of taxes	\$ 47	\$ 52

During the first three months of 2013 and 2012, the Company granted 32 thousand RSUs with a weighted-average grant date fair value of \$41.09 per RSU and 33 thousand RSUs with a weighted-average grant date fair value of \$38.63 per RSU, respectively.

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

During the first three months of 2013, the Company did not grant any stock options. During the first three months of 2012, the Company granted 19 thousand options with a weighted-average exercise price of \$38.63 per option. The weighted-average fair value of options granted for the first three months of 2012 was \$5.17 per option and was determined using the following assumptions:

	Three Months Ended March 31, 2012
Expected dividend yield	4.4%
Risk-free interest rate	1.4%
Expected volatility	24.6%
Expected life (years)	7.0

At March 31, 2013, there was \$636 million of total pretax unrecognized compensation expense related to nonvested stock options, RSU and PSU awards which will be recognized over a weighted-average period of 2.3 years.

The Company typically communicates the value of annual share-based compensation awards to employees during the first quarter, but the related share amounts are not established and communicated until early May. Therefore, while the number of RSU and stock option grants disclosed above do not reflect any amounts relating to the annual grants, share-based compensation costs for the first quarter of 2013 and 2012 and unrecognized compensation expense at March 31, 2013 reflect an impact relating to the awards communicated to employees. For segment reporting, share-based compensation costs are unallocated expenses.

#### 11. Pension and Other Postretirement Benefit Plans

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

<i>(\$ in millions)</i>	Three Months Ended March 31,	
	2013	2012
Service cost	\$ 175	\$ 142
Interest cost	166	166
Expected return on plan assets	(275)	(244)
Net amortization	84	48
Termination benefits	2	5
	\$ 152	\$ 117

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:

<i>(\$ in millions)</i>	Three Months Ended March 31,	
	2013	2012
Service cost	\$ 24	\$ 21
Interest cost	27	31
Expected return on plan assets	(31)	(34)
Net amortization	(12)	(8)
Termination benefits		2
Curtailments		(2)
	\$ 8	\$ 10

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

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 other postretirement benefit plans as reflected in the tables above.

- 25 -



Notes to Interim Consolidated Financial Statements (unaudited) (continued)**12. Other (Income) Expense, Net**

Other (income) expense, net, consisted of:

(\$ in millions)	Three Months Ended	
	March 31,	
	2013	2012
Interest income	\$ (57)	\$ (55)
Interest expense	184	175
Exchange losses	212	67
Other, net	(57)	(45)
	\$ 282	\$ 142

The higher exchange losses in the first quarter of 2013 as compared with the first quarter of 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 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.

Interest paid for the three months ended March 31, 2013 and 2012 was \$211 million and \$187 million, respectively, which excludes commitment fees.

**13. Taxes on Income**

The effective income tax rates of (4.3)% and 29.5% for the first quarter 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 rate in the first quarter of 2013 reflects the favorable impact of various discrete items, including the impact of tax legislation enacted in the first quarter of 2013 that extended the R&D tax credit for both 2012 and 2013, a reduction in tax reserves upon expiration of applicable statute of limitations, 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.

In 2010, the Internal Revenue Service (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. The IRS began its examination of the 2007-2009 tax years in 2010.

Notes to Interim Consolidated Financial Statements (unaudited) (continued)**14. 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:

(\$ and shares in millions except per share amounts)	Three Months Ended March 31,	
	2013	2012
<i>Basic Earnings per Common Share</i>		
Net income attributable to Merck & Co., Inc.	\$ 1,593	\$ 1,738
Less: Income allocated to participating securities		2
Net income allocated to common shareholders	\$ 1,593	\$ 1,736
Average common shares outstanding	3,022	3,043
	\$ 0.53	\$ 0.57
<i>Earnings per Common Share Assuming Dilution</i>		
Net income attributable to Merck & Co., Inc.	\$ 1,593	\$ 1,738
Less: Income allocated to participating securities		2
Net income allocated to common shareholders	\$ 1,593	\$ 1,736
Average common shares outstanding	3,022	3,043
Common shares issuable <sup>(1)</sup>	31	31
Average common shares outstanding assuming dilution	3,053	3,074
	\$ 0.52	\$ 0.56

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

For the three months ended March 31, 2013 and 2012, 86 million and 117 million, respectively, of common shares issuable under share-based compensation plans were excluded from the computation of earnings per common share assuming dilution because the effect would have been antidilutive.

Notes to Interim Consolidated Financial Statements (unaudited) (continued)**15. 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)	Derivatives	Investments	Employee Benefit Plans	Cumulative Translation Adjustment	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	(58)	29		(56)	(85)
Balance March 31, 2012, net of taxes	\$ (54)	\$ 50	\$ (2,346)	\$ (867)	\$ (3,217)
Balance January 1, 2013, net of taxes	\$ (97)	\$ 73	\$ (3,667)	\$ (991)	\$ (4,682)
Other comprehensive income (loss) before reclassifications adjustments, pretax	349	36	133	(253)	265
Tax	(133)	(12)	(23)	(92)	(260)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	216	24	110	(345)	5
Reclassification adjustments, pretax	32	(28)	72		76
Tax	(12)	5	(21)		(28)
Reclassification adjustments, net of taxes	20 <sup>(1)</sup>	(23) <sup>(2)</sup>	51 <sup>(3)</sup>		48
Other comprehensive income (loss), net of taxes	236	1	161	(345)	53
Balance March 31, 2013, net of taxes	\$ 139	\$ 74	\$ (3,506)	\$ (1,336)	\$ (4,629)

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

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

<sup>(3)</sup> Includes net amortization of prior service cost and actuarial gains and losses included in net periodic benefit cost (see note 11).

