Merck & Co. Inc. Form 10-Q November 09, 2012

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-Q**

(Mark One)

p QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the quarterly period ended September 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 October 31, 2012: 3,040,071,937

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 b 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 b No "

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

Large accelerated filer b

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  $\flat$ 

# Part I - Financial Information

# Item 1. Financial Statements

# MERCK & CO., INC. AND SUBSIDIARIES

# INTERIM CONSOLIDATED STATEMENT OF INCOME

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

		onths Ended aber 30, 2011	Nine Mont Septemb 2012	
Sales	\$ 11,488	\$ 12,022	\$ 35,530	\$ 35,753
Costs, Expenses and Other				
Materials and production	4,137	4,352	12,286	12,695
Marketing and administrative	3,063	3,340	9,386	10,029
Research and development	1,918	1,954	5,944	6,048
Restructuring costs	110	119	473	773
Equity income from affiliates	(158)	(161)	(410)	(354)
Other (income) expense, net	200	66	446	809
	9,270	9,670	28,125	30,000
Income Before Taxes	2,218	2,352	7,405	5,753
Taxes on Income	455	628	2,055	904
Net Income	\$ 1,763	\$ 1,724	\$ 5,350	\$ 4,849
Less: Net Income Attributable to Noncontrolling Interests	34	32	89	89
Net Income Attributable to Merck & Co., Inc.	\$ 1,729	\$ 1,692	\$ 5,261	\$ 4,760
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	\$ 0.57	\$ 0.55	\$ 1.73	\$ 1.54
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	\$ 0.56	\$ 0.55	\$ 1.71	\$ 1.53
Dividends Declared per Common Share	\$ 0.42	\$ 0.38	\$ 1.26	\$ 1.14

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 Mor Septem 2012			ths Ended aber 30, 2011
Net Income Attributable to Merck & Co., Inc.	\$ 1,729	\$ 1,692	\$ 5,261	\$ 4,760
Other Comprehensive Income Net of Taxes:				
Net unrealized (loss) gain on derivatives, net of reclassifications	(143)	60	(99)	(77)
Net unrealized gain (loss) on investments, net of reclassifications	32	(6)	62	(11)
Benefit plan net gain and prior service cost, net of amortization	27	31	45	59
Cumulative translation adjustment	170	(22)	84	532
	86	63	92	503
Comprehensive Income Attributable to Merck & Co., Inc.	\$ 1,815	\$ 1,755	\$ 5,353	\$ 5,263

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

# $\mathbf{MERCK} \; \& \; \mathbf{CO., INC. \; AND \; SUBSIDIARIES}$

# CONSOLIDATED BALANCE SHEET

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

	Sep	otember 30, 2012	Dec	cember 31, 2011
Assets				
Current Assets				
Cash and cash equivalents	\$	17,360	\$	13,531
Short-term investments		757		1,441
Accounts receivable (net of allowance for doubtful accounts of \$163 in 2012 and \$131 in 2011)		7,952		8,261
Inventories (excludes inventories of \$1,446 in 2012 and \$1,379 in 2011 classified in Other assets - see				
Note 6)		6,731		6,254
Deferred income taxes and other current assets		3,429		3,694
Total current assets		36,229		33,181
Investments		5,560		3,458
Property, Plant and Equipment, at cost, net of accumulated depreciation of \$17,475 in 2012 and \$16,176 in 2011		15,884		16,297
Goodwill		12,168		12,155
Other Intangibles, Net		30,325		34,302
Other Assets		6,135		5,735
	\$	106,301	\$	105,128
Liabilities and Equity				
Current Liabilities				
Loans payable and current portion of long-term debt	\$	2,029	\$	1,990
Trade accounts payable		1,804		2,023
Accrued and other current liabilities		8,923		10,170
Income taxes payable		1,512		781
Dividends payable		1,315		1,281
		·		,
Total current liabilities		15,583		16,245
Long-Term Debt		17,571		15,525
Deferred Income Taxes and Noncurrent Liabilities		14,935		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		40,471		40,663
Retained earnings		40,390		38,990
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Accumulated other comprehensive loss	(3,040)	(3,132)
	79,609	78,309
Less treasury stock, at cost:		
532,699,267 shares in 2012 and 536,109,713 shares in 2011	23,862	23,792
Total Merck & Co., Inc. stockholders equity	55,747	54,517
Noncontrolling Interests	2,465	2,426
	,	,
Total equity	58,212	56,943
20th oquay	30,212	30,713
	\$ 106.301	\$ 105.128
	\$ 106,301	\$ 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)

