

Merck & Co. Inc.
Form 10-Q
August 07, 2012

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 June 30, 2012

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from ____ to ____

Commission File No. 1-6571

Merck & Co., Inc.

One Merck Drive

Whitehouse Station, N.J. 08889-0100

(908) 423-1000

Incorporated in New Jersey

I.R.S. Employer

Identification No. 22-1918501

The number of shares of common stock outstanding as of the close of business on July 31, 2012: 3,045,632,274

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):

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

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 June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Sales	\$ 12,311	\$ 12,151	\$ 24,041	\$ 23,732
Costs, Expenses and Other				
Materials and production	4,112	4,284	8,150	8,343
Marketing and administrative	3,249	3,525	6,322	6,689
Research and development	2,165	1,936	4,026	4,094
Restructuring costs	144	668	363	654
Equity income from affiliates	(142)	(55)	(253)	(193)
Other (income) expense, net	103	121	247	744
	9,631	10,479	18,855	20,331
Income Before Taxes	2,680	1,672	5,186	3,401
Taxes on Income	860	(382)	1,599	276
Net Income	\$ 1,820	\$ 2,054	\$ 3,587	\$ 3,125
Less: Net Income Attributable to Noncontrolling Interests	27	30	56	58
Net Income Attributable to Merck & Co., Inc.	\$ 1,793	\$ 2,024	\$ 3,531	\$ 3,067
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	\$ 0.59	\$ 0.65	\$ 1.16	\$ 0.99
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	\$ 0.58	\$ 0.65	\$ 1.15	\$ 0.98
Dividends Declared per Common Share	\$ 0.42	\$ 0.38	\$ 0.84	\$ 0.76

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

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2012	2011	2012	2011
Net Income Attributable to Merck & Co., Inc.	\$ 1,793	\$ 2,024	\$ 3,531	\$ 3,067
Other Comprehensive Income Net of Taxes:				
Net unrealized gain (loss) on derivatives, net of reclassifications	102	(30)	44	(137)
Net unrealized gain (loss) on investments, net of reclassifications	1	(4)	30	(5)
Benefit plan net gain (loss) and prior service cost (credit), net of amortization	18	10	18	28
Cumulative translation adjustment	(30)	418	(86)	554
	91	394	6	440
Comprehensive Income Attributable to Merck & Co., Inc.	\$ 1,884	\$ 2,418	\$ 3,537	\$ 3,507

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

MERCK & CO., INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEET

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

	June 30, 2012	December 31, 2011
Assets		
Current Assets		
Cash and cash equivalents	\$ 16,752	\$ 13,531
Short-term investments	698	1,441
Accounts receivable (net of allowance for doubtful accounts of \$144 in 2012 and \$131 in 2011)	8,152	8,261
Inventories (excludes inventories of \$1,490 in 2012 and \$1,379 in 2011 classified in Other assets - see Note 6)	6,249	6,254
Deferred income taxes and other current assets	3,788	3,694
Total current assets	35,639	33,181
Investments	4,085	3,458
Property, Plant and Equipment, at cost, net of accumulated depreciation of \$17,049 in 2012 and \$16,176 in 2011	15,867	16,297
Goodwill	12,158	12,155
Other Intangibles, Net	31,620	34,302
Other Assets	6,156	5,735
	\$ 105,525	\$ 105,128
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	\$ 3,922	\$ 1,990
Trade accounts payable	1,674	2,023
Accrued and other current liabilities	8,917	10,170
Income taxes payable	1,091	781
Dividends payable	1,308	1,281
Total current liabilities	16,912	16,245
Long-Term Debt	15,057	15,525
Deferred Income Taxes and Noncurrent Liabilities	15,883	16,415
Merck & Co., Inc. Stockholders Equity		
Common stock, \$0.50 par value		
Authorized - 6,500,000,000 shares		
Issued - 3,577,103,522 shares in 2012 and 2011	1,788	1,788
Other paid-in capital	40,550	40,663
Retained earnings	39,950	38,990
Accumulated other comprehensive loss	(3,126)	(3,132)
	79,162	78,309
Less treasury stock, at cost:		
538,194,526 shares in 2012 and 536,109,713 shares in 2011	23,968	23,792
Total Merck & Co., Inc. stockholders equity	55,194	54,517
Noncontrolling Interests	2,479	2,426
Total equity	57,673	56,943
	\$ 105,525	\$ 105,128

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

MERCK & CO., INC. AND SUBSIDIARIES

INTERIM CONSOLIDATED STATEMENT OF CASH FLOWS

(Unaudited, \$ in millions)

	Six Months Ended June 30,	
	2012	2011
Cash Flows from Operating Activities		
Net income	\$ 3,587	\$ 3,125
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	3,594	3,663
Intangible asset impairment charges	136	439
Equity income from affiliates	(253)	(193)
Dividends and distributions from equity affiliates	122	121
Deferred income taxes	(365)	(841)
Share-based compensation	169	200
Other	143	(456)
Net changes in assets and liabilities	(2,059)	(1,485)
Net Cash Provided by Operating Activities	5,074	4,573
Cash Flows from Investing Activities		
Capital expenditures	(762)	(689)
Purchases of securities and other investments	(4,001)	(3,066)
Proceeds from sales of securities and other investments	4,174	2,890
Dispositions of businesses, net of cash divested	-	323
Acquisitions of businesses, net of cash acquired	-	(373)
Other	21	(28)
Net Cash Used in Investing Activities	(568)	(943)
Cash Flows from Financing Activities		
Net change in short-term borrowings	1,637	1,396
Payments on debt	(2)	(1,265)
Purchases of treasury stock	(985)	(314)
Dividends paid to stockholders	(2,559)	(2,351)
Proceeds from exercise of stock options	601	162
Other	(3)	(57)
Net Cash Used in Financing Activities	(1,311)	(2,429)
Effect of Exchange Rate Changes on Cash and Cash Equivalents	26	241
Net Increase in Cash and Cash Equivalents	3,221	1,442
Cash and Cash Equivalents at Beginning of Year	13,531	10,900
Cash and Cash Equivalents at End of Period	\$ 16,752	\$ 12,342

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

Notes to 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, 2012.

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

Certain reclassifications have been made to prior year amounts to conform to the current year presentation.

Recently Adopted Accounting Standards

In the first quarter of 2012, the Company retrospectively adopted amended guidance issued by the Financial Accounting Standards Board (the FASB) on the presentation of comprehensive income in financial statements. As a result of adopting this standard, the Company has presented a separate Statement of Comprehensive Income. The adoption of this new guidance did not impact the Company's financial position, results of operations or cash flows.

Recently Issued Accounting Standards

In July 2012, the FASB issued amended guidance that simplifies how an entity tests indefinite-lived intangibles for impairment. The amended guidance will allow 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 updated guidance is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012, with early adoption permitted. The Company is currently evaluating the impact of adoption on its financial position and results of operations.

2. Restructuring

Merger Restructuring Program

In February 2010, subsequent to the Merck and Schering-Plough Corporation (Schering-Plough) merger (the Merger), the Company commenced actions under a global restructuring program (the Merger Restructuring Program) in conjunction with the integration of the legacy Merck and legacy Schering-Plough businesses. This Merger Restructuring Program is intended to optimize the cost structure of the combined company. In July 2011, the Company announced the latest phase of the Merger Restructuring Program during 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 in this phase of the Merger Restructuring Program relate to manufacturing (including Animal Health), administrative and headquarters organizations. Previously announced workforce reductions of approximately 17% in earlier phases of the program primarily reflect the elimination of positions in sales, administrative and headquarters organizations, as well as from the sale or closure of certain manufacturing and research and development sites and the consolidation of office facilities. The Company will continue to hire employees in strategic growth areas of the business as necessary. The Company will continue to pursue productivity efficiencies and evaluate its manufacturing supply chain capabilities on an ongoing basis which may result in future restructuring actions.

The Company recorded total pretax restructuring costs of \$291 million and \$808 million in the second quarter of 2012 and 2011, respectively, and \$568 million and \$921 million in the first six months of 2012 and 2011, respectively, related to this program. Since inception of the Merger Restructuring Program through June 30, 2012, Merck has recorded total pretax accumulated costs of approximately \$5.7 billion and eliminated approximately 20,230 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, which are expected to be substantially completed by 2015. The Company originally estimated the total cumulative pretax costs for this program to be approximately \$5.8 billion to \$6.6 billion and the Company now expects the cumulative costs to be near the upper end of this range. 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

Notes to Consolidated Financial Statements (unaudited) (continued)

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 \$(4) million and \$1 million were recorded in the second quarter of 2012 and 2011, respectively, and \$10 million and \$5 million were recorded in the first six months of 2012 and 2011, respectively, related to the 2008 Restructuring Program. Since inception of the 2008 Restructuring Program through June 30, 2012, Merck has recorded total pretax accumulated costs of \$1.6 billion and eliminated approximately 6,390 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 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 June 30, 2012				Six Months Ended June 30, 2012			
	Separation Costs	Accelerated Depreciation	Other	Total	Separation Costs	Accelerated Depreciation	Other	Total
<i>Merger Restructuring Program</i>								
Materials and production	\$ -	\$ 56	\$ 20	\$ 76	\$ -	\$ 33	\$ 37	\$ 70
Marketing and administrative	-	20	1	21	-	43	2	45
Research and development	-	41	-	41	-	82	4	86
Restructuring costs	124	-	29	153	304	-	63	367
	124	117	50	291	304	158	106	568
<i>2008 Restructuring Program</i>								
Materials and production	-	1	4	5	-	3	11	14
Restructuring costs	(13)	-	4	(9)	(11)	-	7	(4)
	(13)	1	8	(4)	(11)	3	18	10
	\$ 111	\$ 118	\$ 58	\$ 287	\$ 293	\$ 161	\$ 124	\$ 578

(\$ in millions)	Three Months Ended June 30, 2011				Six Months Ended June 30, 2011			
	Separation Costs	Accelerated Depreciation	Other	Total	Separation Costs	Accelerated Depreciation	Other	Total
<i>Merger Restructuring Program</i>								
Materials and production	\$ -	\$ 91	\$ 5	\$ 96	\$ -	\$ 152	\$ 5	\$ 157
Marketing and administrative	-	22	1	23	-	45	1	46
Research and development	-	38	(22)	16	-	80	(19)	61
Restructuring costs	646	-	27	673	607	-	50	657
	646	151	11	808	607	277	37	921
<i>2008 Restructuring Program</i>								
Materials and production	-	4	2	6	-	6	2	8
Restructuring costs	(7)	-	2	(5)	(8)	-	5	(3)
	(7)	4	4	1	(8)	6	7	5
	\$ 639	\$ 155	\$ 15	\$ 809	\$ 599	\$ 283	\$ 44	\$ 926

Separation costs are associated with actual headcount reductions, as well as those headcount reductions which were probable and could be reasonably estimated. In the second quarter of 2012 and 2011, approximately 780 positions and 585 positions, respectively, were eliminated under the Merger Restructuring Program. In addition, approximately 60 positions were eliminated in the second quarter of 2011 under the 2008 Restructuring Program. In the first six months of 2012 and 2011, approximately 1,800 positions and 1,335 positions, respectively, were

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

eliminated under the Merger Restructuring Program and approximately 140 positions and 180 positions,

- 7 -

Notes to Consolidated Financial Statements (unaudited) (continued)

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. Site closure dates, particularly related to manufacturing locations, have been and may continue to be adjusted to reflect changes resulting from regulatory or other factors.

Other activity in 2012 and 2011 includes asset abandonment, shut-down and other related costs. Additionally, other activity includes employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans (see Note 12) and share-based compensation costs.

The following table summarizes the charges and spending relating to Merger Restructuring Program and 2008 Restructuring Program activities for the six months ended June 30, 2012:

(\$ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
<i>Merger Restructuring Program</i>				
Restructuring reserves January 1, 2012	\$ 1,144	\$ -	\$ 51	\$ 1,195
Expense	304	158	106	568
(Payments) receipts, net	(634)	-	(66)	(700)
Non-cash activity	-	(158)	(51)	(209)
Restructuring reserves June 30, 2012 ⁽¹⁾	\$ 814	\$ -	\$ 40	\$ 854
<i>2008 Restructuring Program</i>				
Restructuring reserves January 1, 2012	\$ 126	\$ -	\$ -	\$ 126
Expense	(11)	3	18	10
(Payments) receipts, net	(15)	-	(8)	(23)
Non-cash activity	-	(3)	(10)	(13)
Restructuring reserves June 30, 2012 ⁽¹⁾	\$ 100	\$ -	\$ -	\$ 100

⁽¹⁾ 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 2015. 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.

Legacy Schering-Plough Program

Prior to the Merger, Schering-Plough commenced a Productivity Transformation Program which was designed to reduce and avoid costs and increase productivity. The Company recorded accelerated depreciation costs included in *Materials and production* costs of \$2 million and \$7 million for the second quarter of 2012 and 2011, respectively, and \$4 million and \$16 million for the first six months of 2012 and 2011, respectively. The remaining reserve associated with this program, which is substantially complete, was \$18 million at June 30, 2012.

3. Acquisitions, Divestitures, Research Collaborations and License Agreements

In April 2012, the Company entered into an agreement with Endocyte, Inc. (Endocyte) to develop and commercialize Endocyte's novel investigational therapeutic candidate vintafolide (MK-8109). Vintafolide is currently being evaluated in a Phase III clinical trial for platinum-resistant ovarian cancer (PROCEED) and a Phase II trial for non-small cell lung cancer. Under the agreement, Merck gained worldwide rights to develop and commercialize vintafolide. Endocyte received a \$120 million upfront payment, which the Company recorded in *Research and development* expenses in the second quarter of 2012, and is eligible for milestone payments of up to \$880 million based on the

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

successful achievement of development, regulatory and commercialization goals for vintafolide for a total of six cancer indications. In addition, if vintafolide receives regulatory approval, Endocyte will receive an equal share of the profit in the United States as well as a royalty on sales of

Notes to Consolidated Financial Statements (unaudited) (continued)

the product in the rest of the world. Endocyte has retained the right to co-promote vintafolide with Merck in the United States and Merck has the exclusive right to promote vintafolide in the rest of world. Endocyte will be responsible for the majority of funding and completion of the PROCEED trial. Merck will be responsible for most other development activities, all other costs and will have most decision rights for vintafolide. Merck has the right to terminate the agreement on 90 days notice. Merck and Endocyte both have the right to terminate the agreement due to the material breach or insolvency of the other party. Endocyte has the right to terminate the agreement in the event that Merck challenges an Endocyte patent right relating to vintafolide. 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 vintafolide and, in the case of termination for cause by Merck, certain royalty obligations and U.S. profit and loss sharing.

In May 2011, Merck completed the acquisition of Inspire Pharmaceuticals, Inc. (Inspire), a specialty pharmaceutical company focused on developing and commercializing ophthalmic products. Under the terms of the merger agreement, Merck acquired all outstanding shares of common stock of Inspire at a price of \$5.00 per share in cash for a total of approximately \$420 million. The transaction was accounted for as an acquisition of a business; accordingly, the assets acquired and liabilities assumed were recorded at their respective fair values as of the acquisition date. The determination of fair value requires management to make significant estimates and assumptions. In connection with the acquisition, substantially all of the purchase price was allocated to Inspire's product and product right intangible assets and related deferred tax liabilities, a deferred tax asset relating to Inspire's net operating loss carryforwards, and goodwill. This transaction closed on May 16, 2011, and accordingly, the results of operations of the acquired business have been included in the Company's results of operations since the acquisition date. Pro forma financial information has not been included because Inspire's historical financial results are not significant when compared with the Company's financial results.

In March 2011, the Company sold the Merck BioManufacturing Network, a provider of contract manufacturing and development services for the biopharmaceutical industry and wholly owned by Merck, to Fujifilm Corporation (Fujifilm). Under the terms of the agreement, Fujifilm purchased all of the equity interests in two Merck subsidiaries which together owned all of the assets of the Merck BioManufacturing Network comprising facilities located in Research Triangle Park, North Carolina and Billingham, United Kingdom. As part of the agreement with Fujifilm, Merck has committed to purchase certain development and manufacturing services at fair value from Fujifilm over a three-year period following the closing of the transaction. The transaction resulted in a gain of \$127 million in the first six months of 2011 reflected in *Other (income) expense, net*.

4. Collaborative Arrangements

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.