**16. 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.

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

Sales of the Company's products were as follows:

(\$ in millions)	Three Months Ended March 31,	
	2013	2012
Primary Care and Women's Health		
<i>Cardiovascular</i>		
Zetia	\$ 629	\$ 614
Vytorin	394	444
<i>Diabetes and Obesity</i>		
Januvia	884	919
Janumet	409	392
<i>Respiratory</i>		
Nasonex	385	375
Singulair	337	1,340
Dulera	68	39
Asmanex	40	48
<i>Women's Health and Endocrine</i>		
NuvaRing	151	146
Fosamax	137	184
Follistim AQ	122	116
Implanon	84	76
Cerazette	61	67
<i>Other</i>		
Arcoxia	121	112
Avelox	36	73
Hospital and Specialty		
<i>Immunology</i>		
Remicade	549	519
Simponi	108	74
<i>Infectious Disease</i>		
Isentress	362	337
Cancidas	162	145
PegIntron	126	162
Victrelis	110	111
Invanz	110	101
Noxafil	65	59
<i>Oncology</i>		
Temodar	216	237
Emend	116	102
<i>Other</i>		
Cosopt/Trusopt	105	124
Bridion	63	58
Integrilin	47	53
Diversified Brands		
Cozaar/Hyzaar	267	336
Primaxin	84	88
Zocor	82	103
Claritin Rx	76	87
Propecia	68	108
Clarinex	61	134
Remeron	52	57
Maxalt	40	156
Proscar	39	51
Vaccines <sup>(1)</sup>		
Gardasil	390	284
ProQuad/M-M-R II/Varivax	272	255
Zostavax	168	76
RotaTeq	162	142
Pneumovax 23	111	112

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

Other pharmaceutical <sup>(2)</sup>	1,022	1,066
Total Pharmaceutical segment sales	8,891	10,082
Other segment sales <sup>(3)</sup>	1,712	1,593
Total segment sales	10,603	11,675
Other <sup>(4)</sup>	68	56
	\$ 10,671	\$ 11,731

<sup>(1)</sup> These amounts do not reflect sales of vaccines sold in most major European markets through the Company's joint venture, Sanofi Pasteur MSD, the results of which are reflected in Equity income from affiliates. These amounts do, however, reflect supply sales to Sanofi Pasteur MSD.

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

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

<sup>(4)</sup> 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 March 31,	
	2013	2012
<b>Segment profits:</b>		
Pharmaceutical segment	\$ 5,345	\$ 6,596
Other segments	899	804
Total segment profits	6,244	7,400
Other profits (losses)	(14)	(73)
<b>Unallocated:</b>		
Interest income	57	55
Interest expense	(184)	(175)
Equity income from affiliates	(2)	(20)
Depreciation and amortization	(479)	(551)
Research and development	(1,692)	(1,643)
Amortization of purchase accounting adjustments	(1,184)	(1,229)
Restructuring costs	(119)	(219)
Other unallocated, net	(1,077)	(1,038)
	\$ 1,550	\$ 2,507

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. 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 has 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 over the next 12 months, 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.

**Management**

In March 2013, the Company announced the appointment of Roger M. Perlmutter, M.D., Ph.D., as executive vice president and president of Merck Research Laboratories, effective April 15, 2013. Dr. Perlmutter succeeded Peter S. Kim, Ph.D., who served in the role since 2003.

**Operating Results**

*Sales*

Worldwide sales were \$10.7 billion for the first quarter of 2013, a decline of 9% compared with the first quarter of 2012, 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% for the first quarter of 2013. The revenue decline in the first quarter also reflects lower sales of *Maxalt*, *Clarinox* (desloratadine), *Cozaar* (losartan potassium), *Hyzaar* (losartan potassium hydrochlorothiazide), *Vytorin* (ezetimibe/simvastatin), *Fosamax* (alendronate sodium), *Propecia*, *Avelox* (moxifloxacin hydrochloride) and *PegIntron* (peginterferon alpha-2b). These declines were partially offset by growth in *Gardasil* [human papillomavirus quadrivalent (types 6, 11, 16 and 18) vaccine, recombinant], *Zostavax* [Zoster Vaccine Live], *Simponi* (golimumab), *Remicade* (infliximab), *Dulera* Inhalation Aerosol (mometasone furoate/formoterol fumarate dihydrate) and *Isentress* (raltegravir), as well as higher revenue from the Company's relationship with AstraZeneca LP (AZLP).

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 quarter of 2013 and the Company anticipates these measures will continue to negatively affect revenue performance for the remainder of 2013.