		Nine Months En September 3				
	2012	-	20	11		
Cash Flows from Operating Activities						
Net income	\$ 5,	350	\$	4,849		
Adjustments to reconcile net income to net cash provided by operating activities:						
Depreciation and amortization	5,,	317	:	5,566		
Intangible asset impairment charges		176		461		
Equity income from affiliates	(4	<b>1</b> 10)		(354)		
Dividends and distributions from equity affiliates		181		186		
Deferred income taxes	(2	283)		(974)		
Share-based compensation	,	257		287		
Other		(34)		(207)		
Net changes in assets and liabilities	(2,3	341)		(664)		
Net Cash Provided by Operating Activities	8,	213	!	9,150		
Cash Flows from Investing Activities						
Capital expenditures	(1,	176)	(	1,120)		
Purchases of securities and other investments	(6,8	391)	(4	4,686)		
Proceeds from sales of securities and other investments	5,0	507	4	4,740		
Dispositions of businesses, net of cash divested		-		323		
Acquisitions of businesses, net of cash acquired		-		(373)		
Other		53		(90)		
Net Cash Used in Investing Activities	(2,4	107)	(	1,206)		
Cash Flows from Financing Activities						
Net change in short-term borrowings	(2	280)		1,356		
Proceeds from issuance of debt	2,	504		-		
Payments on debt		(4)	(	1,277)		
Purchases of treasury stock	(1,4	139)	(	1,359)		
Dividends paid to stockholders	(3,8	336)	(.	3,526)		
Proceeds from exercise of stock options	1,0	060		194		
Other		(54)		(61)		
Net Cash Used in Financing Activities	(2,0	)49)	(4	4,673)		
Effect of Exchange Rate Changes on Cash and Cash Equivalents		72		82		

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Net Increase in Cash and Cash Equivalents	3,829	3,353
Cash and Cash Equivalents at Beginning of Year	13,531	10,900
Cash and Cash Equivalents at End of Period	\$ 17,360	\$ 14,253

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 also 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 \$150 million and \$255 million in the third quarter of 2012 and 2011, respectively, and \$718 million and \$1.2 billion in the first nine months of 2012 and 2011, respectively, related to this program. Since inception of the Merger Restructuring Program through September 30, 2012, Merck has recorded total pretax accumulated costs of approximately \$5.8 billion and eliminated approximately 20,750 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 2016. The Company now expects the estimated total cumulative pretax costs for this program to be approximately \$7.2 billion to \$7.5 billion. The increase from original estimates primarily reflects accelerated depreciation related to additional facility closures identified during the Company s ongoing assessment of worldwide capacity requirements for its manufacturing, research and administrative facilities subsequent to the Merger, including the recently

announced move of the Company s worldwide headquarters to Summit, New Jersey. The Company estimates that approximately two-thirds of the cumulative pretax costs relate to cash outlays, primarily related to employee separation expense. Approximately

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

#### 2008 Global Restructuring Program

In October 2008, Merck announced a global restructuring program (the 2008 Restructuring Program ) to reduce its cost structure, increase efficiency, and enhance competitiveness. As part of the 2008 Restructuring Program, the Company expects to eliminate approximately 7,200 positions 6,800 active employees and 400 vacancies across the Company worldwide. Pretax restructuring costs of \$13 million and \$20 million were recorded in the third quarter of 2012 and 2011, respectively, and \$23 million and \$25 million were recorded in the first nine months of 2012 and 2011, respectively, related to the 2008 Restructuring Program. Since inception of the 2008 Restructuring Program through September 30, 2012, Merck has recorded total pretax accumulated costs of \$1.6 billion and eliminated approximately 6,400 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:

	Three Months Ended September 30, 2012 Separation							Nine Months Ended September 30, 2						2012
(\$ in millions)			lerated eciation	C	ther	То	otal	Separatio Costs 1				ther	To	tal
Merger Restructuring Program														
Materials and production	\$ -	\$	42	\$	13	\$	55	\$ -	\$	75	\$	50	\$	125
Marketing and administrative	φ - -	φ	16	φ	3	φ	19	φ - -	φ	59	φ	5	φ	64
Research and development	_		(33) (1)		1		(32)	_		49		5		54
Restructuring costs	59		-		49		108	363		-		112		475
	59		25		66		150	363		183		172		718
2008 Restructuring Program														
Materials and production	_		1		4		5	_		4		15		19
Marketing and administrative	-		6		-		6	_		6		-		6
Restructuring costs	(1)		-		3		2	(12)		-		10		(2)
	(1)		7		7		13	(12)		10		25		23
	\$ 58	\$	32	\$	73	\$	163	\$ 351	\$	193	\$	197	\$	741
(\$ in millions)	Separati	oAcc	Months Endelerated reciation		eptembo Other		, 2011 'otal	Separation	n <b>A</b> cc	onths En celerated reciatio	1	eptembe Other	er 30, 2 To	
Merger Restructuring Program														

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Materials and production	\$ -	\$ 81	\$ 7	\$ 88	\$	-	\$ 233	\$ 12	\$ 245
Marketing and administrative	-	22	9	31		-	67	10	77
Research and development	-	27	1	28		-	107	(18)	89
Restructuring costs	63	-	45	108	6	70	-	95	765
	63	130	62	255	6	70	407	99	1,176
	03	130	02	233	O	70	407	,,,	1,170
2008 Restructuring Program									
Materials and production	_	10	(1)	9		_	16	1	17
Restructuring costs	5	-	6	11		(3)	-	11	8
	5	10	5	20		(3)	16	12	25
	5	10	5	20		(5)	10	12	25
	\$ 68	\$ 140	\$ 67	\$ 275	\$ 6	67	\$ 423	\$ 111	\$ 1,201

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

Separation costs are associated with actual headcount reductions, as well as those headcount reductions which were probable and could be reasonably estimated. In the third quarter of 2012 and 2011, approximately 525 positions and 1,300 positions, respectively, were eliminated under the Merger Restructuring Program and

approximately 10 and 110 positions, respectively, were eliminated under the 2008 Restructuring Program. In the first nine months of 2012 and 2011, approximately 2,325 positions and 2,635 positions, respectively, were eliminated under the Merger Restructuring Program and approximately 150 positions and 290 positions, respectively, were eliminated under the 2008 Restructuring Program. These position eliminations were comprised of actual headcount reductions and the elimination of contractors and vacant positions.

Accelerated depreciation costs primarily relate to manufacturing, research and administrative facilities and equipment to be sold or closed as part of the programs. Accelerated depreciation costs represent the difference between the depreciation expense to be recognized over the revised useful life of the site, based upon the anticipated date the site will be closed or divested, and depreciation expense as determined utilizing the useful life prior to the restructuring actions. All of the sites have and will continue to operate up through the respective closure dates, and since future cash flows were sufficient to recover the respective book values, Merck was required to accelerate depreciation of the site assets rather than write them off immediately. Anticipated site closure dates, particularly related to manufacturing locations, have been and may continue to be adjusted to reflect changes resulting from regulatory or other factors.

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 13) 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 nine months ended September 30, 2012:

(\$ in millions)	paration Costs	Accelerated Depreciation		Other		,	Total
Merger Restructuring Program							
Restructuring reserves January 1, 2012  Expense (Payments) receipts, net Non-cash activity  Restructuring reserves September 30, 2012 (1)	\$ 1,144 363 (742) - 765	\$	183 - (183)	\$	51 172 (131) (74)	\$	1,195 718 (873) (257) 783
2008 Restructuring Program							
Restructuring reserves January 1, 2012 Expense (Payments) receipts, net Non-cash activity	\$ 126 (12) (19)	\$	10 - (10)	\$	25 (8) (17)	\$	126 23 (27) (27)
Restructuring reserves September 30, 2012 (1)	\$ 95	\$	-	\$	-	\$	95

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 for the

<sup>(1)</sup> The cash outlays associated with the Merger Restructuring Program are expected to be substantially completed by the end of 2013 with the exception of certain actions, principally manufacturing-related, which are expected to be substantially completed by 2016. The cash outlays associated with the remaining restructuring reserves for the 2008 Restructuring Program are primarily manufacturing-related and are expected to be completed by the end of 2015. Legacy Schering-Plough Program

third quarter of 2011 and \$4 million and \$18 million for the first nine months of 2012 and 2011, respectively. The remaining reserve associated with this program, which is substantially complete, was \$17 million at September 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 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 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 nine 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 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) e

# 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

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collar strategy reduces to zero and the Company benefits from the increase in the U.S. dollar equivalent value of its anticipated foreign currency cash flows, however this benefit would be capped at the strike level of the written call. If the U.S. dollar strengthens relative to the currency of the hedged anticipated sales, the written call option value of the collar strategy reduces to zero and the changes in the purchased put cash flows of the collar strategy would offset the decline in the expected future U.S. dollar equivalent cash flows of the hedged foreign currency sales.