Cozaar/Hyzaar

In 1989, Merck and E.I. duPont de Nemours and Company (DuPont) agreed to form a long-term research and marketing collaboration to develop a class of therapeutic agents for high blood pressure and heart disease, discovered by DuPont, called angiotensin II receptor antagonists, which include *Cozaar* and *Hyzaar*. In return, Merck provided DuPont marketing rights in the United States and Canada to its prescription medicines, *Sinemet* and *Sinemet CR* (the Company has since regained global marketing rights to *Sinemet* and *Sinemet CR*). Pursuant to a 1994 agreement with DuPont, the Company has an exclusive licensing agreement to market *Cozaar* and *Hyzaar* in return for royalties and profit share payments to DuPont. The patents that provided market exclusivity in the United States and in a number of major European markets for *Cozaar* and *Hyzaar* expired in 2010.

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 had exclusive marketing rights to both products outside the United States, Japan and

Notes to Consolidated Financial Statements (unaudited) (continued)

certain other Asian markets. 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. In April 2011, Merck and J&J reached an agreement to amend the agreement governing the distribution rights to *Remicade* and *Simponi*. Under the terms of the amended distribution agreement, Merck relinquished marketing rights for *Remicade* and *Simponi* to J&J in territories including Canada, Central and South America, the Middle East, Africa and Asia Pacific effective July 1, 2011. Merck retained exclusive marketing rights throughout Europe, Russia and Turkey (the Retained Territories). In addition, beginning July 1, 2011, all profits derived from Merck's exclusive distribution of the two products in the Retained Territories are being equally divided between Merck and J&J. J&J also received a one-time payment from Merck of \$500 million in April 2011, which the Company recorded as a charge to *Other (income) expense, net* in the first quarter of 2011.

5. 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, such that it is probable the hedged transaction will occur. 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 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.

Notes to Consolidated Financial Statements (unaudited) (continued)

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, unrealized gains or losses are recorded in *Sales* each period. The cash flows from these 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 \$92 million and \$(178) million for the first six months of 2012 and 2011, respectively, from the euro-denominated notes.

Notes to 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.

In June 2011, the Company terminated nine interest rate swap contracts with a total notional amount of \$3.5 billion. These swaps effectively converted \$3.5 billion of its fixed-rate notes, with maturity dates varying from March 2015 to June 2019, to floating rate instruments. As a result of the swap terminations, the Company received \$175 million in cash, which included \$36 million in accrued interest. The corresponding \$139 million basis adjustment of the debt associated with the terminated swap contracts was deferred and is being amortized as a reduction of interest expense over the respective term of the notes. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

At June 30, 2011, the Company was a party to 13 pay-floating, receive-fixed interest rate swap contracts with notional amounts of \$1.9 billion in the aggregate designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes. The interest rate swap contracts were designated hedges of the fair value changes in the notes attributable to changes in the benchmark London Interbank Offered Rate (LIBOR) swap rate. The fair value changes in the notes attributable to changes in the benchmark interest rate were recorded in interest expense and offset by the fair value changes in the swap contracts. The Company terminated certain of these interest rate swap contracts in the third quarter of 2011 and the remaining interest rate swap contracts matured in the fourth quarter of 2011. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

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

(\$ in millions)	Balance Sheet Caption	June 30, 2012			December 31, 2011		
		Fair Value of Derivative Asset	Liability	U.S. Dollar Notional	Fair Value of Derivative Asset	Liability	U.S. Dollar Notional
<i>Derivatives Designated as Hedging Instruments</i>							
Foreign exchange contracts (current)	Deferred income taxes and other current assets	\$ 279	\$ -	\$ 5,005	\$ 196	\$ -	\$ 3,727
Foreign exchange contracts (non-current)	Other assets	470	-	5,177	420	-	4,956
Foreign exchange contracts (current)	Accrued and other current liabilities	-	13	411	-	53	1,718
Foreign exchange contracts (non-current)	Deferred income taxes and noncurrent liabilities	-	7	436	-	1	104
		\$ 749	\$ 20	\$ 11,029	\$ 616	\$ 54	\$ 10,505
<i>Derivatives Not Designated as Hedging Instruments</i>							
Foreign exchange contracts (current)	Deferred income taxes and other current assets	\$ 100	\$ -	\$ 4,511	\$ 139	\$ -	\$ 5,306
Foreign exchange contracts (non-current)	Other assets	35	-	339	-	-	-
Foreign exchange contracts (current)	Accrued and other current liabilities	-	28	3,740	-	54	5,013
		\$ 135	\$ 28	\$ 8,590	\$ 139	\$ 54	\$ 10,319
		\$ 884	\$ 48	\$ 19,619	\$ 755	\$ 108	\$ 20,824

Notes to Consolidated Financial Statements (unaudited) (continued)

The table below provides information on the location and pretax gain or loss amounts for derivatives that are: (i) designated in a fair value hedging relationship, (ii) designated in a cash flow hedging relationship, (iii) designated in a foreign currency net investment hedging relationship and (iv) not designated in a hedging relationship:

(\$ in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
<i>Derivatives designated in fair value hedging relationships</i>				
Interest rate swap contracts				
Amount of gain recognized in <i>Other (income) expense, net</i> on derivatives	\$ -	\$ (126)	\$ -	\$ (163)
Amount of loss recognized in <i>Other (income) expense, net</i> on hedged item	-	126	-	163
<i>Derivatives designated in foreign currency cash flow hedging relationships</i>				
Foreign exchange contracts				
Amount of loss reclassified from <i>AOCI to Sales</i>	26	20	53	27
Amount of (gain) loss recognized in <i>OCI</i> on derivatives	(154)	69	(34)	252
<i>Derivatives designated in foreign currency net investment hedging relationships</i>				
Foreign exchange contracts				
Amount of gain recognized in <i>Other (income) expense, net</i> on derivatives ⁽¹⁾	(2)	(2)	(11)	(8)
Amount of loss (gain) recognized in <i>OCI</i> on derivatives	86	33	(56)	34
<i>Derivatives not designated in a hedging relationship</i>				
Foreign exchange contracts				
Amount of (gain) loss recognized in <i>Other (income) expense, net</i> on derivatives ⁽²⁾	(279)	33	(26)	349

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

⁽²⁾ These derivative contracts mitigate changes in the value of remeasured foreign currency denominated monetary assets and liabilities attributable to changes in foreign currency exchange rates.

At June 30, 2012, the Company estimates \$2 million of pretax net unrealized gains on derivatives maturing within the next 12 months that hedge foreign currency denominated sales over that same period will be reclassified from *AOCI* to *Sales*. The amount ultimately reclassified to *Sales* may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity.

Investments in Debt and Equity Securities

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

(\$ in millions)	June 30, 2012				December 31, 2011			
	Fair Value	Amortized Cost	Gross Gains	Unrealized Losses	Fair Value	Amortized Cost	Gross Gains	Unrealized Losses

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

Corporate notes and bonds	\$ 2,787	\$ 2,759	\$ 30	\$ (2)	\$ 2,032	\$ 2,024	\$ 16	\$ (8)
U.S. government and agency securities	773	772	1	-	1,021	1,018	3	-
Asset-backed securities	441	439	2	-	292	292	1	(1)
Mortgage-backed securities	271	270	2	(1)	223	223	1	(1)
Commercial paper	220	220	-	-	1,029	1,029	-	-
Foreign government bonds	76	75	1	-	72	72	-	-
Other debt securities	3	1	2	-	3	1	2	-
Equity securities	383	354	29	-	397	383	14	-
	\$ 4,954	\$ 4,890	\$ 67	\$ (3)	\$ 5,069	\$ 5,042	\$ 37	\$ (10)

Available-for-sale debt securities included in *Short-term investments* totaled \$698 million at June 30, 2012. Of the remaining debt securities, \$3.4 billion mature within five years. At June 30, 2012, there were no debt securities pledged as collateral.

Notes to Consolidated Financial Statements (unaudited) (continued)**Fair Value Measurements**

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

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

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

Level 3 - Unobservable inputs that are supported by little or no market activity. Level 3 assets are those whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques with significant unobservable inputs, as well as instruments for which the determination of fair value requires significant judgment or estimation. The Company had no Level 3 assets at June 30, 2012 or December 31, 2011.

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

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

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

	Fair Value Measurements Using				Fair Value Measurements Using			
	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
	June 30, 2012				December 31, 2011			
<i>(\$ in millions)</i>								
Assets								
<i>Investments</i>								
Corporate notes and bonds	\$ -	\$ 2,787	\$ -	\$ 2,787	\$ -	\$ 2,032	\$ -	\$ 2,032
U.S. government and agency securities	-	773	-	773	-	1,021	-	1,021
Asset-backed securities ⁽¹⁾	-	441	-	441	-	292	-	292
Mortgage-backed securities ⁽¹⁾	-	271	-	271	-	223	-	223
Commercial paper	-	220	-	220	-	1,029	-	1,029
Foreign government bonds	-	76	-	76	-	72	-	72
Equity securities	203	9	-	212	205	22	-	227
Other debt securities	-	3	-	3	-	3	-	3
	203	4,580	-	4,783	205	4,694	-	4,899
<i>Other assets</i>								
Securities held for employee compensation	171	-	-	171	170	-	-	170
<i>Derivative assets ⁽²⁾</i>								
Purchased currency options	-	763	-	763	-	613	-	613
Forward exchange contracts	-	121	-	121	-	142	-	142
	-	884	-	884	-	755	-	755
Total assets	\$ 374	\$ 5,464	\$ -	\$ 5,838	\$ 375	\$ 5,449	\$ -	\$ 5,824
Liabilities								
<i>Derivative liabilities ⁽²⁾</i>								
Forward exchange contracts	\$ -	\$ 48	\$ -	\$ 48	\$ -	\$ 107	\$ -	\$ 107
Written currency options	-	-	-	-	-	1	-	1

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

Total liabilities \$ - \$ 48 \$ - \$ 48 \$ - \$ 108 \$ - \$ 108

- (1) Primarily all of the asset-backed securities are highly-rated (Standard & Poor's rating of AAA and Moody's Investors Service rating of Aaa), secured primarily by credit card, auto loan, and home equity receivables, with weighted-average lives of primarily 5 years or less. Mortgage-backed securities represent AAA-rated securities issued or unconditionally guaranteed as to payment of principal and interest by U.S. government agencies.*
- (2) The fair value determination of derivatives includes the impact of the credit risk of counterparties to the derivatives and the Company's own credit risk, the effects of which were not significant.*

Notes to Consolidated Financial Statements (unaudited) (continued)

There were no transfers between Level 1 and Level 2 during the first six months of 2012. As of June 30, 2012, *Cash and cash equivalents* of \$16.8 billion included \$15.9 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.

The estimated fair value of loans payable and long-term debt (including current portion) at June 30, 2012 was \$21.2 billion compared with a carrying value of \$19.0 billion and at December 31, 2011 was \$19.5 billion compared with a carrying value of \$17.5 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 40% of the Company's cash and cash equivalents are invested in five highly rated money market funds.

The majority of the Company's accounts receivable arise from product sales in the United States and Europe and are primarily due from drug wholesalers and retailers, hospitals, government agencies, managed health care providers and pharmacy benefit managers. The Company monitors the financial performance and credit worthiness 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, Spain, Italy 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. 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 June 30, 2012, the Company's accounts receivable in Greece, Italy, Spain and Portugal totaled approximately \$1.0 billion. Of this amount, hospital and public sector receivables were approximately \$700 million in the aggregate, of which approximately 16%, 38%, 28% and 18% related to Greece, Italy, Spain and Portugal, respectively. As of June 30, 2012, the Company's total accounts receivable outstanding for more than one year were approximately \$200 million, of which approximately 70% related to accounts receivable in Greece, Italy, Spain and Portugal, mostly comprised of hospital and public sector receivables.

During the second quarter of 2012, the Company collected approximately \$500 million of accounts receivable in connection with the Spanish government's debt stabilization/stimulus plan. In addition, in the second and first quarters of 2012, the Company completed non-recourse factorings of approximately \$120 million and \$110 million, respectively, of hospital and public sector accounts receivable in Italy.

As previously disclosed, the Company received zero coupon bonds from the Greek government in settlement of 2007-2009 receivables related to certain government sponsored institutions. The Company had recorded impairment charges to reduce the bonds to fair value. During 2011, the Company sold a portion of these bonds and the remainder was sold during the first quarter of 2012.

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

Notes to Consolidated Financial Statements (unaudited) (continued)

counterparty. As of June 30, 2012 and December 31, 2011, the Company had received cash collateral of \$539 million and \$327 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 June 30, 2012 or December 31, 2011.

6. Inventories

Inventories consisted of:

<i>(\$ in millions)</i>	June 30, 2012	December 31, 2011
Finished goods	\$ 1,808	\$ 1,983
Raw materials and work in process	5,705	5,396
Supplies	265	297
Total (approximates current cost)	7,778	7,676
Reduction to LIFO costs	(39)	(43)
	\$ 7,739	\$ 7,633
Recognized as:		
Inventories	\$ 6,249	\$ 6,254
Other assets	1,490	1,379

Amounts recognized as *Other assets* are comprised almost entirely of raw materials and work in process inventories. At both June 30, 2012 and December 31, 2011, these amounts included \$1.3 billion of inventories not expected to be sold within one year. In addition, these amounts included \$169 million and \$127 million at June 30, 2012 and December 31, 2011, respectively, of inventories produced in preparation for product launches.

7. 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 second quarter of 2012 and 2011, the Company recorded \$127 million and \$19 million, respectively, and during the first six months of 2012 and 2011, recorded \$136 million and \$321 million, respectively, of in-process research and development (IPR&D) impairment charges within *Research and development* expenses primarily for pipeline programs that had previously been deprioritized and were deemed to have no alternative use in the period. Also, during the second quarter of 2011, the Company recorded an intangible asset impairment charge of \$118 million within *Materials and production* costs related to a marketed product. 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.

8. 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:

<i>(\$ in millions)</i>	Three Months Ended		Six Months Ended	
	June 30, 2012	June 30, 2011	June 30, 2012	June 30, 2011
AstraZeneca LP	\$ 140	\$ 44	\$ 253	\$ 177
Other ⁽¹⁾	2	11	-	16
	\$ 142	\$ 55	\$ 253	\$ 193

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

⁽¹⁾ 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

- 16 -

Notes to Consolidated Financial Statements (unaudited) (continued)

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 June 2012, Merck and AstraZeneca amended the 1998 option agreement which gave AstraZeneca the option to buy Merck's common stock interest in KBI and, through it, Merck's interest in Nexium and Prilosec as well as AZLP. The updated agreement eliminates AstraZeneca's option to acquire Merck's interest in KBI in 2012 and provides AstraZeneca a new option to acquire Merck's interest in KBI in June 2014. As a result of the amended agreement, Merck will continue to record supply sales and equity income from the partnership for the remainder of 2012 and 2013. In 2014, AstraZeneca has the option to purchase Merck's interest in KBI based in part on the value of Merck's interest in Prilosec and Nexium. 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 June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Sales	\$ 1,150	\$ 1,181	\$ 2,192	\$ 2,336
Materials and production costs	520	516	959	1,061
Other expense, net	350	345	732	646
Income before taxes ⁽¹⁾	\$ 280	\$ 320	\$ 501	\$ 629

⁽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.

9. Contingencies and Environmental Liabilities

The Company is involved in various claims and legal proceedings of a nature considered normal to its business, including product liability, intellectual property, and commercial litigation, as well as additional matters such as antitrust actions and environmental matters. Except for the Vioxx Litigation and the ENHANCE Litigation (each as defined below) for which separate assessments are 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 ENHANCE 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

Notes to Consolidated Financial Statements (unaudited) (continued)

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 100 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 is one U.S. *Vioxx* Product Liability Lawsuit currently scheduled for trial in 2012. Merck has previously disclosed the outcomes of several *Vioxx* Product Liability Lawsuits that were tried prior to 2012. All post-trial appeals have been resolved.

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*. The *Vioxx* MDL court issued an order in April 2012 enjoining the Missouri plaintiffs from offering any evidence that does not sufficiently exclude damages attributable to claims already settled through the prior personal injury and third-party payor settlements and from executing any judgment obtained through admission of such evidence. The Missouri plaintiffs have appealed that decision to the U.S. Court of Appeals for the Fifth Circuit, which has set an expedited briefing schedule on plaintiffs' appeal. Trial has been rescheduled for November 1, 2012, in light of the appeal. 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, on February 10, 2012, the Kentucky Court of Appeals reversed the trial court's amended class certification order and denied certification. The plaintiff has petitioned the Kentucky Supreme Court to review the Court of Appeals' order. Merck opposed the petition, and the Kentucky Supreme Court has not yet ruled.