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

Sales of the Company's products were as follows:

(\$ in millions)	Three Months Ended March 31,	
	2013	2012
Primary Care and Women's Health		
<i>Cardiovascular</i>		
Zetia	\$ 629	\$ 614
Vytorin	394	444
Diabetes and Obesity		
Januvia	884	919
Janumet	409	392
Respiratory		
Nasonex	385	375
Singulair	337	1,340
Dulera	68	39
Asmanex	40	48
<i>Women's Health and Endocrine</i>		
NuvaRing	151	146
Fosamax	137	184
Follistim AQ	122	116
Implanon	84	76
Cerazette	61	67
<i>Other</i>		
Arcoxia	121	112
Avelox	36	73
Hospital and Specialty		
<i>Immunology</i>		
Remicade	549	519
Simponi	108	74
<i>Infectious Disease</i>		
Isentress	362	337
Cancidas	162	145
PegIntron	126	162
Victrelis	110	111
Invanz	110	101
Noxafil	65	59
<i>Oncology</i>		
Temodar	216	237
Emend	116	102
<i>Other</i>		
Cosopt/Trusopt	105	124
Bridion	63	58
Integrilin	47	53
Diversified Brands		
Cozaar/Hyzaar	267	336
Primaxin	84	88
Zocor	82	103
Claritin Rx	76	87
Propecia	68	108
Clarinex	61	134
Remeron	52	57
Maxalt	40	156
Proscar	39	51
<i>Vaccines <sup>(1)</sup></i>		
Gardasil	390	284
ProQuad/M-M-R II/Varivax	272	255
Zostavax	168	76
RotaTeq	162	142
Pneumovax 23	111	112
Other pharmaceutical <sup>(2)</sup>	1,022	1,066
Total Pharmaceutical segment sales	8,891	10,082
Other segment sales <sup>(3)</sup>	1,712	1,593
Total segment sales	10,603	11,675



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

Other <sup>(4)</sup>	68	56
	\$ 10,671	\$ 11,731

<sup>(1)</sup> These amounts do not reflect sales of vaccines sold in most major European markets through the Company's joint venture, Sanofi Pasteur MSD, the results of which are reflected in Equity income from affiliates. These amounts do, however, reflect supply sales to Sanofi Pasteur MSD.

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

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

<sup>(4)</sup> 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 revenues by \$1.3 billion and \$1.5 billion for the three months ended March 31, 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) (also marketed as *Ezetrol* outside the United States), a cholesterol absorption inhibitor, were \$629 million in the first quarter of 2013, an increase of 2% compared with the first quarter of 2012. Foreign exchange unfavorably affected global sales performance by 2% in the first quarter of 2013. The sales increase reflects positive performance in the United States.

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 \$394 million in the first quarter of 2013, representing a decline of 11% compared with the first quarter of 2012. The sales decline reflects lower volumes in the United States and internationally.

In March 2013, the Data Safety Monitoring Board of the IMPROVE-IT trial, a large cardiovascular outcomes study evaluating ezetimibe/simvastatin against simvastatin alone in patients presenting with acute coronary syndrome, completed its planned review of study data and recommended that the study continue. The study design calls for the collection of 5,250 clinical endpoints. Merck remains blinded to the actual results of this analysis and to other IMPROVE-IT safety and efficacy data. IMPROVE-IT is an 18,141 patient event-driven trial and, based on the targeted number of clinical endpoints and the rate at which events are being reported, the trial is projected to conclude in September 2014. The IMPROVE-IT executive committee and Merck will continue to monitor the progress of the study, and Merck will update the study timeline if appropriate. No additional interim analyses are planned.

#### Diabetes and Obesity

Global sales of *Januvia* (sitagliptin), Merck's dipeptidyl peptidase-4 (DPP-4) inhibitor for the treatment of type 2 diabetes, were \$884 million in the first quarter of 2013, a decline of 4% compared with the first quarter of 2012, reflecting lower sales in the United States due primarily to lower customer inventory levels. Foreign exchange unfavorably affected global sales performance by 3% in the first quarter of 2013.

Worldwide sales of *Janumet* (sitagliptin/metformin HCl), 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 \$409 million for the first quarter of 2013, representing an increase of 4% compared with the same period of 2012, reflecting volume growth in Europe, Canada and the emerging markets.

#### Respiratory

Global sales of *Nasonex* (mometasone furoate monohydrate), an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, increased 3% in the first quarter of 2013 to \$385 million reflecting volume growth in Japan, partially offset by declines in the United States and Latin America. Foreign exchange unfavorably affected global sales performance by 4% in the first quarter of 2013. In 2009, Apotex Inc. and Apotex Corp. (collectively, Apotex) filed an Abbreviated New Drug 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 (see Note 8 to the interim consolidated financial statements). The Company has appealed the U.S. District Court decision. 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 \$1.7 billion at March 31, 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, fell 75% in the first quarter of 2013 to \$337 million compared with the first



quarter of 2012, driven primarily by lower sales in United States and Europe. Revenue declines in Japan and Latin America also contributed to the *Singulair* sales decline in the quarter. The patent that provided U.S. market exclusivity for *Singulair* expired in August 2012 and the Company has lost substantially 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 these markets following the patent expiries and expects the decline to continue. Sales of *Singulair* in Europe declined 34% to \$111 million in the first quarter of 2013 compared with the first quarter of 2012.

Global sales of *Dulera* Inhalation Aerosol, a combination medicine for the treatment of asthma, were \$68 million in the first quarter of 2013 compared with \$39 million in the first quarter of 2012 reflecting volume growth in the United States. In January 2012, Merck received a Complete Response Letter 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 is planning to conduct an additional clinical study and update the application in the future.

#### Women's Health and Endocrine

Worldwide sales of *NuvaRing* (etonogestrel/ethinyl estradiol vaginal ring), a vaginal contraceptive product, increased 4% in the first quarter of 2013 to \$151 million primarily reflecting positive performance in the United States.