The Company may also utilize forward contracts in its revenue hedging program. If the U.S. dollar strengthens relative to the currency of the hedged anticipated sales, the increase in the fair value of the forward contracts offsets the decrease in the expected future U.S. dollar cash flows of the hedged foreign currency sales. Conversely, if the U.S. dollar weakens, the decrease in the fair value of the forward contracts offsets the increase in the value of the anticipated foreign currency cash flows.

The fair values of these derivative contracts are recorded as either assets (gain positions) or liabilities (loss positions) in the Consolidated Balance Sheet. Changes in the fair value of derivative contracts are recorded each period in either current earnings or *Other comprehensive income* ( *OCI* ), depending on whether the derivative is designated as part of a hedge transaction and, if so, the type of hedge transaction. For derivatives that are designated as cash flow hedges, the effective portion of the unrealized gains or losses on these contracts is recorded in *Accumulated other comprehensive income* ( *AOCI* ) and reclassified into *Sales* when the hedged anticipated revenue is recognized. The hedge relationship is highly effective and hedge ineffectiveness has been *de minimis*. For those derivatives which are not designated as cash flow hedges, 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 \$35 million and \$(84) million for the first nine months of 2012 and 2011, respectively, from the euro-denominated notes.

#### Interest Rate Risk Management

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

In the third quarter of 2011, the Company terminated 11 interest rate swap contracts with a total notional amount of \$1.6 billion. These swaps effectively converted \$1.6 billion of its fixed-rate notes, with maturity dates ranging from June 2015 to January 2016, to floating-rate instruments. As a result of the third quarter swap terminations, the Company received \$113 million in cash, which included \$7 million in accrued interest. The corresponding \$106 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. In the second quarter of 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 ranging from March 2015 to June 2019, to floating-rate instruments. As a result of the second quarter 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 September 30, 2011, the Company was a party to two pay-floating, receive-fixed interest rate swap contracts with notional amounts of \$250 million 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. These 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:

	,		nber 30		I Fair Value	nber 31	*	
(\$ in millions)	Balance Sheet Caption	Asset	ability	Notional	Asset	ability		Notional
Derivatives Designated as Hedging Instru	nents							
Foreign exchange contracts (current)	Deferred income taxes and other current assets	\$ 163	\$ -	\$ 4,450	\$ 196	\$ -	\$	3,727
Foreign exchange contracts (non-current)	Other assets	350	-	5,637	420	-		4,956
Foreign exchange contracts (current)	Accrued and other current liabilities	-	48	1,668	-	53		1,718
Foreign exchange contracts (non-current)	Deferred income taxes and noncurrent liabilities	_	7	426	_	1		104
			•			_		
		\$ 513	\$ 55	\$ 12,181	\$ 616	\$ 54	\$	10,505
Derivatives Not Designated as Hedging In.	struments							
Foreign exchange contracts (current)	Deferred income taxes and other current							
	assets	\$ 55	\$ -	\$ 4,256	\$ 139	\$ -	\$	5,306
Foreign exchange contracts (non-current)	Other assets	18	-	290	-	-		-
Foreign exchange contracts (current)	Accrued and other current liabilities	-	125	6,129	-	54		5,013
		\$ 73	\$ 125	\$ 10,675	\$ 139	\$ 54	\$	10,319
		\$ 586	\$ 180	\$ 22,856	\$ 755	\$ 108	\$	20,824