Merck has also been named as a defendant in several lawsuits brought by, or on behalf of, government entities. Six of these suits are being brought by state Attorneys General and one has been brought on behalf of a county. All of these actions except for an action brought by the Kentucky Attorney General 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. Judge Fallon remanded the Kentucky case to state court on January 3, 2012. Merck's petition to appeal that decision to the U.S. Court of Appeals for the Fifth Circuit was denied. The lawsuit brought by the county is a putative class action filed by Santa Clara County, California on behalf of all similarly situated California counties. Merck moved for judgment on the pleadings in the case brought by Santa Clara County in September 2011. The court granted Merck's motion on March 20, 2012, but gave the county leave to file an amended complaint.

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. Discovery is currently proceeding in accordance with the court's scheduling order.

Notes to Consolidated Financial Statements (unaudited) (continued)

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 was filed in the District of New Jersey by several foreign institutional investors; that case is also consolidated with the *Vioxx* Securities Lawsuits. On January 20, 2012, defendants filed motions to dismiss in one of the individual lawsuits (the ABP Lawsuit). Briefing on the motions to dismiss was completed on March 26, 2012. On August 1, 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. By stipulation and order, defendants are not required to respond to the complaints in the remaining individual securities lawsuits until on or about September 15, 2012.

Insurance

The Company has Directors and Officers insurance coverage applicable to the *Vioxx* Securities Lawsuits with remaining stated upper limits of approximately \$175 million. As a result of the previously disclosed insurance arbitration, additional insurance coverage for these claims should also be available, if needed, under upper-level excess policies that provide coverage for a variety of risks. There are disputes with the insurers about the availability of some or all of the Company's insurance coverage for these claims and there are likely to be additional disputes. The amounts actually recovered under the policies discussed in this paragraph may be less than the stated upper limits.

Investigations

As previously disclosed, Merck received subpoenas from the Department of Justice (the DOJ) requesting information related to Merck's research, marketing and selling activities with respect to *Vioxx* in a federal health care investigation under criminal statutes. As previously disclosed, in March 2009, Merck received a letter from the U.S. Attorney's Office for the District of Massachusetts identifying it as a target of the grand jury investigation regarding *Vioxx*. In 2010, the Company established a \$950 million reserve (the *Vioxx* Liability Reserve) in connection with the anticipated resolution of the DOJ's investigation.

In November 2011, the Company announced that it had reached a resolution with federal and state authorities regarding this matter, pending court approval. Under civil settlement agreements signed with the United States and individually with 44 states and the District of Columbia, Merck paid approximately two-thirds of the *Vioxx* Liability Reserve to resolve civil allegations related to *Vioxx*. As a result, the United States and the participating states have released Merck from civil liability related to the government's allegations regarding the sale and promotion of *Vioxx*. The Company also has agreed to plead guilty to one count of misdemeanor misbranding of *Vioxx* under the Federal Food, Drug, and Cosmetic Act by promoting the drug for the treatment of rheumatoid arthritis prior to the approval of that indication by the U.S. Food and Drug Administration (the FDA) in April 2002. The Company paid a fine of approximately one-third of the *Vioxx* Liability Reserve to the federal government as part of the plea agreement.

In December 2011, the U.S. District Court for the District of Massachusetts conducted a hearing with regard to the resolution. During that hearing, the parties advised the court as to the nature of the resolution and the core documents comprising the resolution. On April 19, 2012, the court accepted the resolution and thereafter the Company made the payments noted above.

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 Australia, Brazil, Canada, Europe and Israel (collectively, the *Vioxx* Foreign Lawsuits). As previously disclosed, the Company has entered into an agreement to resolve all claims related to *Vioxx* in Canada. The agreement is pending approval 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* Foreign Lawsuits (collectively, the *Vioxx* Lawsuits) and will vigorously defend against them. In view of the inherent difficulty of predicting the outcome of litigation, particularly where there are many claimants and the claimants seek indeterminate damages, the Company is unable to predict the outcome of these matters and, at this time, cannot reasonably estimate the possible loss or range of loss with respect to the remaining *Vioxx* Lawsuits. As previously disclosed, the Company has a reserve with respect to the Canada Settlement Agreement. The Company also has an immaterial remaining reserve relating to the *Vioxx* investigation discussed above 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.

Notes to Consolidated Financial Statements (unaudited) (continued)**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 June 30, 2012, approximately 3,615 cases, which include approximately 4,175 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 1,200 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 2,415 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 950 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, which is scheduled to take place on September 18, 2012. Merck intends to appeal the verdict in *Boles* after the new trial on damages has concluded. Three other cases have been tried to verdict in the *Fosamax* ONJ MDL. Defense verdicts in favor of Merck were returned in each of those three cases.

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. On March 28, 2012, the court selected *Scheinberg v. Merck* as the next case to be tried and set the trial date for January 14, 2013.

Outside the *Fosamax* ONJ MDL, in Florida, *Carballo v. Merck* has been set for trial on October 15, 2012 and *Anderson v. Merck* has been set for trial on January 14, 2013.

In addition, in July 2008, an application was made by the Atlantic County Superior Court of New Jersey requesting that all of the *Fosamax* cases pending in New Jersey be considered for mass tort designation and centralized management before one judge in New Jersey. In October 2008, the New Jersey Supreme Court ordered that all pending and future actions filed in New Jersey arising out of the use of *Fosamax* and seeking damages for existing dental and jaw-related injuries, including ONJ, but not solely seeking medical monitoring, be designated as a mass tort for centralized management purposes before Judge Carol E. Higbee in Atlantic County Superior Court. As of June 30, 2012, approximately 240 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.

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 are expected to be tried in 2013.

Discovery is ongoing in the *Fosamax* ONJ MDL litigation, the New Jersey coordinated proceeding, and the remaining jurisdictions where *Fosamax* 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*

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

Femur Fracture MDL). As a result of the JPML order, approximately 510 cases were pending in the *Fosamax* Femur Fracture MDL as of June 30, 2012. A Case Management Order has been entered that requires the parties to review

- 20 -

Notes to Consolidated Financial Statements (unaudited) (continued)

40 cases (later reduced to 33 cases) with a fact discovery deadline of July 31, 2012 and an expert discovery deadline of November 28, 2012. Judge Joel Pisano has selected four cases to be tried as the initial bellwether cases in the *Fosamax* Femur Fracture MDL and has set an April 8, 2013 trial date for the first bellwether case.

As of June 30, 2012, approximately 1,535 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. Plaintiffs subsequently dismissed or advised that they will dismiss seven of the cases that were selected and discovery in the remaining cases is continuing. Judge Higbee has set March 4, 2013 as the date for the first trial of the New Jersey state Femur Fracture cases.

As of June 30, 2012, approximately 350 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* 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.

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 June 30, 2012, there were approximately 1,100 *NuvaRing* cases. Of these cases, approximately 950 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 135 are pending in coordinated discovery proceedings in the Bergen County Superior Court of New Jersey before Judge Brian R. Martinotti. Six additional cases are pending in various other state courts.

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 has since been narrowed to eight cases from which the first trials in the *NuvaRing* MDL will be selected. Pursuant to Judge Martinotti's order in the New Jersey proceeding, the parties selected 10 trial pool cases to be prepared for trial and the first trial is expected to commence in February 2013. The parties have completed fact discovery in the originally selected trial pool cases in each jurisdiction and the Company anticipates expert discovery to be completed in those first trial pool cases by the summer of 2012. Certain replacement trial pool cases remain in fact discovery. Moreover, on January 31, 2012, the parties in the New Jersey coordinated proceeding selected an additional 10 trial pool cases for completion of fact discovery.

The Company anticipates filing motions related to the admissibility of expert testimony beginning in the summer of 2012 and continuing through the fall with status conferences to be held in each coordinated proceeding following the completion of briefing to discuss the timing of hearings related to the motions. The Company expects substantive hearings on those motions to take place in late 2012. The Company anticipates that status conferences will be held in each coordinated proceeding following rulings on the substantive evidentiary motions to determine a methodology for selecting the first cases to be tried. The Company intends to defend against these lawsuits.

Propecia/Proscar

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving *Propecia* and/or *Proscar*. As of June 30, 2012, approximately 200 lawsuits involving a total of approximately 325 plaintiffs (in a few instances spouses are joined in the suits) who allege that they have experienced persistent sexual side effects following cessation of treatment with *Propecia* and/or *Proscar* have

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

been filed against Merck. The lawsuits, which are in their early stages, are pending in federal courts in New Jersey, Washington, Washington D.C., Florida, Illinois, Colorado, Missouri and Ohio, and in state court in New Jersey.

- 21 -

Notes to Consolidated Financial Statements (unaudited) (continued)

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.

Governmental Proceedings

As publicly disclosed, on June 21, 2012, the U.S. District Court for the Eastern District of Pennsylvania unsealed a complaint that has been filed against the Company under the federal False Claims Act by two former employees alleging, among other things, that the Company defrauded the U.S. government by falsifying data in connection with a clinical study conducted on the mumps component of the Company's *M-M-R II* vaccine. The complaint alleges the fraud took place between 1999 and 2001. The U.S. government had the right to participate in and take over the prosecution of this lawsuit, but has advised the Company that it will decline to exercise that right. Thus, the two former employees are pursuing the lawsuit without the involvement of the U.S. government. The Company intends to defend against this lawsuit.

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 and named as defendants Merck; Merck/Schering-Plough Pharmaceuticals, 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 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 June 2011, lead plaintiffs filed a motion for leave to further amend the consolidated complaint, which was granted on February 7, 2012. On February 9, 2012, plaintiffs filed a second amended consolidated complaint, which defendants answered on February 23, 2012. In February 2012, the parties completed briefing on lead plaintiffs' motion for class certification. That motion is now pending before the court. On March 1, 2012, defendants filed a motion for summary judgment. That motion is now fully briefed and pending before the court.

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 February 2012, the parties completed briefing on lead plaintiffs' motion for class certification. That motion is now pending before the court. On March 1, 2012, the Schering-Plough defendants filed a motion for partial summary judgment and the underwriter defendants filed a motion for summary judgment. Those motions are now fully briefed and pending before the court.

As previously disclosed, in April 2008, a member of a Merck ERISA plan filed a putative class action lawsuit against Merck and certain of the Company's current and former officers and directors alleging they breached their fiduciary duties under ERISA. Since that time, there have been other similar ERISA lawsuits filed against Merck in the District of New Jersey, and all of those lawsuits have been consolidated under the caption *In re Merck & Co., Inc. Vytorin ERISA Litigation*. A consolidated amended complaint was filed in February 2009, and names as defendants Merck and various current and former members of the Company's Board of Directors. The plaintiffs allege that the ERISA plans investment in Merck stock was imprudent because Merck's earnings were dependent on the commercial success of its cholesterol drug *Vytorin*, and defendants knew or should have known that the results of a scientific study would cause the medical community to turn to less expensive drugs for cholesterol management. On May 24, 2012, the plaintiffs filed an unopposed motion for preliminary approval of settlement, conditional certification of a settlement class, approval of the class notice, and scheduling of a final fairness hearing. The court granted that motion on June 22, 2012 and scheduled a hearing on final approval of the settlement for September 25, 2012. Pursuant to the settlement agreement, Merck's insurers have paid \$10.4 million into a settlement fund which (after enumerated costs, fees, and awards are withdrawn) will be allocated to members of the settlement class according to a plan of allocation to be approved by the court. The settlement agreement provides that, in exchange for such consideration, the plaintiffs and settlement class members will issue broad releases with prejudice.

There was a similar consolidated, putative class action ERISA lawsuit pending in the District of New Jersey, filed by a member of a Schering-Plough ERISA plan against Schering-Plough and certain of its then-current and former officers and directors, alleging they breached

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

their fiduciary duties under ERISA, bearing the caption *In re Schering-Plough Corp. ENHANCE ERISA*

- 22 -

Notes to Consolidated Financial Statements (unaudited) (continued)

Litigation. The consolidated amended complaint was filed in October 2009 and named as defendants Schering-Plough, various then-current and former members of Schering-Plough's Board of Directors and then-current and former members of committees of Schering-Plough's Board of Directors. On February 10, 2012, the plaintiffs filed an executed class action settlement agreement and preliminary approval order. The court signed the preliminary approval order on February 16, 2012, and held a final fairness hearing on May 30, 2012. On May 31, 2012, the court issued an opinion, order, and final judgment. Among other things, the final judgment dismissed this action with prejudice, provided releases to the defendants, and approved the settlement agreement pursuant to which Merck's insurers have paid \$12.25 million into a settlement fund.

Discovery in the lawsuits referred to in this section (collectively, the ENHANCE Litigation) has concluded. The Company believes that it has meritorious defenses to the ENHANCE Litigation and intends to vigorously defend against these lawsuits. 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 ENHANCE Litigation. Unfavorable outcomes resulting from the ENHANCE Litigation could have a material adverse effect on the Company's financial position, liquidity and results of operations.

Insurance

The Company has Directors and Officers insurance coverage applicable to the *Vytorin* shareholder lawsuits brought by legacy Schering-Plough shareholders with stated upper limits of approximately \$250 million, which is currently being used to partially fund the Company's legal fees. 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 limits. The Company also has Fiduciary and other insurance for the *Vytorin* ERISA lawsuits which funded the costs of the two ERISA settlements discussed above.

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, and Mississippi. The Company and/or certain of its subsidiaries continue to be defendants in cases brought by six states.

A motion has also been filed to reinstate the Company as a defendant in a putative class action in New Jersey State 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 dismissed against the Company without prejudice in 2007.

K-DUR Antitrust Litigation

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

Coupon Litigation

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

Since March 2012, a number of private health plans have 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 filed in U.S. District Court for the District of New Jersey and the Southern District of Illinois, seek damages and injunctive relief barring the Company from issuing coupons that would reduce beneficiary co-pays on

- 23 -

Notes to Consolidated Financial Statements (unaudited) (continued)

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. The Company intends to defend against these lawsuits.

Patent Litigation

From time to time, generic manufacturers of pharmaceutical products file ANDAs with 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 marketed via agreements with other companies) currently involved in such patent infringement litigation in the United States include: *AzaSite*, *Cancidas*, *Emend* for Injection, *Nasonex*, *Nexium*, *Noxafil*, *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 legacy Schering-Plough products, potentially significant intangible asset impairment charges.

AzaSite In May 2011, a patent infringement suit 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.

Cancidas In November 2009, a patent infringement lawsuit was filed 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 *Cancidas*. That lawsuit has been dismissed with no rights granted to TPM. Also, in March 2010, 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 sell a generic version of *Cancidas*. In April 2012, the parties entered into a settlement agreement allowing Sandoz to sell a generic version of *Cancidas* commencing on August 28, 2017.

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' 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' 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 TPM in respect of TPM's application to the FDA seeking approval to sell a generic version of *Integrilin* prior to the expiry of the last to expire listed patent. In October 2011, the parties entered a settlement agreement allowing TPM to sell a generic version of *Integrilin* beginning June 2, 2015.

Nasonex In December 2009, a patent infringement suit 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 on June 15, 2012, holding that the Merck patent covering mometasone furoate monohydrate was valid, but that it was not infringed by Apotex's proposed product. The finding of non-infringement is under appeal.

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 (Hetero) 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 Hamni USA, Inc. (Hamni) and Mylan Laboratories Limited (Mylan Labs) related to their applications to the FDA seeking pre-patent expiry approval to sell generic versions of Nexium. The Hamni and Mylan Labs applications to the FDA remain stayed until May 2013 and August 2014, respectively, or until earlier adverse court decisions, if any.

Notes to Consolidated Financial Statements (unaudited) (continued)

Noxafil In May 2011, 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 *Noxafil*. In May 2012, Sandoz withdrew its challenge to Merck's *Noxafil* patents and the lawsuit has been dismissed.

NuvaRing In February 2011, a patent infringement suit was brought against Merck in the International Trade Commission (the ITC) by Femina Pharma Incorporated (Femina) in respect of the product *NuvaRing*. The complaint alleged that *NuvaRing* infringes a patent owned by Femina. Femina's ITC complaint sought an exclusion order against the importation of *NuvaRing* into the United States. A hearing began in the ITC proceeding on January 17, 2012 and on January 18, 2012 Femina withdrew its complaint and terminated the action. In addition, in November 2011, Femina brought a patent infringement lawsuit against Merck in the Eastern District of Virginia asserting that *NuvaRing* infringes the same patent. That case was stayed pending the outcome of the ITC proceeding. In April 2012, Femina voluntarily withdrew its lawsuit.

Propecia In December 2010, a patent infringement lawsuit was filed in the United States against Hetero in respect of Hetero's application to the FDA seeking pre-patent expiry approval to sell a generic version of *Propecia*. In March 2011, the Company settled this lawsuit with Hetero by agreeing to allow Hetero to sell a generic 1 mg finasteride product beginning on July 1, 2013. By virtue of a previous litigation settlement agreement, another generic manufacturer has been given the right to enter the U.S. market in January 2013.