Worldwide sales of *Fosamax* and *Fosamax Plus D* (alendronate sodium/cholecalciferol) (marketed as *Fosavance* throughout the EU and as *Fosamac* in Japan) for the treatment and, in the case of *Fosamax*, prevention of osteoporosis declined 26% in the first quarter of 2013 to \$137 million compared with the first quarter of 2012 driven primarily by declines in Europe and Japan. These medicines have lost market exclusivity in the United States and in most major European 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 5% in the first quarter of 2013 to \$122 million driven largely by demand growth in China and the United States, partially offset by declines in Europe. *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

Sales of *Avelox*, a broad-spectrum fluoroquinolone antibiotic for the treatment of certain respiratory and skin infections marketed by the Company in the United States, declined 51% in the first quarter of 2013 to \$36 million due primarily to a competitor's product that became available in generic form. 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.

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; and *Arcoxia* (etoricoxib) for the treatment of arthritis and pain.

#### Hospital and Specialty

##### Immunology

Sales of *Remicade*, a treatment for inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), grew 6% to \$549 million for the first quarter of 2013 compared with the first quarter of 2012 reflecting volume growth in Europe. Foreign exchange favorably affected global sales performance by 1% in the first quarter of 2013.

Sales of *Simponi*, a once-monthly subcutaneous treatment for certain inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were \$108 million in the first quarter of 2013 compared with \$74 million in the first quarter of 2012 driven by continued uptake since launch. *Simponi* was approved by the European Commission (the EC) in October 2009. In July 2012, a submission was made to the European Medicines Agency requesting approval of *Simponi* for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.



---

## Infectious Disease

Global sales of *Isentress*, an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection, grew 8% in the first quarter of 2013 to \$362 million primarily reflecting volume growth in the emerging markets and Europe.

Global sales of *Cancidas* (caspofungin acetate), an anti-fungal product, increased 12% in the first quarter of 2013 to \$162 million largely reflecting growth in the emerging markets and Europe.

Worldwide sales of *PegIntron*, a treatment for chronic hepatitis C, declined 23% to \$126 million in the first quarter of 2013 driven largely by lower sales in the United States and Japan. The Company believes that the sales decline in the United States was 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 the first quarter of 2013.

Worldwide sales of *Victrelis* (boceprevir), the Company's innovative oral medicine for the treatment of chronic hepatitis C, declined 1% in the first quarter of 2013 to \$110 million. Foreign exchange unfavorably affected global sales performance by 2%. Excluding the impact of foreign exchange, sales performance reflects volume growth in the emerging markets which was offset by declines in the United States. The Company believes that the sales decline in the United States was attributable in part to patient treatment being delayed by health care providers in anticipation of new therapeutic options becoming available. *Victrelis* was approved by the FDA in May 2011 and by the EC in July 2011.

## Oncology

Sales of *Temodar* (temozolomide) (marketed as *Temodal* outside the United States), a treatment for certain types of brain tumors, were \$216 million for the first quarter of 2013, a decline of 9% compared with the first quarter of 2012. Foreign exchange unfavorably affected global sales performance by 2% in the first quarter of 2013. Sales performance primarily reflects generic competition in Europe and declines in certain emerging markets. *Temodar* lost patent exclusivity in the EU in 2009. As previously disclosed, by agreement, a generic manufacturer may launch a generic version of *Temodar* in the United States in August 2013. Accordingly, the Company anticipates that U.S. sales of *Temodar*, which were \$423 million for the full year of 2012, will decline significantly in 2013. The U.S. patent and exclusivity periods will otherwise expire in February 2014.

Global sales of *Emend* (aprepitant), for the prevention of chemotherapy-induced and post-operative nausea and vomiting, were \$116 million in the first quarter of 2013, an increase of 14% compared with the first quarter of 2012. Sales performance primarily reflects volume growth in the emerging markets, Europe and the United States.

## Other

Worldwide sales of ophthalmic products *Cosopt* (dorzolamide hydrochloride-timolol maleate ophthalmic solution) and *Trusopt* (dorzolamide hydrochloride ophthalmic solution) declined 15% in the first quarter of 2013 to \$105 million reflecting lower sales in Japan and Europe. Foreign exchange unfavorably affected global sales performance by 5% in the first quarter of 2013. 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 8% to \$63 million in the first quarter of 2013. Foreign exchange unfavorably affected global sales performance by 9% in the first quarter of 2013. Sugammadex sodium injection is currently under review by the FDA.

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 European Union ( 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 \$30 million and \$41 million in the first quarter of 2013 and 2012, respectively. Merck continues to focus on building and maintaining the brand awareness of *Saphris* in the United States. If these efforts in the United States or Lundbeck's on-going launch of the product in the EU are not successful, the Company may take a non-cash impairment charge with respect to the value of the *Saphris/Sycrest* intangible asset, which had a carrying value of approximately \$525 million at March 31, 2013. If the *Saphris/Sycrest* intangible asset is determined to be impaired, the impairment charge could be material.



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, declined 21% in the first quarter of 2013 to \$267 million compared with the first quarter of 2012 including a 5% negative effect from foreign exchange. 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 is experiencing significant declines in *Cozaar* and *Hyzaar* sales in those markets and the Company expects the declines to continue. The declines were partially offset by higher sales in the emerging markets.