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)		Months embe	s Ended r 30, 2011		nths Ended nber 30, 2011
Derivatives designated in fair value hedging relationships					
Interest rate swap contracts					
Amount of gain recognized in Other (income) expense, net on derivatives	\$	- \$	(40)	\$ -	\$ (203)
Amount of loss recognized in Other (income) expense, net on hedged item		-	40	-	203
Derivatives designated in foreign currency cash flow hedging relationships					
Foreign exchange contracts					
Amount of (gain) loss reclassified from AOCI to Sales	(4	1)	30	49	57
Amount of loss (gain) recognized in OCI on derivatives	23	6	(70)	202	183
Derivatives designated in foreign currency net investment hedging relationships					
Foreign exchange contracts					
Amount of gain recognized in Other (income) expense, net on derivatives (1)	(:	5)	(1)	(15)	(9)
Amount of loss (gain) recognized in OCI on derivatives	5	1	124	(2)	158
Derivatives not designated in a hedging relationship					
Foreign exchange contracts					
Amount of loss (gain) recognized in Other (income) expense, net on derivatives (2)	15	7	(351)	131	(31)
Amounts of loss recognized in Sales on hedged item	1	7	-	17	-

At September 30, 2012, the Company estimates \$103 million of pretax net unrealized losses 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)	S Fair Value	eptember 30, Amortized Cost			Fair Value	December 3 Amortized Cost	Gross U	nrealized Losses
Corporate notes and bonds	\$ 3,705	\$ 3,650	\$ 56	\$ (1)	\$ 2,032	\$ 2,024	\$ 16	\$ (8)
U.S. government and agency securities	1,156	1,154	2	-	1,021	1,018	3	-
Asset-backed securities	648	644	4	-	292	292	1	(1)
Mortgage-backed securities	334	334	2	(2)	223	223	1	(1)
Commercial paper	168	168	-	-	1,029	1,029	-	-
Foreign government bonds	72	71	1	-	72	72	-	-
Other debt securities	-	-	-	-	3	1	2	-
Equity securities	420	384	36	-	397	383	14	-

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

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

\$ 6,503 \$ 6,405 \$ 101 \$ (3) \$ 5,069 \$ 5,042 \$ 37 \$ (10)

Available-for-sale debt securities included in *Short-term investments* totaled \$757 million at September 30, 2012. Of the remaining debt securities, \$4.7 billion mature within five years. At September 30, 2012, there were no debt securities pledged as collateral.

#### **Fair Value Measurements**

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

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

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

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

(\$ in millions)	Quoted Pric In Active Markets fo Identical Ass	Significant or Other Set Observable Inputs (Level 2)	Significant Inobservable Inputs	·	Quoted Pric In Active Markets for dentical Ass	Significant Other Observable sets Inputs (Level 2)	Significant Jnobservable Inputs (Level 3) per 31, 2011	Jsing Total
Assets								
Investments								
Corporate notes and bonds	\$ -	\$ 3,705	\$ - :	\$ 3,705	\$ -	\$ 2,032	\$ - 3	\$ 2,032
U.S. government and agency securities	-	1,156	-	1,156	-	1,021	-	1,021
Asset-backed securities (1)	-	648	-	648	-	292	-	292
Mortgage-backed securities (1)	-	334	-	334	-	223	-	223
Commercial paper	-	168	-	168	-	1,029	-	1,029
Foreign government bonds	-	72	-	72	-	72	-	72
Equity securities	209	25	-	234	205	22	-	227
Other debt securities	-	-	-	-	-	3	-	3
	209	6,108	-	6,317	205	4,694	-	4,899
Other assets								
Securities held for employee compensation	186	-	-	186	170	-	-	170
Derivative assets (2)								
Purchased currency options	-	541	-	541	-	613	-	613
Forward exchange contracts	-	45	-	45	-	142	-	142

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	-	586	-	586	-	755	-	755
Total assets	\$ 395	\$ 6,694	\$ -	\$ 7,089	\$ 375	\$ 5,449	\$ -	\$ 5,824
Liabilities								
Derivative liabilities (2)								
Forward exchange contracts	\$ -	\$ 176	\$ -	\$ 176	\$ -	\$ 107	\$ -	\$ 107
Written currency options	-	4	-	4	-	1	-	1
Total liabilities	\$ -	\$ 180	\$ -	\$ 180	\$ -	\$ 108	\$ -	\$ 108

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

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

There were no transfers between Level 1 and Level 2 during the first nine months of 2012. As of September 30, 2012, *Cash and cash equivalents* of \$17.4 billion included \$16.6 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 September 30, 2012 was \$22.1 billion compared with a carrying value of \$19.6 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 50% 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 September 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 19%, 41%, 30% and 10% related to Greece, Italy, Spain and Portugal, respectively. As of September 30, 2012, the Company s total accounts receivable outstanding for more than one year were approximately \$300 million, of which approximately 60% related to accounts receivable in Greece, Italy, Spain and Portugal, mostly comprised of hospital and public sector receivables.