Temodar In July 2007, a patent infringement action was filed (jointly with Cancer Research Technologies, Limited (CRT)) in the United States against Barr Laboratories (Barr) (later acquired by Teva) in respect of Barr's application to the FDA seeking pre-patent expiry approval to sell a generic version of *Temodar*. In January 2010, the court issued a decision finding the CRT patent unenforceable on grounds of prosecution laches and inequitable conduct. In November 2010, the appeals court issued a decision reversing the trial court's finding. In December 2010, Barr filed a petition seeking a rehearing *en banc* of the appeal, which petition was denied. In June 2011, Barr filed a petition for review by the U.S. Supreme Court, which was denied. By virtue of an agreement that Barr not launch a product during the appeal process, the Company has agreed that Barr can launch a product in August 2013.

In September 2010, a patent infringement lawsuit was filed (jointly with CRT) in the United States against Sun Pharmaceutical Industries Inc. (Sun) in respect of Sun's application to the FDA seeking pre-patent expiry approval to sell a generic version of *Temodar*. The lawsuit automatically stayed FDA approval of Sun's ANDA until February 2013 or until an adverse court decision, if any, whichever may occur earlier. In November 2010, a patent infringement lawsuit was filed (jointly with CRT) in the United States against Accord HealthCare Inc. (Accord) in respect of its application to the FDA seeking pre-patent expiry approval to sell a generic version of *Temodar*. The lawsuit automatically stayed FDA approval of Accord's application until April 13, 2013 or until an adverse court decision, if any, whichever may occur earlier. The Company and CRT entered into agreements with Sun and Accord to stay the respective lawsuits pending the outcome of the U.S. Supreme Court appeal process in the Barr lawsuit. In light of the U.S. Supreme Court's denial of Barr's petition, Sun and Accord withdrew their challenges to the *Temodar* patent and the respective lawsuits have been withdrawn.

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. Mylan has appealed that decision. 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*.

Notes to Consolidated Financial Statements (unaudited) (continued)

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. Mylan has appealed that decision. 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.

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 June 30, 2012 and December 31, 2011 of approximately \$250 million and \$240 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.

Environmental Matters

The Company and its subsidiaries are parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation and Liability Act, commonly known as Superfund, and other federal and state equivalents. These proceedings seek to require the operators of hazardous waste disposal facilities, transporters of waste to the sites and generators of hazardous waste disposed of at the sites to clean up the sites or to reimburse the government for cleanup costs. The Company has been made a party to these proceedings as an alleged generator of waste disposed of at the sites. In each case, the government alleges that the defendants are jointly and severally liable for the cleanup costs. Although joint and several liability is alleged, these proceedings are frequently resolved so that the allocation of cleanup costs among the parties more nearly reflects the relative contributions of the parties to the site situation. The Company's potential liability varies greatly from site to site. For some sites the potential liability is *de minimis* and for others the final costs of cleanup have not yet been determined. While it is not feasible to predict the outcome of many of these proceedings brought by federal or state agencies or private litigants, in the opinion of the Company, such proceedings should not ultimately result in any liability which would have a material adverse effect on the financial position, results of operations, liquidity or capital resources of the Company. The Company has taken an active role in identifying and providing for these costs and such amounts do not include any reduction for anticipated recoveries of cleanup costs from former site owners or operators or other recalcitrant potentially responsible parties.

As previously disclosed, approximately 2,200 plaintiffs have 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

Notes to Consolidated Financial Statements (unaudited) (continued)

subsidiary in Merced, California. Certain of the other defendants in this suit have settled with plaintiffs regarding some or all aspects of plaintiffs claims. This lawsuit is proceeding in a phased manner. A jury trial commenced in February 2011 during which a jury was asked to make certain factual findings regarding whether contamination moved off-site to any areas where plaintiffs could have been exposed to such contamination and, if so, when, where and in what amounts. Defendants in this Phase 1 trial included Merck and three of the other original 12 defendants. In March 2011, the Phase 1 jury returned a mixed verdict, finding in favor of Merck and the other defendants as to some, but not all, of plaintiffs claims. Specifically, the jury found that contamination from the site did not enter or affect plaintiffs municipal water supply wells or any private domestic wells. The jury found, however, that plaintiffs could have been exposed to contamination via air emissions prior to 1994, as well as via surface water in the form of storm drainage channeled into an adjacent irrigation canal, including during a flood in April 2006. In response to post-trial motions by Merck and other defendants, on September 7, 2011, the court entered an order setting aside a part of the Phase 1 jury's findings that had been in favor of plaintiffs. Specifically, the court held that plaintiffs could not have been exposed to any contamination in surface or flood water during the April 2006 flood or, in fact, at any time later than 1991. Merck's motion for reconsideration of the remainder of the jury's Phase I verdict that was adverse to Merck was denied. Following the retirement of the judge handling this case, on September 21, 2011, the case was assigned to Judge David O. Carter of the U.S. District Court for the Central District of California. Judge Carter selected 10 plaintiffs whose claims would be reviewed and, depending on the outcome of Merck's anticipated summary judgment motions, possibly tried in early 2013. Plaintiffs subsequently withdrew the claim of one of those 10 plaintiffs, leaving nine whose claims may proceed to trial. 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.

10. Equity

(\$ and shares in millions)	Common Stock		Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock		Non-Controlling Interests	Total
	Shares	Par Value				Shares	Cost		
Balance January 1, 2011	3,577	\$ 1,788	\$ 40,701	\$ 37,536	\$ (3,216)	495	\$ (22,433)	\$ 2,429	\$ 56,805
Net income attributable to Merck & Co., Inc.	-	-	-	3,067	-	-	-	-	3,067
Cash dividends declared on common stock	-	-	-	(2,360)	-	-	-	-	(2,360)
Treasury stock shares purchased	-	-	-	-	-	9	(314)	-	(314)
Share-based compensation plans and other	-	-	(44)	-	-	(10)	331	-	287
Other comprehensive income	-	-	-	-	440	-	-	-	440
Net income attributable to noncontrolling interests	-	-	-	-	-	-	-	58	58
Distributions attributable to noncontrolling interests	-	-	-	-	-	-	-	(61)	(61)
Balance June 30, 2011	3,577	\$ 1,788	\$ 40,657	\$ 38,243	\$ (2,776)	494	\$ (22,416)	\$ 2,426	\$ 57,922
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.	-	-	-	3,531	-	-	-	-	3,531
Cash dividends declared on common stock	-	-	-	(2,571)	-	-	-	-	(2,571)
Treasury stock shares purchased	-	-	-	-	-	26	(985)	-	(985)
Share-based compensation plans and other	-	-	(113)	-	-	(24)	809	-	696

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

Other comprehensive income	-	-	-	-	6	-	-	-	6
Net income attributable to noncontrolling interests	-	-	-	-	-	-	-	56	56
Distributions attributable to noncontrolling interests	-	-	-	-	-	-	-	(3)	(3)
Balance June 30, 2012	3,577	\$ 1,788	\$ 40,550	\$ 39,950	\$ (3,126)	538	\$ (23,968)	\$ 2,479	\$ 57,673

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 8), this preferred stock obligation will be retired.

Notes to Consolidated Financial Statements (unaudited) (continued)

The accumulated balances related to each component of other comprehensive income (loss), net of taxes, were as follows:

<i>(\$ in millions)</i>	Derivatives	Investments	Employee Benefit Plans	Cumulative Translation Adjustment	Accumulated Other Comprehensive Loss
Balance January 1, 2011	\$ 41	\$ 31	\$ (2,043)	\$ (1,245)	\$ (3,216)
Other comprehensive (loss) income	(137)	(5)	28	554	440
Balance at June 30, 2011	\$ (96)	\$ 26	\$ (2,015)	\$ (691)	\$ (2,776)
Balance January 1, 2012	\$ 4	\$ 21	\$ (2,346)	\$ (811)	\$ (3,132)
Other comprehensive income (loss)	44	30	18	(86)	6
Balance at June 30, 2012	\$ 48	\$ 51	\$ (2,328)	\$ (897)	\$ (3,126)

Included in cumulative translation adjustment are pretax gains of approximately \$340 million for the first six months of 2011 relating to translation impacts of intangible assets recorded in conjunction with the Merger.

11. Share-Based Compensation Plans

The Company has share-based compensation plans under which employees and non-employee directors may be granted restricted stock units (RSUs). In addition, the Company grants options to purchase shares of Company common stock at the fair market value at the time of grant and performance share units (PSUs) to certain management-level employees. The Company recognizes the fair value of share-based compensation in net income on a straight-line basis over the requisite service period.

The following table provides amounts of share-based compensation cost recorded in the Consolidated Statement of Income:

<i>(\$ in millions)</i>	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Pretax share-based compensation expense	\$ 93	\$ 107	\$ 169	\$ 200
Income tax benefit	(29)	(37)	(53)	(69)
Total share-based compensation expense, net of taxes	\$ 64	\$ 70	\$ 116	\$ 131

During the first six months of 2012 and 2011, the Company granted 7 million RSUs with a weighted-average grant date fair value of \$39.29 per RSU and 8 million RSUs with a weighted-average grant date fair value of \$36.47 per RSU, respectively.

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

During the first six months of 2012 and 2011, the Company granted 7 million options with a weighted-average exercise price of \$39.26 per option and 8 million options with a weighted-average exercise price of \$36.55 per option, respectively. The weighted-average fair value of options granted for the first six months of 2012 and 2011 was \$5.46 and \$5.37 per option, respectively, and was determined using the following assumptions:

	Six Months Ended	
	June 30,	
	2012	2011
Expected dividend yield	4.4%	4.3%
Risk-free interest rate	1.3%	2.6%
Expected volatility	25.3%	23.2%
Expected life (years)	7.0	7.0

At June 30, 2012, there was \$555 million of total pretax unrecognized compensation expense related to nonvested stock options, RSU and PSU awards which will be recognized over a weighted-average period of 2.0 years. For segment reporting, share-based compensation costs are unallocated expenses.

Notes to Consolidated Financial Statements (unaudited) (continued)**12. Pension and Other Postretirement Benefit Plans**

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

(\$ in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Service cost	\$ 141	\$ 151	\$ 283	\$ 303
Interest cost	166	180	332	359
Expected return on plan assets	(244)	(242)	(488)	(485)
Net amortization	48	46	96	91
Termination benefits	4	7	9	17
Curtailments	(1)	(6)	(1)	(10)
Settlements	-	-	-	(1)
	\$ 114	\$ 136	\$ 231	\$ 274

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

(\$ in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Service cost	\$ 21	\$ 28	\$ 42	\$ 56
Interest cost	31	35	62	71
Expected return on plan assets	(34)	(36)	(68)	(71)
Net amortization	(8)	(6)	(16)	(9)
Termination benefits	3	4	5	6
Curtailments	(2)	-	(4)	1
	\$ 11	\$ 25	\$ 21	\$ 54

In connection with restructuring actions (see Note 2), termination charges for the three and six months ended June 30, 2012 and 2011 were recorded on pension and other postretirement benefit plans related to expanded eligibility for certain employees exiting Merck. Also, in connection with these restructuring actions, curtailments were recorded on pension and other postretirement benefit plans and settlements were recorded on pension plans as reflected in the tables above.

13. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

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

(\$ in millions)	Three Months Ended		Six Months Ended	
	June 30, 2012	June 30, 2011	June 30, 2012	June 30, 2011
Interest income	\$ (76)	\$ (39)	\$ (129)	\$ (69)
Interest expense	172	170	346	345
Exchange losses	13	1	80	43
Other, net	(6)	(11)	(50)	425
	\$ 103	\$ 121	\$ 247	\$ 744

Notes to Consolidated Financial Statements (unaudited) (continued)

As a result of significant collections of accounts receivable in Spain during the second quarter (see Note 5), the Company recognized incremental interest income of approximately \$35 million in the second quarter and first six months of 2012 for accelerated accretion of time value of money discounts related to these receivables. Other, net (as presented in the table above) for the first six months of 2011 reflects a \$500 million charge related to the resolution of the arbitration proceeding involving the Company's rights to market *Remicade* and *Simponi* (see Note 4), as well as a \$127 million gain on the sale of certain manufacturing facilities and related assets. Interest paid for the six months ended June 30, 2012 and 2011 was \$324 million and \$194 million, respectively, which excludes commitment fees. Interest paid for the six months ended June 30, 2011 is net of \$175 million received by the Company from the termination of certain interest rate swap contracts during the period (see Note 5).

14. Taxes on Income

The effective tax rates of 32.1% and 30.8% for the second quarter and first six months of 2012 and (22.8)% and 8.1% for the second quarter and first six months of 2011 reflect the impacts of acquisition-related costs and restructuring costs, partially offset by the beneficial impact of foreign earnings. In addition, the effective tax rates for the second quarter and first six months of 2011 also reflect a net favorable impact relating to the settlement of Merck's 2002-2005 federal income tax audit as discussed below, as well as the net favorable impact of certain foreign and state tax rate changes that resulted in a net \$230 million reduction of deferred tax liabilities on intangibles established in purchase accounting. In addition, the effective tax rate for the first six months of 2011 also reflects the impact of the \$500 million charge related to the resolution of the arbitration proceeding with J&J.

In April 2011, the Internal Revenue Service (the IRS) concluded its examination of Merck's 2002-2005 federal income tax returns and as a result the Company was required to make net payments of approximately \$465 million. The Company's unrecognized tax benefits for the years under examination exceeded the adjustments related to this examination period and therefore the Company recorded a net \$700 million tax provision benefit in the second quarter of 2011. This net benefit reflects the decrease of unrecognized tax benefits for the years under examination partially offset by increases to the unrecognized tax benefits for years subsequent to the examination period as a result of this settlement. The Company disagrees with the IRS treatment of one issue raised during this examination and is appealing the matter through the IRS administrative process.

As previously disclosed, the Canada Revenue Agency (the CRA) has proposed adjustments for 1999 and 2000 relating to intercompany pricing matters and, in July 2011, the CRA issued assessments for other miscellaneous audit issues for tax years 2001-2004. These adjustments would increase Canadian tax due by approximately \$330 million plus approximately \$390 million of interest through June 30, 2012. The Company disagrees with the positions taken by the CRA and believes they are without merit. The Company continues to contest the assessments through the CRA appeals process. The CRA is expected to prepare similar adjustments for later years. Management believes that resolution of these matters will not have a material effect on the Company's financial position or liquidity.

15. Earnings Per Share

The Company calculates earnings per share pursuant to the two-class method, which is an earnings allocation formula that determines earnings per share for common stock and participating securities according to dividends declared and participation rights in undistributed earnings. Under this method, 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 to certain management level employees participate in dividends on the same basis as common shares and such dividends are nonforfeitable by the holder. As a result, these RSUs and PSUs meet the definition of a participating security. For RSUs and PSUs issued on or after January 1, 2010, dividends declared during the vesting period are payable to the employees only upon vesting and therefore such RSUs and PSUs do not meet the definition of a participating security.

Notes to Consolidated Financial Statements (unaudited) (continued)

The calculations of earnings per share under the two-class method are as follows:

<i>(\$ and shares in millions except per share amounts)</i>	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
<i>Basic Earnings per Common Share</i>				
Net income attributable to Merck & Co., Inc.	\$ 1,793	\$ 2,024	\$ 3,531	\$ 3,067
Less: Income allocated to participating securities	1	4	3	8
Net income allocated to common shareholders	\$ 1,792	\$ 2,020	\$ 3,528	\$ 3,059
Average common shares outstanding	3,041	3,086	3,042	3,085
	\$ 0.59	\$ 0.65	\$ 1.16	\$ 0.99
<i>Earnings per Common Share Assuming Dilution</i>				
Net income attributable to Merck & Co., Inc.	\$ 1,793	\$ 2,024	\$ 3,531	\$ 3,067
Less: Income allocated to participating securities	1	4	3	8
Net income allocated to common shareholders	\$ 1,792	\$ 2,020	\$ 3,528	\$ 3,059
Average common shares outstanding	3,041	3,086	3,042	3,085
Common shares issuable ⁽¹⁾	31	24	32	21
Average common shares outstanding assuming dilution	3,072	3,110	3,074	3,106
	\$ 0.58	\$ 0.65	\$ 1.15	\$ 0.98

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

For the three months ended June 30, 2012 and 2011, 107 million and 138 million, respectively, and for the first six months of 2012 and 2011, 112 million and 173 million, respectively, of common shares issuable under share-based compensation plans were excluded from the computation of earnings per common share assuming dilution because the effect would have been antidilutive.

16. 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 and are included in all other in the table below. The

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

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.