Worldwide sales of *Propecia* (finasteride), a product for the treatment of male pattern hair loss, declined 37% in the first quarter of 2013 to \$68 million, including a 4% negative effect from foreign exchange, driven by declines in the United States and Japan. The formulation/use patent that provides U.S. market exclusivity for *Propecia* expires in October 2013; however, as previously disclosed, by agreement, one generic manufacturer entered the U.S. market in January 2013 and another has been given the right to enter in July 2013. Accordingly, the Company is experiencing a significant decline in U.S. sales of *Propecia* and expects the decline to continue. U.S. sales of *Propecia* were \$124 million for the full year of 2012.

Global sales of *Clarinox* (marketed as *Aerius* in many countries outside the United States), a non-sedating antihistamine, were \$61 million for the first quarter of 2013, a decline of 55%, compared with the same period of 2012, reflecting lower volumes in the United States and 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 *Clarinox* will continue to decline.

Global sales of *Maxalt*, a product for the acute treatment of migraine, declined 74% to \$40 million for the first quarter of 2013 driven by lower sales in the United States. 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 provides market exclusivity for *Maxalt* will expire in a number of major European markets in August 2013 and the Company anticipates that sales in those markets will decline significantly thereafter. Sales of *Maxalt* were \$491 million in the United States and \$92 million in Europe for the full year of 2012.

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.

#### *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 cancers and other diseases caused by human papillomavirus (HPV) types 6, 11, 16 and 18, grew 37% in the first quarter of 2013 to \$390 million driven primarily by growth in the United States, reflecting continued uptake in males and higher public sector purchases, as well as growth in certain emerging markets, particularly in Latin America and the Asia Pacific region.

*ProQuad* [Measles, Mumps, Rubella and Varicella Virus Vaccine Live], 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 \$62 million in the first quarter of 2013.

Merck's sales of *Varivax*, a vaccine to help prevent chickenpox (varicella), were \$143 million for the first quarter of 2013 compared with \$176 million for the first quarter 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 \$67 million for the first quarter of 2013 compared with \$80 million for the first quarter 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* [Rotavirus Vaccine, Live, Oral, Pentavalent], a vaccine to help protect against rotavirus gastroenteritis in infants and children, recorded by Merck were \$162 million in the first quarter of 2013, an increase of 14% compared with the first quarter of 2012, due primarily to higher public sector purchases in the United States.

Merck's sales of *Zostavax*, a vaccine to help prevent shingles (herpes zoster) in adults 50 years of age and older, were \$168 million in the first quarter of 2013 compared with \$76 million in the first quarter of 2012 due to strong demand in the United States and Canada. The Company anticipates limited launches of *Zostavax* outside of the United States later in 2013.

Merck's sales of *Pneumovax 23* [pneumococcal vaccine polyvalent], a vaccine to help prevent pneumococcal disease, declined 1% to \$111 million in the first quarter of 2013 driven primarily by lower sales in Japan, partially offset by positive performance in the United States due to higher volumes and favorable pricing.

## 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 \$840 million for the first quarter of 2013, an increase of 2% compared with the first quarter of 2012, driven primarily by higher sales of companion animal and poultry products. Foreign exchange unfavorably affected global sales performance by 2% in the first quarter of 2013.

### *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 \$571 million for the first quarter of 2013, an increase of 3% compared with the first quarter of 2012, driven by growth in *Coppertone* and *Claritin*. Foreign exchange unfavorably affected global sales performance by 1% in the first quarter of 2013. Consumer Care product sales are affected by competition and consumer spending patterns. In January 2013, the FDA approved *Oxytrol for Women*, the first and only over-the-counter treatment for overactive bladder in women, which the Company anticipates will be available to customers in the fall of 2013.

### *Alliances*

The alliances segment includes results from the Company's relationship with AZLP. Revenue from AZLP, primarily relating to sales of Nexium and Prilosec, was \$262 million and \$186 million in the first quarter 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 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. These initial actions, which are expected to result in workforce reductions of approximately 17%, 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. In July 2011, the Company initiated further actions under the Merger Restructuring Program through which the Company expects to reduce its workforce measured at the time of the Merger by an additional 12% to 13% across the Company worldwide. A majority of the workforce reductions associated with these additional actions relate to manufacturing (including Animal Health), administrative and headquarters organizations. The Company will continue to hire employees in strategic growth areas of the business as necessary.

The Company recorded total pretax restructuring costs of \$153 million and \$279 million in the first quarter 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 2015. The Company expects the estimated total cumulative pretax costs for this program to be approximately \$7.2 billion to \$7.5 billion. The Company estimates that approximately two-thirds of the cumulative pretax costs relate to cash outlays, primarily related to employee separation expense. Approximately one-third of the cumulative pretax costs are non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested. The Company expects the Merger Restructuring Program to yield annual savings 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. As part of the 2008 Restructuring Program, the Company expects to eliminate approximately 7,200 positions (6,800 active employees and 400 vacancies) across the Company worldwide. Pretax restructuring costs of \$41 million and \$14 million were recorded in the first quarter 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 2015, with the total cumulative pretax costs estimated to be up to \$2.0 billion. The Company estimates that two-thirds of the cumulative pretax costs relate to cash outlays, primarily from 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. Merck expects the 2008 Restructuring Program to yield cumulative pretax savings of \$3.8 billion to \$4.2 billion from 2008 to 2013.