During the third quarter of 2012, the Company collected approximately \$60 million of accounts receivable from the government of Portugal, which pertained to accounts receivable outstanding from 2011 and prior. 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 counterparty. As of September 30, 2012 and December 31, 2011, the Company had received cash collateral of \$313

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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 September 30, 2012 or December 31, 2011.

#### 6. Inventories

Inventories consisted of:

	Septe	mber 30,	December 31,	
(\$ in millions)	2	012	2	011
Finished goods	\$	1,952	\$	1,983
Raw materials and work in process		5,971		5,396
Supplies		264		297
Total (approximates current cost)		8,187		7,676
Reduction to LIFO costs		(10)		(43)
	\$	8,177	\$	7,633
Recognized as:				
Inventories	\$	6,731	\$	6,254
Other assets		1,446		1,379

Amounts recognized as *Other assets* are comprised almost entirely of raw materials and work in process inventories. At both September 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 \$191 million and \$127 million at September 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 third quarter of 2012 and 2011, the Company recorded \$40 million and \$22 million, respectively, and during the first nine months of 2012 and 2011, recorded \$176 million and \$343 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 subsequently deemed to have no alternative use in the period. Certain of the charges in 2011 were also attributable to compounds that were out-licensed to a third party for consideration that was less than the related asset s carrying value. Also, during the first nine months 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:

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	Three Months Ended September 30,					Nine Months Ended September 30,				
(\$ in millions)	2	2012	2	2011	2	2012	2	2011		
AstraZeneca LP Other (1)	\$	134 24	\$	141 20	\$	387 23	\$	318 36		
o uno	\$	158	\$	161	\$	410	\$	354		

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

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

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

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

Summarized financial information for AZLP is as follows:

(\$ in millions)	Three Mo Septer 2012	nber 30			nded ), 2011		
Sales	\$ 1,232	\$	1,124	\$	3,424	\$	3,460
Materials and production costs	561		464		1,520		1,524
Other expense, net	204		357		936		1,004
Income before taxes (1)	\$ 467	\$	303	\$	968	\$	932

Johnson & Johnson Merck Consumer Pharmaceuticals Company

In September 2011, Merck sold its 50% interest in the Johnson & Johnson Merck Consumer Pharmaceuticals Company (JJMCP) joint venture to J&J. The venture between Merck and J&J was formed in 1989 to develop, manufacture, market and distribute certain over-the-counter consumer products in the United States and Canada. Merck received a one-time payment of \$175 million and recognized a pretax gain of \$136 million in the third quarter of 2011 reflected in *Other (income) expense, net*. The partnership assets also included a manufacturing facility.

#### 9. Long-Term Debt

In September 2012, the Company closed an underwritten public offering of \$2.5 billion senior unsecured notes consisting of \$1.0 billion aggregate principle amount of 1.1% notes due 2018, \$1.0 billion aggregate principle amount of 2.4% notes due 2022 and \$500 million aggregate principle amount of 3.6% notes due 2042. Interest on the notes is payable semi-annually. The notes of each series are redeemable in whole or in part at any time at the Company s option at varying redemption prices. Proceeds from the notes will be used for general corporate purposes, including making contributions to the Company s pension plans and the repayment of outstanding commercial paper and upcoming debt maturities.

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

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

purposes. The Company has not drawn funding from this facility.

# 10. 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 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 are no U.S. *Vioxx* Product Liability Lawsuits currently scheduled for trial in 2012, and none scheduled for 2013. 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*. On October 15, 2012, the parties executed a settlement agreement to resolve the litigation. The Company established a reserve of \$39 million in the third quarter of 2012 in connection with that settlement agreement, which is the minimum amount that the Company is required to pay under the agreement. The agreement is subject to court approval and certain other conditions.

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 state Attorneys General. 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.

#### 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. On April 10, 2012, plaintiffs filed a motion for class certification. Briefing is ongoing. Discovery is currently proceeding in accordance with the court s scheduling order.