- 31 -

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

Notes to Consolidated Financial Statements (unaudited) (continued)

Sales of the Company's products were as follows:

(\$ in millions)	Three Months Ended		Six Months Ended	
	2012	June 30, 2011	2012	June 30, 2011
Primary Care and Women's Health				
<i>Cardiovascular</i>				
Zetia	\$ 632	\$ 592	\$ 1,246	\$ 1,174
Vytorin	445	459	889	939
<i>Diabetes and Obesity</i>				
Januvia	1,058	779	1,977	1,518
Janumet	411	321	802	626
<i>Respiratory</i>				
Singulair	1,431	1,354	2,771	2,682
Nasonex	293	323	668	696
Clarinx	140	209	273	364
Asmanex	51	47	99	107
Dulera	50	25	89	37
<i>Women's Health and Endocrine</i>				
Fosamax	186	221	370	429
NuvaRing	157	154	303	297
Follistim AQ	125	143	241	276
Implanon	85	81	161	141
Cerazette	72	66	139	125
<i>Other</i>				
Maxalt	154	131	310	304
Arcoxia	117	100	229	214
Avelox	44	61	117	167
Hospital and Specialty				
<i>Immunology</i>				
Remicade	518	842	1,037	1,595
Simponi	76	75	150	129
<i>Infectious Disease</i>				
Isentress	398	337	735	629
PegIntron	183	154	345	319
Cancidas	166	168	311	326
Victrelis	126	21	238	22
Invanz	110	103	211	189
Primaxin	104	136	192	272
Noxafil	66	56	125	110
<i>Oncology</i>				
Temodar	225	234	461	481
Emend	145	120	247	207
<i>Other</i>				
Cosopt/Trusopt	105	122	229	236
Bridion	60	47	118	89
Integrilin	60	56	113	120
Diversified Brands				
Cozaar/Hyzaar	337	406	674	832
Propecia	100	112	208	218
Zocor	96	107	199	234
Claritin Rx	48	65	134	186
Remeron	66	57	123	117
Proscar	55	53	106	113
Vasotec/Vaseretic	49	59	102	116
Vaccines ⁽¹⁾				
Gardasil	324	277	608	490

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

ProQuad/M-M-R II/Varivax	316	291	571	535
RotaTeq	142	148	284	272
Zostavax	148	122	224	146
Pneumovax	101	64	213	143
Other pharmaceutical ⁽²⁾	985	1,062	2,000	1,957
Total Pharmaceutical segment sales	10,560	10,360	20,642	20,179
Other segment sales ⁽³⁾	1,680	1,690	3,273	3,323
Total segment sales	12,240	12,050	23,915	23,502
Other ⁽⁴⁾	71	101	126	230
	\$ 12,311	\$ 12,151	\$ 24,041	\$ 23,732

⁽¹⁾ 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.

⁽²⁾ Other pharmaceutical primarily includes sales of other human health pharmaceutical products not listed separately.

⁽³⁾ Reflects other non-reportable segments, including Animal Health and Consumer Care, and revenue from the Company's relationship with AZLP primarily relating to sales of Nexium. Revenue from AZLP was \$223 million and \$306 million for the second quarter of 2012 and 2011, respectively, and \$409 million and \$628 million for the first six months of 2012 and 2011, respectively.

⁽⁴⁾ Other revenues are primarily comprised of miscellaneous corporate revenues, third-party manufacturing sales, sales related to divested products or businesses and supply sales not included in segment results. The declines in other revenues in the second quarter and first six months of 2012 as compared with the same periods of 2011 reflect lower third-party manufacturing sales, which for the year-to-date period were attributable in part to the divestiture of certain manufacturing facilities in the first quarter of 2011.

Notes to Consolidated Financial Statements (unaudited) (continued)

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

(\$ in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Segment profits:				
Pharmaceutical segment	\$ 6,906	\$ 6,443	\$ 13,502	\$ 12,659
Other segments	774	726	1,578	1,517
Total segment profits	7,680	7,169	15,080	14,176
Other profits (losses)	45	34	(28)	(15)
Unallocated:				
Interest income	76	39	129	69
Interest expense	(172)	(170)	(346)	(345)
Equity income from affiliates	11	(87)	(9)	(81)
Depreciation and amortization	(574)	(623)	(1,135)	(1,194)
Research and development	(1,930)	(1,679)	(3,573)	(3,618)
Amortization of purchase accounting adjustments	(1,226)	(1,225)	(2,455)	(2,504)
Restructuring costs	(144)	(668)	(363)	(654)
Arbitration settlement charge	-	-	-	(500)
Other unallocated, net	(1,086)	(1,118)	(2,114)	(1,933)
	\$ 2,680	\$ 1,672	\$ 5,186	\$ 3,401

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 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 assets and other miscellaneous income or expense items.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**U.S. Health Care Reform Legislation**

In 2010, the United States enacted major health care reform legislation. Various market reforms advanced in 2011 and will continue through full implementation in 2014.

Effective in 2011, the law requires pharmaceutical manufacturers to pay a 50% discount to Medicare Part D beneficiaries when they are in the Medicare Part D coverage gap (i.e., the so-called "donut hole"). Approximately \$38 million and \$36 million was recorded as a reduction to revenue in the second quarter of 2012 and 2011, respectively, and \$76 million and \$70 million for the first six months of 2012 and 2011, respectively, related to the estimated impact of this provision of health care reform.

Also, beginning in 2011, pharmaceutical manufacturers are required to pay an annual health care reform fee. The total annual industry fee, which was \$2.5 billion in 2011 and will be \$2.8 billion in 2012, is assessed on each company in proportion to its share of sales to certain government programs, such as Medicare and Medicaid. The Company's portion of the annual fee is payable no later than September 30 of the applicable calendar year and is not tax deductible. Each year, the liability related to the annual fee is estimated by the Company and recorded in full during the first quarter with a corresponding offset to a deferred asset. The deferred asset is amortized to *Marketing and administrative* expenses on a straight-line basis (net of any revisions) during the year. The liability related to the annual fee recognized in 2012 was \$190 million and for 2011 was \$162 million. The Company recognized expenses of \$48 million and \$43 million for the second quarter of 2012 and 2011, respectively, and \$95 million and \$85 million for the first six months of 2012 and 2011, respectively, related to this fee.

Arbitration Settlement

In April 2011, Merck and Johnson & Johnson (J&J) reached an agreement to amend the agreement governing the distribution rights to *Remicade* (infliximab) and *Simponi* (golimumab). This agreement concluded the arbitration proceeding J&J initiated in May 2009. Under the terms of the amended distribution agreement, Merck relinquished marketing rights for *Remicade* and *Simponi* to J&J in territories including Canada, Central and South America, the Middle East, Africa and Asia Pacific effective July 1, 2011. Merck retained exclusive marketing rights throughout Europe, Russia and Turkey (the "Retained Territories"). In addition, beginning July 1, 2011, all profits derived from Merck's exclusive distribution of the two products in the Retained Territories are being equally divided between Merck and J&J. J&J also received a one-time payment from Merck of \$500 million in April 2011.

Singulair Patent Expiries

The patent that provided U.S. market exclusivity for *Singulair* expired in August 2012. In addition, the patent that provides market exclusivity for *Singulair* will expire in a number of major European markets in February 2013. The Company expects a significant and rapid reduction in sales thereafter in those markets. The patent that provides market exclusivity for *Singulair* in Japan will expire in 2016. For the full year of 2011, sales of *Singulair* were \$3.5 billion in the United States, \$724 million in Europe and \$641 million in Japan.

Operating Results**Sales**

Worldwide sales were \$12.3 billion for the second quarter of 2012, an increase of 1% compared with the second quarter of 2011. Global sales for the first six months of 2012 were \$24.0 billion, an increase of 1% compared with the same period in 2011. Foreign exchange unfavorably affected global sales performance by 4% and 2% for the second quarter and first six months of 2012, respectively. The revenue increases largely reflect higher sales of *Januvia* (sitagliptin), *Vitreolis* (boceprevir), *Janumet* (sitagliptin/metformin hydrochloride HCl), *Gardasil* [human papillomavirus quadrivalent (types 6, 11, 16 and 18) vaccine, recombinant], *Isentress* (raltegravir), *Singulair* (montelukast sodium) and *Zostavax* [Zoster Vaccine Live]. Also contributing to revenue growth in both periods were higher sales of the Company's animal health products. These increases were partially offset by lower sales of *Remicade* due to the relinquishment of marketing rights in certain territories as a result of the arbitration settlement discussed above. Sales growth was also negatively affected by lower revenue from the Company's relationship with AstraZeneca LP (AZLP), as well as by lower sales of *Cozaar* (losartan potassium), *Hyzaar* (losartan potassium hydrochlorothiazide), *Clarinox* (desloratadine) and *Primaxin* (imipenem and cilastatin sodium).

While several of the Company's brands experienced positive volume growth trends in the European Union (the "EU") in the first half of 2012, the environment in the EU continues to be challenging. Many countries have announced austerity measures, which include the implementation of pricing actions to reduce prices of generic and patented drugs. While the Company is taking steps to mitigate the impact in the EU, the austerity measures continued to negatively affect the Company's revenue performance in the first six months of 2012 and the Company anticipates high mid-single digit pricing pressures for the full year of 2012 across Europe as well as from the biennial price reductions in Japan.

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

Sales of the Company's products were as follows:

(\$ in millions)	Three Months Ended		Six Months Ended	
	2012	June 30, 2011	2012	June 30, 2011
Primary Care and Women's Health				
<i>Cardiovascular</i>				
Zetia	\$ 632	\$ 592	\$ 1,246	\$ 1,174
Vytorin	445	459	889	939
<i>Diabetes and Obesity</i>				
Januvia	1,058	779	1,977	1,518
Janumet	411	321	802	626
<i>Respiratory</i>				
Singulair	1,431	1,354	2,771	2,682
Nasonex	293	323	668	696
Clarinx	140	209	273	364
Asmanex	51	47	99	107
Dulera	50	25	89	37
<i>Women's Health and Endocrine</i>				
Fosamax	186	221	370	429
NuvaRing	157	154	303	297
Follistim AQ	125	143	241	276
Implanon	85	81	161	141
Cerazette	72	66	139	125
<i>Other</i>				
Maxalt	154	131	310	304
Arcoxia	117	100	229	214
Avelox	44	61	117	167
Hospital and Specialty				
<i>Immunology</i>				
Remicade	518	842	1,037	1,595
Simponi	76	75	150	129
<i>Infectious Disease</i>				
Isentress	398	337	735	629
PegIntron	183	154	345	319
Cancidas	166	168	311	326
Victrilis	126	21	238	22
Invanz	110	103	211	189
Primaxin	104	136	192	272
Noxafil	66	56	125	110
<i>Oncology</i>				
Temodar	225	234	461	481
Emend	145	120	247	207
<i>Other</i>				
Cosopt/Trusopt	105	122	229	236
Bridion	60	47	118	89
Integrilin	60	56	113	120
Diversified Brands				
Cozaar/Hyzaar	337	406	674	832
Propecia	100	112	208	218
Zocor	96	107	199	234
Claritin Rx	48	65	134	186
Remeron	66	57	123	117
Proscar	55	53	106	113
Vasotec/Vaseretic	49	59	102	116
<i>Vaccines ⁽¹⁾</i>				
Gardasil	324	277	608	490
ProQuad/M-M-R II/Varivax	316	291	571	535
RotaTeq	142	148	284	272
Zostavax	148	122	224	146
Pneumovax	101	64	213	143
Other pharmaceutical ⁽²⁾	985	1,062	2,000	1,957

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

Total Pharmaceutical segment sales	10,560	10,360	20,642	20,179
Other segment sales ⁽³⁾	1,680	1,690	3,273	3,323
Total segment sales	12,240	12,050	23,915	23,502
Other ⁽⁴⁾	71	101	126	230
	\$ 12,311	\$ 12,151	\$ 24,041	\$ 23,732

⁽¹⁾ 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.

⁽²⁾ Other pharmaceutical primarily includes sales of other human health pharmaceutical products not listed separately.

⁽³⁾ Reflects other non-reportable segments, including Animal Health and Consumer Care, and revenue from the Company's relationship with AZLP primarily relating to sales of Nexium. Revenue from AZLP was \$223 million and \$306 million for the second quarter of 2012 and 2011, respectively, and \$409 million and \$628 million for the first six months of 2012 and 2011, respectively.

⁽⁴⁾ Other revenues are primarily comprised of miscellaneous corporate revenues, third-party manufacturing sales, sales related to divested products or businesses and supply sales not included in segment results. The declines in other revenues in the second quarter and first six months of 2012 as compared with the same periods of 2011 reflect lower third-party manufacturing sales, which for the year-to-date period were attributable in part to the divestiture of certain manufacturing facilities in the first quarter of 2011.

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 \$1.5 billion and \$1.3 billion for the three months ended June 30, 2012 and 2011, respectively, and \$3.0 billion and \$2.5 billion for the six months ended June 30, 2012 and 2011, 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

Sales of *Zetia* (ezetimibe) (also marketed as *Ezetrol* outside the United States), a cholesterol-absorption inhibitor, were \$632 million in the second quarter of 2012, an increase of 7% compared with the second quarter of 2011, and were \$1.2 billion for the first six months of 2012, an increase of 6% compared with the same period in 2011. Foreign exchange unfavorably affected global sales performance by 2% and 1% in the second quarter and first six months of 2012, respectively. The sales increases reflect positive performance in the United States due to pricing, partially offset by volume declines. Sales growth in the first six months of 2012 also reflects volume growth in Japan and the emerging markets. Sales of *Vytorin* (ezetimibe/simvastatin) (marketed outside the United States as *Inegy*), a combination product containing the active ingredients of both *Zetia* and *Zocor* (simvastatin), were \$445 million and \$889 million in the second quarter and first six months of 2012, respectively, representing declines of 3% and 5%, respectively, compared with the same periods in 2011. Foreign exchange unfavorably affected global sales performance by 4% and 2% in the second quarter and first six months of 2012, respectively. The sales declines reflect volume declines in the United States, partially offset by pricing in the United States and volume growth in international markets.

In March 2012, the Data Safety Monitoring Board (the DSMB) of the IMPROVE-IT trial, a large cardiovascular outcomes study evaluating ezetimibe/simvastatin against simvastatin alone in patients presenting with acute coronary syndrome, completed the second pre-specified interim efficacy analysis of the study. The DSMB conducted the planned interim efficacy analysis after the trial had reached approximately 75% of the targeted 5,250 clinical endpoints called for in the study design. The DSMB recommended that the study continue without change in design and stated it planned to review the data again in approximately nine months. That review has been scheduled for March 2013, at which point nine months of additional data will have been adjudicated. Merck remains blinded to IMPROVE-IT safety and efficacy data. IMPROVE-IT is an 18,000 patient event-driven trial and, based on the current rate at which events are being reported, the Company now anticipates the targeted 5,250 clinical endpoints for study completion will be reached in 2014.

Diabetes and Obesity

Global sales of *Januvia*, Merck's dipeptidyl peptidase-4 (DPP-4) inhibitor for the treatment of type 2 diabetes, were \$1.1 billion in the second quarter of 2012 and \$2.0 billion for the first six months of 2012, representing increases of 36% and 30%, respectively, compared with the same periods of 2011, reflecting volume growth in international markets, including in Japan, and in the United States. DPP-4 inhibitors represent a class of prescription medications that improve blood sugar control in patients with type 2 diabetes by enhancing a natural body system called the incretin system, which helps to regulate glucose by affecting the beta cells and alpha cells in the pancreas.

Worldwide sales of *Janumet*, Merck's oral antihyperglycemic agent that combines sitagliptin (*Januvia*) with metformin in a single tablet to target all three key defects of type 2 diabetes, were \$411 million for the second quarter of 2012 and \$802 million for the first six months of 2012, representing increases of 28% in each of those periods compared with the same periods of 2011, reflecting growth in the United States, Europe and the emerging markets.

In February 2012, the U.S. Food and Drug Administration (the FDA) approved *Janumet XR*, a treatment for type 2 diabetes that combines sitagliptin with extended-release metformin. *Janumet XR* provides a convenient once-daily treatment option for health care providers and patients who need help to control their blood sugar.