The Company anticipates that total costs associated with restructuring activities in 2013 for the Merger Restructuring Program and the 2008 Restructuring Program will be in the range of \$500 million to \$700 million.

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 \$4.0 billion for the first quarter of 2013, a decline of 2% compared with the first quarter of 2012. Costs in both the first quarter of 2013 and the first quarter of 2012 include \$1.2 billion of expenses for the amortization of intangible assets recognized in connection with mergers and acquisitions. Also included in materials and production costs were costs associated with restructuring activities which amounted to \$43 million and \$5 million in the first quarter 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 62.9% in the first quarter of 2013 compared with 65.6% in the first quarter of 2012. The amortization of intangible assets and restructuring charges noted above reduced gross margin by 11.5 and 10.5 percentage points for the first quarter of 2013 and 2012, respectively. The gross margin decline primarily reflects 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* and *Propecia* also negatively affected gross margin in the first quarter of 2013. These declines were partially offset by improvements resulting from other changes in product mix and 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* and *Propecia* for the remainder of 2013.

---

*Marketing and Administrative*

Marketing and administrative expenses were \$3.0 billion in the first quarter of 2013, a decline of 3% compared with the first quarter of 2012. The decline was due to the favorable impact of foreign exchange and lower selling costs. Expenses for the first quarter of 2013 and 2012 include restructuring costs of \$17 million and \$24 million, respectively, 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 \$23 million and \$51 million of acquisition-related costs in the first quarter of 2013 and 2012, respectively, consisting of incremental, third-party integration costs related to the Merger, including costs related to legal entity and system integration.

*Research and Development*

Research and development expenses were \$1.9 billion for the first quarter of 2013, an increase of 2% compared with the first quarter 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 \$1.1 billion in both the first quarter of 2013 and the first quarter of 2012. 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 \$769 million and \$723 million for the first quarter of 2013 and 2012, respectively. Research and development expenses in the first quarter of 2013 reflect higher costs for upfront and milestone payments for in-licensed programs as compared with the first quarter of 2012.

Research and development expenses also include in-process research and development ( IPR&D ) impairment charges and research and development-related restructuring charges. During the first quarter of 2013 and 2012, the Company recorded \$30 million and \$9 million, respectively, of IPR&D impairment charges primarily for 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 \$15 million and \$45 million in the first quarter of 2013 and 2012, respectively.

*Restructuring Costs*

Restructuring costs, primarily representing separation and other related costs associated with restructuring activities, were \$119 million and \$219 million for the first quarter of 2013 and 2012, respectively, nearly all of which 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 790 positions in the first quarter of 2013, of which 740 related to the Merger Restructuring Program and 50 related to the 2008 Restructuring Program. For the first quarter of 2012, Merck eliminated 1,160 positions of which 1,020 related to the Merger Restructuring Program and 140 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 \$133 million in the first quarter of 2013 compared with \$110 million in the first quarter of 2012 reflecting higher equity income from AZLP. (See Selected Joint Venture and Affiliate Information below.)

*Other (Income) Expense, Net*

Other (income) expense, net was \$282 million of expense in the first quarter of 2013 compared with \$142 million of expense in the first quarter of 2012 due primarily to higher exchange losses. 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.



*Segment Profits*

(\$ in millions)	Three Months Ended March 31,	
	2013	2012
Pharmaceutical segment profits	\$ 5,345	\$ 6,596
Other non-reportable segment profits	899	804
Other	(4,694)	(4,893)
Income before income taxes	\$ 1,550	\$ 2,507

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 19% in the first quarter of 2013, 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 (4.3)% and 29.5% for the first quarter 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 rate in the first quarter of 2013 reflects the impact of various discrete items, including the impact of tax legislation enacted in the first quarter of 2013 that extended the R&D tax credit for both 2012 and 2013, a reduction in tax reserves upon expiration of applicable statute of limitations, 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 13 to the interim consolidated financial statements).

*Net Income and Earnings per Common Share*

Net income attributable to Merck & Co., Inc. was \$1.6 billion for the first quarter of 2013 compared with \$1.7 billion for the first quarter of 2012. Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders ( *EPS* ) for the first quarter of 2013 were \$0.52 compared with \$0.56 in the first quarter of 2012. The declines in net income and *EPS* in the first quarter of 2013 as compared with the first quarter of 2012 were due primarily to lower sales reflecting the loss of market exclusivity for certain products, particularly *Singulair*, as well as higher exchange losses, largely offset by the favorable impact of certain tax items and lower operating expenses.

*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 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 March 31,	
	2013	2012
Pretax income as reported under GAAP	\$ 1,550	\$ 2,507
Increase (decrease) for excluded items:		
Acquisition-related costs	1,237	1,289
Restructuring costs	194	293
	2,981	4,089
Taxes on income as reported under GAAP	(66)	740
Estimated tax benefit on excluded items	279	276
Net tax benefit from resolution of legacy Schering-Plough federal income tax issue	160	
	373	1,016
Non-GAAP net income	2,608	3,073
Less: Net income attributable to noncontrolling interests	23	29
Non-GAAP net income attributable to Merck & Co., Inc.	\$ 2,585	\$ 3,044
EPS assuming dilution as reported under GAAP	\$ 0.52	\$ 0.56
EPS difference <sup>(1)</sup>	0.33	0.43
Non-GAAP EPS assuming dilution	\$ 0.85	\$ 0.99

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

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

#### Certain Other Items

Non-GAAP income and non-GAAP EPS exclude certain other items. These items represent substantive, unusual items that are evaluated on an individual basis. Such evaluation considers both the quantitative and the qualitative aspect of their unusual nature and generally represent items that, either as a result of their nature or magnitude, management would not anticipate that they would occur as part of the Company's normal business on a regular basis. Excluded from non-GAAP income and non-GAAP EPS is a tax benefit from the resolution of a legacy Schering-Plough federal income tax issue (see note 13 to the interim consolidated financial statements).



---

## Research and Development Update

In May 2013, Merck announced that the FDA approved *Liptruzet* (ezetimibe and atorvastatin) tablets for the treatment of elevated low-density lipoprotein ( LDL ) cholesterol in patients with primary or mixed hyperlipidemia as adjunctive therapy to diet when diet alone is not enough. *Liptruzet*, a once-daily tablet, inhibits the absorption of cholesterol in the digestive tract (through ezetimibe) and the production of cholesterol in the liver (through atorvastatin). Merck is continuing to move forward with planned filings for the ezetimibe and atorvastatin combination tablet in additional countries around the world.

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 allergen. Merck has partnered with ALK-Abello to develop its investigational sublingual allergy immunotherapy tablets for ragweed pollen, timothy grass pollen and house dust mite 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.

Also in March 2013, Merck announced that the FDA had notified the Company it will take an additional three months to review the New Drug Application ( NDA ) resubmission for MK-8616, sugammadex sodium injection, an investigational agent for the reversal of neuromuscular blockade induced by rocuronium or vecuronium (neuromuscular blocking agents). Merck anticipates the FDA 's review will be completed in the second half of 2013. Sugammadex sodium injection is approved and has been launched in many countries outside of the United States where it is marketed as *Bridion*.

In April 2013, Merck announced that the FDA has designated lambrolizumab (MK-3475) as a Breakthrough Therapy for the treatment of patients with advanced melanoma. Lambrolizumab 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 implications of Breakthrough Therapy Designation cannot be determined at this time.

Also 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. Ertugliflozin is Phase III ready, with trials expected to begin later in 2013. 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 *Januvia* (sitagliptin) tablets. Merck will continue to retain the rights to its existing portfolio of sitagliptin-containing products. Through the first quarter 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. 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 has the right to terminate the agreement at any time up to the commencement of the first Phase III clinical trial. 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.

On May 22, 2013, the FDA 's Peripheral and Central Nervous System Drugs Advisory Committee will meet to discuss the NDA for suvorexant (MK-4305) tablets. Suvorexant is an investigational insomnia medicine in a new class of medicines called orexin receptor antagonists for use in patients with insomnia, characterized by difficulty falling or staying asleep. Suvorexant will be evaluated by the Controlled Substance Staff of the FDA during NDA review. If approved by the FDA, suvorexant will become available after a schedule assessment and determination has been completed by the U.S. Drug Enforcement Administration, which routinely occurs after FDA approval. The Company has also 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.

V212 is an inactivated varicella zoster virus vaccine in development for the prevention of herpes zoster. The Company is enrolling two Phase III trials, one in autologous hematopoietic cell transplant patients and the other in patients with solid tumor malignancies undergoing chemotherapy and hematological malignancies. The Company now anticipates filing a BLA with the autologous hematopoietic cell transplant data and cancer



patient data beyond 2014.

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

The chart below reflects the Company's research pipeline as of May 6, 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
<b>Allergy</b>	<b>Allergy</b>	<b>Allergy</b>
MK-8237, Immunotherapy(1)	MK-3641, Ragweed (September 2009)(1)(4)	MK-7243, Grass pollen (U.S.)(1)
<b>Alzheimer's Disease</b>	<b>Atherosclerosis</b>	<b>Insomnia</b>
MK-8931(2)	MK-0859 (anacetrapib) (May 2008)	MK-4305 (suvorexant) (U.S.)
<b>Asthma</b>	<b>Clostridium difficile Infection</b>	<b>Neuromuscular Blockade Reversal</b>
MK-1029	MK-3415A (actoxumab/bezlotoxumab) (November 2011)	MK-8616 (sugammadex sodium injection) (U.S.)
<b>Bacterial Infection</b>	<b>Contraception</b>	<b>Platinum-Resistant Ovarian Cancer</b>
MK-7655	MK-8175A (NOMAC/E2) (U.S.) (June 2006)(5)	MK-8109 (vintafolide) (EU)
<b>Cancer</b>	<b>Diabetes Mellitus</b>	
MK-0646 (dalotuzumab)	MK-3102 (omarigliptin) (September 2012)	
MK-1775	<b>Fertility</b>	
MK-2206	MK-8962 (corifollitropin alfa injection) (U.S.) (July 2006)	
MK-7965 (dinaciclib)(2)	<b>Hepatitis C</b>	
MK-8669 (ridaforolimus)	MK-7009 (vaniprevir) (June 2011)(6)	
<b>CMV Prophylaxis in Transplant Patients</b>	<b>Herpes Zoster</b>	
MK-8228 (letermovir)	V212 (inactivated VZV vaccine) (December 2010)	
<b>Contraception, Medicated IUS</b>	<b>HPV-Related Cancers</b>	
MK-8342	V503 (HPV vaccine (9 valent)) (September 2008)	
<b>Contraception, Next Generation Ring</b>	<b>Osteoporosis</b>	
MK-8175A	MK-0822 (odanacatib) (September 2007)	
MK-8342B	<b>Parkinson's Disease</b>	
<b>Diabetes</b>	MK-3814 (preladenant) (July 2010)	
MK-8835 (ertugliflozin)(3)		
<b>Hepatitis C</b>		