As previously disclosed, on February 17, 2012, the FDA sent a Warning Letter to the Company relating to *Januvia* and *Janumet* stating that the Company did not fulfill a post-marketing requirement for a 3-month pancreatic safety study in a diabetic rodent model treated with sitagliptin. Merck has been in communication with the FDA regarding this study and Merck's efforts to complete it in a timely and satisfactory manner. Under the terms of the Warning Letter, within 30 days from the date of the letter, the Company must submit to the FDA a final study protocol for a new 3-month rodent study that will satisfy the FDA's requirements and a proposed revised timetable for completion of the study. Within 6 months from the date of the letter, the FDA expects that the Company will have obtained agreement with the FDA on an adequate study protocol and will have initiated the study. The letter states that failure to correct the violation may result in regulatory actions by the FDA, including, but not limited to, civil money penalties. The Company has reached an agreement with the FDA on a study protocol and is proceeding with the study. Merck remains fully committed to fulfilling the FDA's requirements.

Respiratory

Worldwide sales for *Singulair*, a once-a-day oral medicine for the chronic treatment of asthma and for the relief of symptoms of allergic rhinitis, were \$1.4 billion for the second quarter of 2012 and \$2.8 billion for the first six months of 2012, increases of 6% and 3%, respectively, compared with the same periods in 2011. The patent that provided U.S. market exclusivity for *Singulair* expired in August 2012. In addition, the patent that provides market exclusivity for *Singulair* will expire in a number of major European markets in February 2013. The Company expects a significant and rapid reduction in sales thereafter in those markets. The patent that provides market exclusivity for *Singulair* in Japan will expire in 2016. For the full year of 2011, sales of *Singulair* were \$3.5 billion in the United States, \$724 million in Europe and \$641 million in Japan.

Global sales of *Nasonex* (mometasone furoate monohydrate), an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, were \$293 million for the second quarter of 2012 and \$668 million for the first six months of 2012, representing declines of 9% and 4%, respectively, compared with the same periods of 2011. Foreign exchange unfavorably affected global sales performance by 3% and 1% for the second quarter and first six months of 2012, respectively. The sales declines were driven by unfavorable pricing in Europe, as well as lower volumes in the United States and the emerging markets. In addition, for the year-to-date period in 2012, lower volumes in Japan also contributed to the sales decline. 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 Inc. and Apotex Corp. (collectively Apotex) holding that Apotex's generic version of *Nasonex* does not infringe on the Company's patent (see Note 9 to the interim consolidated financial statements). Apotex is seeking FDA approval to sell its generic version of *Nasonex*. If generic versions become available, significant losses of *Nasonex* sales in the U.S. market are anticipated and could result in a material non-cash impairment charge related to the *Nasonex* intangible asset. U.S. sales of *Nasonex* were \$604 million for the full year of 2011. As a result of the unfavorable U.S. District Court decision, the Company evaluated the *Nasonex* intangible asset for impairment and concluded that it was not impaired. The Company has appealed the U.S. District Court decision.

Global sales of *Clarinex* (marketed as *Aerius* in many countries outside the United States), a non-sedating antihistamine, were \$140 million for the second quarter of 2012 and \$273 million for the first six months of 2012, decreases of 33% and 25%, respectively, compared with the same periods of 2011, reflecting volume declines in Europe as a result of generic competition. As previously disclosed, by virtue of litigation settlements, certain generic manufacturers have been given the right to enter the U.S. market in 2012. The U.S. patent and exclusivity periods otherwise expire in 2020. In July 2012, a generic manufacturer launched a generic version of *Clarinex* in the United States. Accordingly, the Company anticipates that U.S. sales of *Clarinex* will be negatively impacted in the third and fourth quarters of 2012 and beyond. U.S. sales of *Clarinex* were \$197 million for the full year of 2011.

Women's Health and Endocrine

Worldwide sales for *Fosamax* (alendronate sodium) 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 were \$186 million for the second quarter of 2012 and \$370 million for the first six months of 2012, representing declines of 16% and 14%, respectively, over the comparable periods of 2011. These medicines have lost market exclusivity in the United States and have also lost market exclusivity in most major European markets. Accordingly, the Company is experiencing sales declines within the *Fosamax* product franchise and the Company expects the declines to continue.

Worldwide sales of *NuvaRing* (etonogestrel/ethinyl estradiol vaginal ring), a vaginal contraceptive product, were \$157 million for the second quarter of 2012 and \$303 million for the first six months of 2012, increases of 2% in each of these periods compared with the same periods of 2011, largely reflecting volume growth in the emerging markets. Foreign exchange negatively affected sales performance by 4% and 3% for the second quarter and first six months of 2012, respectively.

Global sales of *Follistim AQ* (follitropin beta injection) (marketed in most countries outside the United States as *Puregon*), a biological fertility treatment, were \$125 million for the second quarter of 2012 and \$241 million for the first six months of 2012, declines of 12% and 13%, respectively, compared with the same periods of 2011, largely driven by volume declines in Europe. *Puregon* lost market exclusivity in the EU in August 2009. Foreign exchange unfavorably affected global sales performance by 3% and 2% for the second quarter and first six months of 2012, respectively.

The Company is currently experiencing difficulty manufacturing certain women's health products. The Company is working to resolve these issues.

In August 2011, *Zoely* (norgestrel acetate 2.5 mg/17β-estradiol 1.5 mg), an oral contraceptive, was granted marketing authorization by the European Commission (the EC) for use by women to prevent pregnancy. *Zoely* is a combined oral contraceptive tablet containing a unique monophasic combination of two hormones: norgestrel acetate, a highly selective progesterone-derived progestin, and 17β-estradiol, an estrogen that is similar to the one naturally present in a woman's body. In November 2011, Merck received a Complete Response Letter from the FDA for NOMAC/E2 (MK-8175A), which is being marketed as *Zoely* in the EU. The Company is planning to conduct an additional clinical study requested by the FDA and update the application in the future.

Other

Global sales of *Maxalt* (rizatriptan benzoate), a product for the acute treatment of migraine, were \$154 million for the second quarter of 2012, an increase of 17% compared with the second quarter of 2011, largely reflecting positive performance in the United States primarily due to favorable pricing, partially offset by declines in Europe and Canada. Sales of *Maxalt* were \$310 million for the first six months of 2012, an increase of 2% compared with the first six months of 2011, reflecting favorable pricing in the United States, as well as volume growth in Japan, partially offset by volume declines in the United States and declines in Europe and Canada. The patent that provides U.S. market exclusivity for *Maxalt* will expire in December 2012. U.S. sales of *Maxalt* were \$451 million for the full year of 2011. In addition, the patent that provides market exclusivity for *Maxalt* is scheduled to expire in a number of major European markets in February 2013. However, the Company has applied for a six-month pediatric extension in the EU, which has been granted by most major countries and the Company expects to obtain the extension in the remaining countries by February 2013. The Company anticipates that sales in the United States and in these European markets will decline significantly after these patent expiries.

Other products included in the Primary Care and Women's Health customer business line include among others, *Asmanex* (mometasone furoate inhalation powder), an inhaled corticosteroid for asthma; *Dulera* (mometasone furoate/formoterol fumarate dihydrate) Inhalation Aerosol, a fixed-dose combination asthma treatment; *Implanon* (etonogestrel implant), a single-rod subdermal contraceptive implant; *Cerazette* (desogestrel), a progestin only oral contraceptive; *Arcoxia* (etoricoxib) for the treatment of arthritis and pain; and *Avelox* (moxifloxacin hydrochloride), which the Company only markets in the United States, a broad-spectrum fluoroquinolone antibiotic for the treatment of certain respiratory and skin infections. In January 2012, Merck received a Complete Response Letter from the FDA on the Company's supplemental New Drug Application for *Dulera*, for the treatment of chronic obstructive pulmonary disease. The Company is evaluating next steps.

Hospital and Specialty

Immunology

Sales of *Remicade*, a treatment for inflammatory diseases, were \$518 million for the second quarter of 2012 and \$1.0 billion for the first six months of 2012, declines of 38% and 35%, respectively, compared with the same periods of 2011. Prior to July 1, 2011, *Remicade* was marketed by the Company outside of the United States (except in Japan and certain other Asian markets). As a result of the agreement reached in April 2011 to amend the agreement governing the distribution rights to *Remicade* and *Simponi* (as discussed above), effective July 1, 2011, Merck relinquished marketing rights for these products in certain territories including Canada, Central and South America, the Middle East, Africa and Asia Pacific. Sales performance in 2012 as compared with 2011 reflects these changes. In the Retained Territories, *Remicade* sales declined 6% in the second quarter of 2012 and 1% in the first six months of 2012, which reflect 8% and 6% unfavorable impacts, respectively, from foreign exchange. Sales of *Simponi*, a once-monthly subcutaneous treatment for certain inflammatory diseases, were \$76 million in the second quarter of 2012 compared with \$75 million in the second quarter of 2011, and were \$150 million for the first six months of 2012 compared with \$129 million for the first six months of 2011. In the Retained Territories, sales of *Simponi* grew 29% and 49% for the second quarter and first six months of 2012, respectively, due in part to ongoing launches. 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 *Isetress*, an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection, were \$398 million in the second quarter of 2012, an increase of 18% compared with the second quarter of 2011, and \$735 million in the first six months of 2012, an increase of 17% compared with the first six months of 2011, primarily reflecting volume growth in the United States, Latin America and the Eastern Europe, Middle East and Africa region. Foreign exchange unfavorably affected global sales performance by 5% and 3% in the second quarter and first six months of 2012, respectively.

Worldwide sales of *PegIntron* (peginterferon alpha-2b), a treatment for chronic hepatitis C, were \$183 million for the second quarter of 2012, an increase of 19% compared with the second quarter of 2011, and were \$345 million for the first six months of 2012, an increase of 8% compared with the same period in 2011, reflecting volume growth and favorable pricing in the United States and volume growth in the Eastern Europe, Middle East and Africa region.

In May 2011, the FDA approved *Victrelis*, the Company's innovative oral medicine for the treatment of chronic hepatitis C. *Victrelis* is approved for the treatment of chronic hepatitis C genotype 1 infection, in combination with peginterferon alfa and ribavirin, in adult patients (18 years of age and older) with compensated liver disease, including cirrhosis, who are previously untreated or who have failed previous interferon and ribavirin therapy. *Victrelis* is an antiviral agent designed to interfere with the ability of the hepatitis C virus to replicate by inhibiting a key viral enzyme. In July 2011, the EC approved *Victrelis*. The EC's decision grants a single marketing authorization that is valid in the 27 countries that are members of the EU, as well as unified labeling applicable to Iceland, Liechtenstein and Norway. *Victrelis* is approved in 43 countries and has launched in 23 of those markets. Sales of *Victrelis* were \$126 million and \$238 million for the second quarter and first six months of 2012, respectively, compared with \$21 million and \$22 million for the second quarter and first six months of 2011, respectively.

Sales of *Primaxin*, an anti-bacterial product, were \$104 million in the second quarter of 2012 and \$192 million for the first six months of 2012, representing declines of 24% and 30%, respectively, compared with the same periods of 2011, primarily reflecting volume declines in the United States, Europe and for the year-to-date period the Eastern Europe, Middle East Africa region, partially offset by volume growth in China. Patents on *Primaxin* have expired worldwide and multiple generics have been launched. Accordingly, the Company is experiencing a decline in sales of *Primaxin* and the Company expects the decline to continue.

Oncology

Sales of *Temodar* (temozolomide) (marketed as *Temodal* outside the United States), a treatment for certain types of brain tumors, were \$225 million for the second quarter of 2012 and \$461 million for the first six months of 2012, representing declines of 4% compared with the same periods of 2011, primarily reflecting generic competition in Europe, mitigated in part by price increases in the United States. *Temodar* lost patent exclusivity in the EU in 2009. As previously disclosed, by agreement, one generic manufacturer has been given the right to enter the U.S. market in August 2013. The U.S. patent and exclusivity periods otherwise will expire in February 2014.

Global sales of *Emend* (aprepitant), for the prevention of chemotherapy-induced and post-operative nausea and vomiting, were \$145 million in the second quarter of 2012, an increase of 21% compared with the second quarter of 2011, and were \$247 million for the first six months of 2012, an increase of 19% compared with the first six months of 2011, primarily reflecting volume growth in the United States and Japan.

Other

Worldwide sales of ophthalmic products *Cosopt* (dorzolamide hydrochloride-timolol maleate ophthalmic solution) and *Trusopt* (dorzolamide hydrochloride ophthalmic solution) were \$105 million in the second quarter of 2012, a decline of 14% compared with the second quarter of 2011, and were \$229 million for the first six months of 2012, a decrease of 3% compared with the same period in 2011, primarily reflecting lower sales in Europe. The year-to-date decline was mitigated in part by higher *Cosopt* sales in Japan. Foreign exchange unfavorably affected global sales performance by 5% and 2% for the second quarter and first six months of 2012, respectively. The patent that provided U.S. market exclusivity for *Cosopt* and *Trusopt* has expired. *Trusopt* has also lost market exclusivity in a

number of major European markets. The patent for *Cosopt* will expire in a number of major European markets in March 2013 and the Company expects sales in those markets to decline significantly thereafter.

In February 2012, the FDA approved *Cosopt PF* (dorzolamide hydrochloride-timolol maleate ophthalmic solution), Merck's preservative-free formulation of *Cosopt* ophthalmic solution, indicated for the reduction of elevated intraocular pressure in appropriate patients with open-angle glaucoma or ocular hypertension.

Bridion (sugammadex), for the reversal of certain muscle relaxants used during surgery, is currently approved and has been launched in many countries outside of the United States. Sales of *Bridion* were \$60 million and \$47 million for the second quarter of 2012 and 2011, respectively, and were \$118 million and \$89 million for the first six months of 2012 and 2011, respectively. *Bridion* is in Phase III development in the United States.

In 2009, the FDA approved *Saphris* (asenapine), an antipsychotic indicated for the treatment of schizophrenia in adults and for the acute treatment, as monotherapy or adjunctive therapy to lithium or valproate, of manic or mixed episodes associated with bipolar I disorder in adults. In 2010, asenapine, sold under the brand name *Sycrest*, received marketing approval in the EU for the treatment of moderate to severe manic episodes associated with 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 \$43 million and \$23 million in the second quarter of 2012 and 2011, respectively, and were \$83 million and \$46 million for the first six months of 2012 and 2011, respectively. Merck continues to focus on building the brand awareness of *Saphris* in the United States and the Company continues to monitor and assess *Saphris/Sycrest* and the related intangible asset. If increasing the brand awareness or Lundbeck's on-going launch of the product in the EU is not successful, the Company may take a non-cash impairment charge with respect to *Saphris/Sycrest*, and such charge could be material.

In February 2012, the FDA approved *Zioptan* (tafluprost ophthalmic solution), a preservative-free prostaglandin analog ophthalmic solution for reducing elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension. Merck has exclusive commercial rights to tafluprost in Western Europe (excluding Germany), North America, South America, Africa, the Middle East, India and Australia. *Zioptan* is marketed as *Saftutan* in certain markets outside the United States.

Other products contained in the Hospital and Specialty customer business line include among others, *Candidas* (caspofungin acetate), an anti-fungal product; *Invanz* (ertapenem sodium) for the treatment of certain infections; *Noxafil* (posaconazole) for the prevention of certain invasive fungal infections; and *Integrilin* (eptifibatide) Injection, a treatment for patients with acute coronary syndrome, which is sold by the Company in the United States and Canada. The compound patent that provides U.S. market exclusivity for *Candidas* expires in September 2013.

Diversified Brands

Merck's diversified brands are 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 17% in the second quarter of 2012 and 19% in the first six months of 2012 compared with the same periods of 2011. The patents that provided market exclusivity for *Cozaar* and *Hyzaar* in the United States and in a number of major European markets expired in 2010. Accordingly, the Company is experiencing significant declines in *Cozaar* and *Hyzaar* sales and the Company expects the declines to continue.

Other products contained in the Diversified Brands customer business line include among others, *Propecia* (finasteride), a product for the treatment of male pattern hair loss; *Zocor*, a statin for modifying cholesterol; prescription *Claritin* (loratadine), a treatment for seasonal outdoor allergies and year-round indoor allergies; *Remeron* (mirtazapine), an antidepressant; *Proscar* (finasteride), a urology product for the treatment of symptomatic benign prostate enlargement; and *Vasotec* (enalapril maleate) and *Vaseretic* (enalapril maleate-hydrochlorothiazide), hypertension and/or heart failure products.

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.

Worldwide sales of *Gardasil* recorded by Merck grew 17% in the second quarter of 2012 to \$324 million and rose 24% to \$608 million for the first six months of 2012 driven by positive performance in the United States and the launch in Japan. In addition, growth in the Asia Pacific region also contributed to the performance of *Gardasil* in the year-to-date period. *Gardasil*, the world's top-selling human papillomavirus (HPV) vaccine, is indicated for girls and women 9 through 26 years of age for the prevention of cervical, vulvar, vaginal and anal cancer caused by HPV types 16 and 18, certain precancerous or dysplastic lesions caused by HPV types 6, 11, 16 and 18, and genital warts caused by HPV types 6 and 11. *Gardasil* is also approved in the United States for use in boys and men 9 through 26 years of age for the prevention of anal cancer caused by HPV types 16 and 18, anal dysplasias and precancerous lesions caused by HPV types 6, 11, 16 and 18, and genital warts caused by HPV types 6 and 11.

In recent years, the Company has experienced difficulties in producing its varicella zoster virus (VZV)-containing vaccines. These difficulties have in the past resulted in supply constraints for *ProQuad*, *Varivax* and *Zostavax*. The Company is manufacturing bulk varicella and is producing doses of *Varivax* and *Zostavax*.

ProQuad [Measles, Mumps, Rubella and Varicella Virus Vaccine Live], a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, one of the VZV-containing vaccines, is not currently available for ordering. The Company anticipates that *ProQuad* will become available in the fourth quarter of 2012. Merck's sales of *ProQuad* were \$37 million in the first quarter of 2011 when *ProQuad* was last available.

Merck's sales of *Varivax*, a vaccine to help prevent chickenpox (varicella), were \$216 million for the second quarter of 2012 compared with \$206 million for the second quarter of 2011 and were \$392 million for the first six months of 2012 compared with \$350 million for the first six months of 2011 reflecting positive performance in the United States from volume growth and favorable pricing. 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 \$101 million for the second quarter of 2012 compared with \$86 million for the second quarter of 2011 and were \$180 million for the first six months of 2012 compared with \$149 million for the first six months of 2011 reflecting higher volumes in the United States.

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 \$142 million in the second quarter of 2012, a decline of 4% compared with the second quarter of 2011, primarily reflecting lower public sector sales in the United States, partially offset by volume growth in the Eastern Europe, Middle East and Africa region. Sales for the first six months of 2012 were \$284 million, an increase of 4% compared with the first six months of 2011, reflecting volume growth in the emerging markets, particularly within the Latin America and Eastern Europe, Middle East and Africa regions, partially offset by lower public sector sales 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 \$148 million in the second quarter of 2012 as compared with \$122 million in the second quarter of 2011 and were \$224 million in the first six months of 2012 compared with \$146 million in the first six months of 2011. The Company experienced supply issues in 2011 and filled a significant number of backorders during the second quarter of 2011. The Company has resumed a normal supply schedule for *Zostavax* in the United States. No broad international launches or immunization programs are currently planned for 2012.

Merck's sales of *Pneumovax* [pneumococcal vaccine polyvalent], a vaccine to help prevent pneumococcal disease, were \$101 million in the second quarter of 2012 compared with \$64 million in the second quarter of 2011 and were \$213 million in the first six months of 2012 compared with \$143 million in the first six months of 2011, reflecting favorable pricing in the United States and volume growth in the United States and in Japan.

The Company anticipates that Merck's adult formulation of *Vaqta* [Hepatitis A Vaccine, Inactivated], a vaccine against hepatitis A, will be available in the third quarter of 2012.

Other*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 \$865 million for the second quarter of 2012, an increase of 8% compared with the second quarter of 2011. Foreign exchange unfavorably affected global sales performance by 6% in the second quarter of 2012. The increased sales reflect positive performance in cattle and swine products. Sales of Animal Health products for the first six months of 2012 were \$1.7 billion, an increase of 8% compared with the same period in 2011, which reflects a 4% unfavorable effect from foreign exchange. The sales growth reflects growth in cattle, swine, companion animal and poultry products.

Consumer Care

Consumer Care products include over-the-counter, foot care and sun care products such as *Claritin* non-drowsy antihistamines; *MiraLAX*, a treatment for occasional constipation; *Dr. Scholl's* foot care products; and *Coppertone* sun care products. Global sales of Consumer Care products were \$552 million for the second quarter of 2012, an increase of 2% compared with the second quarter of 2011 and were \$1.1 billion for the first six months of 2012, an increase of 5% compared with the first six months of 2011. The increased sales in both periods reflect higher sales of *MiraLAX*, *Claritin* and *Coppertone*, partially offset by lower sales of *Marvelon*, an oral contraceptive, which is an over-the-counter product in China. Consumer Care product sales are affected by competition and consumer spending patterns.

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. This Merger Restructuring Program is intended to optimize the cost structure of the combined company. In July 2011, the Company announced the latest phase of the Merger Restructuring Program during 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 in this phase of the Merger Restructuring Program relate to manufacturing (including Animal Health), administrative and headquarters organizations. Previously announced workforce reductions of approximately 17% in earlier phases of the program primarily reflect the elimination of positions in sales, administrative and headquarters organizations, as well as from the sale or closure of certain manufacturing and research and development sites and the consolidation of office facilities. The Company will continue to hire employees in strategic growth areas of the business as necessary. The Company will continue to pursue productivity efficiencies and evaluate its manufacturing supply chain capabilities on an ongoing basis which may result in future restructuring actions.

The Company recorded total pretax restructuring costs of \$291 million and \$808 million in the second quarter of 2012 and 2011, respectively, and \$568 million and \$921 million for the first six months of 2012 and 2011, 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, which are expected to be substantially completed by 2015. The Company originally estimated the total cumulative pretax costs for this program to be approximately \$5.8 billion to \$6.6 billion and the Company now expects the cumulative costs to be near the upper end of this range. 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. These cost savings, which are expected to come from all areas of the Company's pharmaceutical business, are in addition to the previously announced ongoing cost reduction initiatives at both legacy companies. Additional savings will come from non-restructuring-related activities.

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 \$(4) million and \$1 million were recorded in the second quarter of 2012 and 2011, respectively, and \$10 million and \$5 million were recorded in the first six months of 2012 and 2011, 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 2012 for the Merger Restructuring Program and the 2008 Restructuring Program will be in the range of \$800 million to \$1.1 billion.

The costs associated with all of these restructuring activities are primarily comprised of accelerated depreciation recorded in *Materials and production*, *Marketing and administrative* and *Research and development* and separation costs recorded in *Restructuring costs* (see Note 2 to the interim consolidated financial statements).

Materials and Production

Materials and production costs were \$4.1 billion for the second quarter of 2012, a decline of 4% compared with the second quarter of 2011, and were \$8.2 billion for the first six months of 2012, a decline of 2% compared with the first six months of 2011. Costs in both the second quarter of 2012 and 2011 include \$1.2 billion, and for both the first six months of 2012 and 2011 include \$2.5 billion, of expenses for the amortization of intangible assets recognized in connection with mergers and acquisitions. Costs in the second quarter and first six months of 2011 include an intangible asset impairment charge of \$118 million. Also included in materials and production costs were costs associated with restructuring activities which amounted to \$83 million and \$109 million in the second quarter of 2012 and 2011, respectively, and \$88 million and \$181 million in the first six months of 2012 and 2011, 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 66.6% in the second quarter of 2012 compared with 64.7% in the second quarter of 2011 and was 66.1% in the first six months of 2012 compared with 64.8% in the first six months of 2011. The amortization of intangible assets, impairment charges and restructuring charges noted above had an unfavorable effect on gross margin of 10.6 and 12.0 percentage points for the second quarter of 2012 and 2011, respectively, and 10.6 and 11.9 percentage points for the first six months of 2012 and 2011, respectively. Excluding these impacts, the gross margins in 2012 as compared with the same periods of 2011 reflect improvements resulting from changes in product mix and lower costs due to manufacturing efficiencies.

Marketing and Administrative

Marketing and administrative expenses were \$3.2 billion in the second quarter of 2012, a decline of 8% compared with the second quarter of 2011, and were \$6.3 billion in the first six months of 2012, a decrease of 5% compared with the first six months of 2011. The declines were due to ongoing productivity measures, as well as the favorable impact of foreign exchange. Expenses for the second quarter of 2012 and 2011 included restructuring costs of \$21 million and \$23 million, respectively, and for the first six months of 2012 and 2011 \$45 million and \$46 million, respectively, primarily related 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 \$64 million and \$77 million of acquisition-related costs in the second quarter of 2012 and 2011, respectively, and \$115 million and \$135 million for the first six months of 2012 and 2011, respectively, consisting largely of integration costs.

Research and Development

Research and development expenses were \$2.2 billion for the second quarter of 2012, an increase of 12% compared with the second quarter of 2011, and were \$4.0 billion for the first six months of 2012, a decline of 2% compared with the first six months of 2011. Research and development expenses are comprised of the costs directly incurred by Merck Research Labs (MRL), the Company's research and development division that focuses on human health-related activities, which were approximately \$1.1 billion and \$1.2 billion in the second quarter of 2012 and 2011, respectively, and were \$2.2 billion and \$2.3 billion in the first six months of 2012 and 2011, respectively. Also included in research and development expenses are costs incurred by other divisions in support of research and development activities, including depreciation, production and general administrative, as well as certain costs from operating segments, including Pharmaceutical, Animal Health and Consumer Care, which were \$888 million and \$742 million in the aggregate for the second quarter of 2012 and 2011, respectively, and \$1.6 billion and \$1.5 billion for the first six months of 2012 and 2011, respectively. Research and development expenses in 2012 and 2011 were favorably affected by cost savings resulting from restructuring activities.

Research and development expenses also include in-process research and development (IPR&D) impairment charges and research and development related restructuring charges. During the second quarter of 2012 and 2011, the Company recorded \$127 million and \$19 million, respectively, and for the first six months of 2012 and 2011 \$136 million and \$321 million, respectively, of IPR&D impairment charges primarily for programs that had previously been deprioritized and were 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 \$41 million and \$16 million in the second quarter of 2012 and 2011, respectively, and \$86 million and \$61 million, respectively, in the first six months of 2012 and 2011. Included in research and development expenses in the second quarter and first six months of 2012 is a \$120 million upfront payment related to an agreement with Endocyte, Inc. (Endocyte). See Research and Development Update below.

Restructuring Costs

Restructuring costs, primarily representing separation and other related costs associated with restructuring activities, were \$144 million and \$363 million for the second quarter and first six months of 2012, nearly all of which related to the Merger Restructuring Program. Restructuring costs were \$668 million and \$654 million for the second quarter and first six months of 2011, respectively. 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 780 positions in the second quarter of 2012, all of which related to the Merger Restructuring Program. During the first six months of 2012, Merck eliminated approximately 1,940 positions of which 1,800 related to the Merger Restructuring Program and 140 related to the 2008 Restructuring Program. For the second quarter of 2011, Merck eliminated 645 positions of which 585 related to the Merger Restructuring Program and 60 related to the 2008 Restructuring Program. During the first six months of 2011, Merck eliminated approximately 1,515 positions of which 1,335 related to the Merger Restructuring Program and 180 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*. (See Note 2 to the interim consolidated financial statements.)

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 \$142 million in the second quarter of 2012 compared with \$55 million in the second quarter of 2011 and \$253 million for the first six months of 2012 compared with \$193 million in the first six months of 2011 largely reflecting higher equity income from AZLP. (See Selected Joint Venture and Affiliate Information below.)

Other (Income) Expense, Net

Other (income) expense, net was \$103 million of expense in the second quarter of 2012 compared with \$121 million of expense in the second quarter of 2011 and \$247 million of expense in the first six months of 2012 compared with \$744 million of expense in the first six months of 2011. Included in other (income) expense, net during the first six months of 2011 was a \$500 million charge related to the resolution of the arbitration proceeding involving the Company's rights to market *Remicade* and *Simponi* (see Note 4 to the interim consolidated financial statements), as well as a \$127 million gain on the sale of certain manufacturing facilities and related assets.

Segment Profits

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2012	2011	2012	2011
<i>(\$ in millions)</i>				
Pharmaceutical segment profits	\$ 6,906	\$ 6,443	\$ 13,502	\$ 12,659
Other non-reportable segment profits	774	726	1,578	1,517
Other	(5,000)	(5,497)	(9,894)	(10,775)
Income before income taxes	\$ 2,680	\$ 1,672	\$ 5,186	\$ 3,401

Segment profits are comprised of segment sales less standard costs and certain operating expenses directly incurred by the segment and 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 arbitration settlement charge and a gain on the sale of certain manufacturing facilities and related assets recorded in 2011, 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 rose 7% in both the second quarter and first six months of 2012 driven largely by the increases in sales discussed above, as well as lower operating expenses.

Taxes on Income

The effective tax rates of 32.1% and 30.8% for the second quarter and first six months of 2012 and (22.8)% and 8.1% for the second quarter and first six months of 2011 reflect the impacts of acquisition-related costs and restructuring costs, partially offset by the beneficial impact of foreign earnings. In addition, the effective tax rates for the second quarter and first six months of 2011 also reflect the net favorable impact of approximately \$700 million relating to the settlement of Merck's 2002-2005 federal income tax audit, as well as the favorable impact of certain foreign and state tax rate changes that resulted in a net \$230 million reduction of deferred tax liabilities on intangibles established in purchase accounting. In addition, the effective tax rate for the first six months of 2011 also reflects the impact of the \$500 million charge related to the resolution of the arbitration proceeding with J&J.

Net Income and Earnings per Common Share

Net income attributable to Merck & Co., Inc. was \$1.8 billion for the second quarter of 2012 compared with \$2.0 billion for the second quarter of 2011 and \$3.5 billion for the first six months of 2012 compared with \$3.1 billion for the first six months of 2011. Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders (EPS) for the second quarter of 2012 were \$0.58 compared with \$0.65 in the second quarter of 2011 and were \$1.15 for the first six months of 2012 compared with \$0.98 for the first six months of 2011. The declines in net income and EPS in the second quarter of 2012 as compared with the second quarter of 2011 are primarily due to the favorable impact of tax items in 2011 as noted above, as well as higher research and development expenses, partially offset by lower restructuring costs and lower marketing and administrative expenses, as well as the arbitration settlement charge recorded in 2011. The increases in net income and EPS in the first six months of 2012 as compared with the same period in 2011 were primarily due to lower restructuring costs, lower marketing and administrative expenses, lower intangible asset impairment charges and the arbitration settlement charge recorded in 2011, partially offset by the favorable impact of tax items in 2011.

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.

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

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

(\$ in millions except per share amounts)	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Pretax income as reported under GAAP	\$ 2,680	\$ 1,672	\$ 5,186	\$ 3,401
Increase (decrease) for excluded items:				
Acquisition-related costs	1,417	1,440	2,706	3,097
Restructuring costs	289	816	582	942
Other items:				
Arbitration settlement charge	-	-	-	500
Loss (gain) on sale of manufacturing facilities and related assets	-	7	-	(127)
	4,386	3,935	8,474	7,813
Taxes on income as reported under GAAP	860	(382)	1,599	276
Estimated tax benefit on excluded items	272	407	548	738
Tax benefit from settlement of federal income tax audit	-	700	-	700
Tax benefit from foreign and state tax rate changes	-	230	-	230
	1,132	955	2,147	1,944
Non-GAAP net income	3,254	2,980	6,327	5,869
Less: Net income attributable to noncontrolling interests	27	30	56	58
Non-GAAP net income attributable to Merck & Co., Inc.	\$ 3,227	\$ 2,950	\$ 6,271	\$ 5,811
EPS assuming dilution as reported under GAAP	\$ 0.58	\$ 0.65	\$ 1.15	\$ 0.98
EPS difference ⁽¹⁾	0.47	0.30	0.89	0.89
Non-GAAP EPS assuming dilution	\$ 1.05	\$ 0.95	\$ 2.04	\$ 1.87

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

Acquisition-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 integration and transaction costs associated with the Merger, 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

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

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. Certain other items are comprised of the arbitration settlement charge and the gain associated with the sale of certain manufacturing facilities and related assets recorded in 2011 discussed above. Also excluded from non-GAAP income and non-GAAP EPS are the tax benefits from the settlement of a federal income tax audit and the favorable impact of certain foreign and state tax rate changes that resulted in a net reduction of deferred tax liabilities on intangibles established in purchase accounting.

- 46 -

Research and Development Update

In July 2012, Merck announced an update on the Phase III trial assessing fracture risk reduction with odanacatib (MK-0822), the Company's investigational cathepsin K inhibitor for osteoporosis. The Data Monitoring Committee (the DMC) for the study recently completed its first planned interim analysis for efficacy and recommended that the study be closed early due to robust efficacy and a favorable benefit-risk profile. As a result, Merck is taking steps to close the trial. The DMC noted that safety issues remain in certain selected areas and made recommendations with respect to following up on them. Merck's previously announced plan to conduct a blinded extension trial will allow further monitoring of the issues. The extension trial will also continue to measure efficacy. Merck anticipates submitting regulatory applications for approval of odanacatib in the United States and EU in the first half of 2013 and Japan in the third quarter of 2013.