**Footnotes:**

- (1) North American rights only.
- (2) Phase II/III adaptive design.
- (3) Licensed from Pfizer, Inc. (see discussion of collaboration agreement above).
- (4) On May 8, 2013, the Company announced that the BLA for MK-3641 was accepted for review by the FDA.
- (5) In November 2011, Merck received a Complete Response letter from the FDA for NOMAC/E2 (MK-8175A). The Company is conducting an additional clinical study requested by the FDA and plans to update the application in the future.

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

MK-5172	<b>Pediatric Hexavalent Combination Vaccine</b>	(6) For development in Japan only.
MK-8742	V419 (April 2011)	
<b>HIV</b>	<b>Platinum-Resistant Ovarian Cancer</b>	
MK-1439	MK-8109 (vintafolide) (U.S.) (April 2011)	
<b>Insomnia</b>	<b>Psoriasis</b>	
MK-6096	MK-3222 (December 2012)	
<b>Melanoma</b>	<b>Thrombosis</b>	
MK-3475 (lambrolizumab)	MK-5348 (vorapaxar) (September 2007)	
<b>Migraine</b>		
MK-1602		
<b>Overactive Bladder</b>		
MK-4618		
<b>Pneumoconjugate Vaccine</b>		
V114		
<b>Rheumatoid Arthritis</b>		
MK-8457		

## 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 \$230 million and \$206 million in the first quarter of 2013 and 2012, respectively. SPMSD sales of *Gardasil* were \$73 million and \$55 million for the first quarter 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

<i>(\$ in millions)</i>	March 31, 2013	December 31, 2012
Cash and investments	\$ 23,970	\$ 23,446
Working capital	16,442	16,509
Total debt to total liabilities and equity	19.6%	19.4%

During the first three months of 2013, cash provided by operating activities was \$2.3 billion compared with \$2.2 billion in the first three months of 2012. 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. As discussed in Note 8 to the interim consolidated financial statements, the Company has preliminarily settled the ENHANCE Litigation, which settlement is subject to court approval. Assuming the settlement is approved by the court, the Company anticipates it will pay \$688 million in 2013 in connection with the settlement; however, the Company expects that \$195 million of this amount will be recovered through insurance.

The global economic downturn and the 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 \$1.2 billion in the first three months of 2013 compared with \$270 million in the first three 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 in the first three months of 2013 was \$1.4 billion compared with \$725 million in the first three months of 2012. The higher use of cash in financing activities was primarily driven by higher payments on debt and lower proceeds from the exercise of stock options, partially offset by an increase in short-term borrowings.



At March 31, 2013, the total of worldwide cash and investments was \$24.0 billion, including \$16.0 billion of cash, cash equivalents and short-term investments and \$7.9 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 \$351 million and \$331 million for the first three months of 2013 and 2012, respectively.

Dividends paid to stockholders were \$1.3 billion for both the first three months of 2013 and the first three months of 2012. In February 2013, the Board of Directors declared a quarterly dividend of \$0.43 per share on the Company's common stock that was paid in April 2013.

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 over the next 12 months, 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 three months of 2013, the Company purchased \$580 million of its common stock (14 million shares) for its treasury under a plan approved by Merck's Board of Directors in April 2011. As of March 31, 2013, the Company had approximately \$1.3 billion remaining under this 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 Officer have concluded that as of March 31, 2013, the Company's disclosure controls and procedures are effective. There have been no changes in internal control over financial reporting for the period covered by this report that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

**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 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 8 included in Part I, Item 1, Financial Statements (unaudited) Notes to Consolidated Financial Statements.

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

Issuer purchases of equity securities for the three months ended March 31, 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>
January 1 - January 31	4,934,200	\$42.31	\$1,686
February 1 - February 28	4,279,500	\$41.94	\$1,507
March 1 - March 31	4,401,500	\$43.57	\$1,315
Total	13,615,200	\$42.60	\$1,315

<sup>(1)</sup> All shares purchased during the period were made as part of a plan approved by the Board of Directors in April 2011 to purchase up to \$5 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
31.1	Rule 13a 14(a)/15d 14(a) Certification of Chief Executive Officer
31.2	Rule 13a 14(a)/15d 14(a) Certification of Chief Financial Officer
32.1	Section 1350 Certification of Chief Executive Officer
32.2	Section 1350 Certification of Chief Financial Officer
101	The following materials from Merck & Co., Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 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: May 9, 2013

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

Date: May 9, 2013

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

EXHIBIT INDEX

<b>Number</b>	<b>Description</b>
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
31.1	Rule 13a 14(a)/15d 14(a) Certification of Chief Executive Officer
31.2	Rule 13a 14(a)/15d 14(a) Certification of Chief Financial Officer
32.1	Section 1350 Certification of Chief Executive Officer
32.2	Section 1350 Certification of Chief Financial Officer
101	The following materials from Merck & Co., Inc. s Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, formatted in XBRL (Extensible Business Reporting Language): (i) the 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.