In June 2012, Merck announced new data from two pivotal Phase III efficacy trials for suvorexant (MK-4305), an investigational medicine Merck is developing for the treatment of insomnia. In the studies, suvorexant significantly reduced the time it took patients to fall asleep and increased the time that patients stayed asleep as early as the first night and at the three-month time point compared to placebo. The investigational medicine met statistical significance for all primary endpoints except for one measurement at month 3 in one of the trials. These data were presented at SLEEP 2012, the 26th Annual Meeting of the Associated Professional Sleep Societies. Merck plans to file a New Drug Application (NDA) for suvorexant with the FDA in 2012. If approved, suvorexant would be the first medicine approved in a new class of medicines, called orexin receptor antagonists, for use in patients with difficulty falling or staying asleep. Commercial launch timing will be impacted by FDA approval and evaluation by the Controlled Substance Staff of the FDA and Drug Enforcement Agency.

Also in June 2012, Merck announced that the FDA issued a Complete Response Letter regarding the NDA for ridaforolimus. Ridaforolimus is an investigational oral mTOR inhibitor under development for maintenance therapy for patients with metastatic soft tissue or bone sarcoma who have stable disease or better after four or more cycles of chemotherapy. The Complete Response Letter states that the FDA cannot approve the application in its present form, and that additional clinical trial(s) would need to be conducted to further assess safety and efficacy. The Company is evaluating next steps. Merck also is in ongoing discussions with health authorities in Europe and other countries as part of their application procedures for ridaforolimus for the treatment of metastatic soft-tissue or bone sarcomas in patients who had a favorable response to chemotherapy. Additionally, Merck is studying ridaforolimus in combination with other mechanisms in several tumor types. As part of an exclusive license agreement with ARIAD Pharmaceuticals, Inc. (ARIAD), Merck is responsible for the development and worldwide commercialization of ridaforolimus in oncology. ARIAD has exercised its option to co-promote ridaforolimus for sarcoma if the drug is approved in the United States.

In March 2012, Merck announced that the FDA issued a Complete Response Letter regarding Merck's NDA for *Atozet* (MK-0653C), an investigational combination medicine for the treatment of primary or mixed hyperlipidemia. In the letter, the FDA advised Merck that it has completed its review of the submission and stated that additional data are needed. Merck is planning to submit additional information to the FDA for ezetimibe and atorvastatin by the end of 2012. The previously disclosed patent litigation with Pfizer has been resolved.

As previously disclosed, the 14,000-patient Phase III event-driven clinical study of V503, the Company's investigational 9-valent HPV vaccine candidate, is ongoing. V503 incorporates antigens against five additional cancer-causing HPV types as compared with *Gardasil*. Based on the current rate at which disease endpoints are being reported in the study, Merck now anticipates filing a Biologics License Application for V503 with the FDA in 2013.

MK-0524B is a drug candidate that combines the novel approach to raising HDL cholesterol and lowering triglycerides from extended-release niacin combined with laropiprant and simvastatin in one combination product. In July 2012, Merck placed the MK-0524B program on hold for business reasons and no longer anticipates filing an NDA for MK-0524B with the FDA in 2014. This has no impact on the HPS2-THRIVE trial or the MK-0524A program, both of which are continuing as planned.

In April 2012, the Company entered into an agreement with Endocyte to develop and commercialize Endocyte's novel investigational therapeutic candidate vintafolide (MK-8109). Vintafolide is currently being evaluated in a Phase III clinical trial for platinum-resistant ovarian cancer (PROCEED) and a Phase II trial for non-small cell lung cancer. Under the agreement, Merck gained worldwide rights to develop and commercialize vintafolide. Endocyte received a \$120 million upfront payment, which the Company recorded in *Research and development* expenses in the second quarter of 2012, and is eligible for milestone payments of up to \$880 million based on the successful achievement of development, regulatory and commercialization goals for vintafolide for a total of six cancer indications. In addition, if vintafolide receives regulatory approval, Endocyte will receive an equal share of the profit in the United States as well as a royalty on sales of the product in the rest of the world. Endocyte has retained the right to co-promote vintafolide with Merck in the United States and Merck has the exclusive right to promote vintafolide in the rest of world. Endocyte will be responsible for the majority of funding and completion of the PROCEED trial. Merck will be responsible for most other development activities, all other costs and have most decision rights for vintafolide. Merck has the right to terminate the agreement on

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

90 days notice. Merck and Endocyte both have the right to terminate the agreement due to the material breach or insolvency of the other party. Endocyte has the right to terminate the agreement in the event that Merck challenges an Endocyte patent right relating to vintafolide. 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 vintafolide and, in the case of termination for cause by Merck, certain royalty obligations and U.S. profit and loss sharing. Endocyte plans to file an application for vintafolide in the EU for the treatment of folate receptor positive platinum-resistant ovarian cancer in 2012. Endocyte remains responsible for the development, manufacture and commercialization worldwide of etarfolatide, a non-invasive companion diagnostic imaging agent that is used to identify folate receptor positive tumor cells.

The chart below reflects the Company's research pipeline as of July 27, 2012. Candidates shown in Phase III include specific products and the date such candidate entered into Phase III development. Candidates shown in Phase II include the most advanced compound with a specific mechanism or, if listed compounds have the same mechanism, they are each currently intended for commercialization in a given therapeutic area. Small molecules and biologics are given MK-number designations and vaccine candidates are given V-number designations. Candidates in Phase I, additional indications in the same therapeutic area and additional claims, line extensions or formulations for in-line products are not shown.

Phase II	Phase III (Phase III entry date)	Under Review
Allergy	Allergy	Atherosclerosis
MK-8237, Immunotherapy ⁽¹⁾	MK-7243, Grass pollen (March 2008) ⁽¹⁾	MK-0653C (<i>Atozet</i>) (U.S.) ⁽⁷⁾
Cancer	MK-3641, Ragweed (September 2009) ⁽¹⁾	Sarcoma
MK-0646 (dalotuzumab)	Atherosclerosis	MK-8669 (ridaforolimus) (EU) (U.S.) ⁽⁸⁾
MK-1775	MK-0524A (extended-release niacin/laropiprant) (U.S.) (December 2005)	
MK-2206	MK-0524B (extended-release niacin/laropiprant/simvastatin) (July 2007) ⁽²⁾	
MK-7965 (dinaciclib)	MK-0859 (anacetrapib) (May 2008)	Footnotes:
Contraception, Medicated IUS	Atrial Fibrillation	
MK-8342	MK-6621 (vernakalant i.v.) (U.S.) (August 2003) ⁽³⁾	⁽¹⁾ North American rights only.
Diabetes Mellitus	Clostridium difficile Infection	⁽²⁾ In July 2012, Merck placed the MK-0524B program on hold.
MK-3102	MK-3415A (actoxumab/bezlotoxumab) (November 2011)	⁽³⁾ The program remains on hold in the United States. The Company plans to have further discussions with the FDA.
Hepatitis C	Contraception	⁽⁴⁾ In November 2011, Merck received a Complete Response letter from the FDA for NOMAC/E2 (MK-8175A). The Company is planning to conduct an additional clinical study requested by the FDA and update the application in the future.
MK-5172	MK-8175A (NOMAC/E2) (U.S.) (June 2006) ⁽⁴⁾	⁽⁵⁾ For development in Japan only.
Insomnia	Diabetes and Atherosclerosis	⁽⁶⁾ Vintafolide started Phase III clinical trials in April 2011 sponsored by Endocyte Inc.
MK-3697	MK-0431E (sitagliptin/atorvastatin) (October 2011)	⁽⁷⁾ In March 2012, Merck received a Complete Response Letter from the FDA for <i>Atozet</i> (MK-0653C). Merck is planning to submit
MK-6096	Fertility	
Migraine	MK-8962 (corifollitropin alfa for injection) (U.S.) (July 2006)	
MK-1602	Hepatitis C	
Overactive Bladder	MK-7009 (vaniprevir) (June 2011) ⁽⁵⁾	
MK-4618		

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

Pneumoconjugate Vaccine

V114

Psoriasis

MK-3222

Rheumatoid Arthritis

MK-8457

Herpes Zoster

V212 (inactivated VZV vaccine) (December 2010)

HPV-Related Cancers

V503 (HPV vaccine (9 valent)) (September 2008)

Insomnia

MK-4305 (suvorexant) (December 2009)

Neuromuscular Blockade Reversal

MK-8616 (*Bridion*) (U.S.) (November 2005)

Osteoporosis

MK-0822 (odanacatib) (September 2007)

Parkinson s Disease

MK-3814 (preladenant) (July 2010)

Pediatric Hexavalent Combination Vaccine

V419 (April 2011)

Platinum-Resistant Ovarian Cancer

MK-8109 (vintafolide) (April 2011)⁽⁶⁾

Thrombosis

MK-5348 (vorapaxar) (September 2007)

additional information to the FDA.

⁽⁸⁾ In June 2012, Merck received a Complete Response Letter from the FDA for ridaforolimus (MK-8669). The Company is evaluating next steps.

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 June 2012, Merck and AstraZeneca amended the 1998 option agreement which gave AstraZeneca the option to buy Merck's common stock interest in KBI and, through it, Merck's interest in Nexium and Prilosec as well as AZLP. The updated agreement eliminates AstraZeneca's option to acquire Merck's interest in KBI in 2012 and provides AstraZeneca a new option to acquire Merck's interest in KBI in June 2014. As a result of the amended agreement, Merck will continue to record supply sales and equity income from the partnership for the remainder of 2012 and 2013. In 2014, AstraZeneca has the option to purchase Merck's interest in KBI based in part on the value of Merck's interest in Prilosec and Nexium. 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 will decline substantially.

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 \$229 million and \$243 million in the second quarter of 2012 and 2011, respectively, and were \$435 million and \$430 million for the first six months of 2012 and 2011, respectively. SPMSD sales of *Gardasil* were \$60 million and \$66 million for the second quarter of 2012 and 2011, respectively, and were \$115 million and \$124 million for the first six months of 2012 and 2011, respectively.

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

Liquidity and Capital Resources

(\$ in millions)	June 30,	
	2012	December 31, 2011
Cash and investments	\$ 21,535	\$ 18,430
Working capital	18,727	16,936
Total debt to total liabilities and equity	18.0%	16.7%

During the first six months of 2012, cash provided by operating activities was \$5.1 billion compared with \$4.6 billion in the first six months of 2011. Cash provided by operating activities in the first six months of 2012 reflects the payment of \$960 million (including interest) related to the resolution of certain litigation related to *Vioxx*. See Note 9 to the interim consolidated financial statements. 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. The global economic downturn and the sovereign debt issues, among other factors, have adversely impacted foreign receivables in certain European countries (see Note 5 to the interim consolidated financial statements). While the Company continues to receive payment on these receivables, including significant collections during the second quarter in connection with the Spanish government's debt stabilization/stimulus plan, 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 \$568 million in the first six months of 2012 compared with \$943 million in the first six months of 2011 primarily reflecting higher proceeds from the sales of securities and other investments and lower use of funds for the acquisitions of businesses, partially offset by higher purchases of

securities and other investments. In addition, the Company received proceeds from the disposition of businesses in the first six months of 2011. Cash used in financing activities in the first six months of 2012 was \$1.3 billion compared with \$2.4 billion in the first six months of 2011. The lower use of cash in financing activities was primarily driven by lower payments on debt, higher proceeds from the exercise of stock options and an increase in short-term borrowings, partially offset by higher purchases of treasury stock and higher dividends paid to stockholders.

At June 30, 2012, the total of worldwide cash and investments was \$21.5 billion, including \$17.5 billion of cash, cash equivalents and short-term investments and \$4.1 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.

In April 2011, the Internal Revenue Service (the IRS) concluded its examination of Merck's 2002-2005 federal income tax returns and as a result the Company was required to make net payments of approximately \$465 million. The Company's unrecognized tax benefits for the years under examination exceeded the adjustments related to this examination period and therefore the Company recorded a net \$700 million tax provision benefit in the second quarter of 2011. This net benefit reflects the decrease of unrecognized tax benefits for the years under examination partially offset by increases to the unrecognized tax benefits for years subsequent to the examination period as a result of this settlement. The Company disagrees with the IRS treatment of one issue raised during this examination and is appealing the matter through the IRS administrative process.

As previously disclosed, the Canada Revenue Agency (the CRA) has proposed adjustments for 1999 and 2000 relating to intercompany pricing matters and, in July 2011, the CRA issued assessments for other miscellaneous audit issues for tax years 2001-2004. These adjustments would increase Canadian tax due by approximately \$330 million plus approximately \$390 million of interest through June 30, 2012. The Company disagrees with the positions taken by the CRA and believes they are without merit. The Company continues to contest the assessments through the CRA appeals process. The CRA is expected to prepare similar adjustments for later years. Management believes that resolution of these matters will not have a material effect on the Company's financial position or liquidity.

Capital expenditures totaled \$762 million and \$689 million for the first six months of 2012 and 2011, respectively. Capital expenditures for full year 2012 are estimated to be \$2.2 billion.

Dividends paid to stockholders were \$2.6 billion and \$2.4 billion for the first six months of 2012 and 2011, respectively. In May and July 2012, the Board of Directors declared a quarterly dividend of \$0.42 per share on the Company's common stock for the third and fourth quarters, respectively, of 2012.

In April 2011, Merck's Board of Directors approved additional purchases of up to \$5 billion of Merck's common stock for its treasury. The Company purchased \$985 million of its common stock (26 million shares) for its treasury during the first six months of 2012. The Company has approximately \$3.5 billion remaining under this program. The treasury stock purchases have no time limit and will be made over time on the open market, in block transactions or in privately negotiated transactions.

In May 2012, the Company terminated its existing credit facilities and entered into a new \$4.0 billion, five-year credit facility maturing 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, 2011 included in Merck's Form 10-K filed on February 28, 2012. Certain of these accounting policies are considered critical as disclosed in the Critical Accounting Policies and Other Matters 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, 2011.

Recently Issued Accounting Standards Not Yet Adopted

In July 2012, the Financial Accounting Standards Board issued amended guidance that simplifies how an entity tests indefinite-lived intangibles for impairment. The amended guidance will allow 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 updated guidance is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012, with early adoption permitted. The Company is currently evaluating the impact of adoption on its financial position and results of operations.

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 June 30, 2012, 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 that they do not relate strictly to historical or current facts. These statements are likely to address the Company's growth strategy, financial results, product development, product approvals, product potential and development programs. One must carefully consider any such statement and should understand that many factors could cause actual results to differ materially from the Company's forward-looking statements. These factors include inaccurate assumptions and a broad variety of other risks and uncertainties, including some that are known and some that are not. No forward-looking statement can be guaranteed and actual future results may vary materially.

The Company does not assume the obligation to update any forward-looking statement. One should carefully evaluate such statements in light of factors, including risk factors, described in the Company's filings with the Securities and Exchange Commission, especially on Forms 10-K, 10-Q and 8-K. In Item 1A. Risk Factors of the Company's Annual Report on Form 10-K for the year ended December 31, 2011, as filed on February 28, 2012, 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 InformationItem 1. Legal Proceedings

The information called for by this Item is incorporated herein by reference to Note 9 included in Part I, Item 1, Financial Statements (unaudited) Notes to Consolidated Financial Statements.

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

Issuer purchases of equity securities for the three months ended June 30, 2012 were as follows:

ISSUER PURCHASES OF EQUITY SECURITIES

Period	Total Number of Shares Purchased ⁽¹⁾	Average Price Paid Per Share	(\$ in millions)
			Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs ⁽¹⁾
April 1 - April 30	3,897,300	\$38.41	\$3,880
May 1 - May 31	4,529,400	\$38.13	\$3,707
June 1 - June 30	5,341,400	\$38.52	\$3,501
Total	13,768,100	\$38.36	\$3,501

⁽¹⁾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 June 30, 2012, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Statement of Income, (ii) the Consolidated Statement of Comprehensive Income, (iii) the Consolidated Balance Sheet, (iv) the Consolidated Statement of Cash Flows, and (v) Notes to 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: August 7, 2012

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

Date: August 7, 2012

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

- 54 -

EXHIBIT INDEX

Number	Description
3.1	Restated Certificate of Incorporation of Merck & Co., Inc. (November 3, 2009) Incorporated by reference to Current Report on Form 8-K filed on November 4, 2009
3.2	By-Laws of Merck & Co., Inc. (effective January 1, 2012) Incorporated by reference to Current Report on Form 8-K filed December 21, 2011
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 June 30, 2012, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Statement of Income, (ii) the Consolidated Statement of Comprehensive Income, (iii) the Consolidated Balance Sheet, (iv) the Consolidated Statement of Cash Flows, and (v) Notes to Consolidated Financial Statements.