As previously disclosed, several individual securities lawsuits filed by foreign institutional investors also are consolidated with the *Vioxx* Securities Lawsuits. In October 2011, plaintiffs filed amended complaints in each of the pending individual securities lawsuits. Also in October 2011, a new individual securities lawsuit (the KBC Lawsuit ) was filed in the District of New Jersey by several foreign institutional investors; that case is also consolidated with the *Vioxx* Securities Lawsuits. 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. On September 15, 2012, defendants answered the complaints in all individual actions other than the KBC Lawsuit; on the same day, defendants moved to dismiss the complaint in the KBC Lawsuit on statute of limitations grounds. The motion to dismiss in the KBC Lawsuit is fully briefed and pending before the court. Discovery is currently proceeding in the individual securities lawsuits together with discovery in the class action.

#### Insurance

The Company has Directors and Officers insurance coverage applicable to the *Vioxx* Securities Lawsuits with remaining stated upper limits of approximately \$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.

#### 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.

#### 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 and 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. On April 19, 2012, the U.S. District Court for the District of Massachusetts accepted the resolution and thereafter the Company made the payments noted above.

#### 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. The Company has established a reserve with respect to the Canada Settlement Agreement and with respect to certain other *Vioxx* Product Liability Lawsuits, including the Missouri matter discussed above. The Company also has an immaterial remaining reserve relating to the *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.

#### **Other Product Liability Litigation**

#### Fosamax

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving *Fosamax* (the *Fosamax* Litigation ). As of September 30, 2012, approximately 4,005 cases, which include approximately 4,580 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 1,215 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 2,785 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 955 of the cases are before Judge Keenan. In the first *Fosamax* ONJ MDL trial, *Boles v. Merck*, the *Fosamax* ONJ MDL court declared a mistrial because the eight person jury could not reach a unanimous verdict. The *Boles* case was retried in June 2010 and resulted in a verdict in favor of the plaintiff in the amount of \$8 million. Merck filed post-trial motions seeking judgment as a matter of law or, in the alternative, a new trial. In October 2010, the court denied Merck s post-trial motions but *sua sponte* ordered a remittitur reducing the verdict to \$1.5 million. Plaintiff rejected the remittitur ordered by the court and requested a new trial on damages. Plaintiff and Merck subsequently entered into a confidential stipulation as to the amount of plaintiff s damages that enabled Merck to appeal the underlying judgment, and Merck filed its appeal in the *Boles* case on October 18, 2012. 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. Plaintiffs have filed an appeal in two of the cases *Graves v. Merck* and *Secrest v. Merck*.

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* was set for trial on October 15, 2012, but plaintiff dismissed the case and refiled it in the *Fosamax* ONJ MDL. *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 September 30, 2012, approximately 255 ONJ cases were pending against Merck in Atlantic County, New Jersey. In July 2009, Judge Higbee entered a Case Management Order (and various amendments thereto) setting forth a schedule that contemplates completing fact and expert discovery in an initial group of cases to be reviewed for trial. In February 2011, the jury in *Rosenberg v. Merck*, the first trial in the New Jersey coordinated proceeding, returned a verdict in Merck s favor. In April 2012, the jury in *Sessner v. Merck*, the second case tried in New Jersey, also returned a verdict in Merck s favor. Plaintiffs have filed an appeal in both cases.

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* Femur Fracture MDL). As a result of the JPML order, approximately 640 cases were pending in the *Fosamax* Femur Fracture MDL as of September 30, 2012. A Case Management Order has been entered that requires the parties to review 40 cases (later reduced to 33 cases). Judge Joel Pisano has selected four cases from that group to be tried as the initial bellwether cases in the *Fosamax* Femur Fracture MDL and has set an April 8, 2013 trial date for the first bellwether case, which will be *Glynn v. Merck*.

As of September 30, 2012, approximately 1,740 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. Judge Higbee has set March 4, 2013 as the date for the first trial of the New Jersey state Femur Fracture cases. On September 27, 2012, Judge Higbee selected the *Unanski v. Merck* and *Su v. Merck* cases to be tried jointly beginning on the March 4, 2013 trial date.

As of September 30, 2012, approximately 380 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 September 30, 2012, there were approximately 1,220 *NuvaRing* cases. Of these cases, approximately 1,030 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 185 are pending in coordinated discovery proceedings in the Bergen County Superior Court of New Jersey before Judge Brian R. Martinotti. Five 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 20 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 expert discovery has been completed in those first trial pool cases. Certain replacement trial pool cases remain in fact discovery.

The Company has filed motions related to the admissibility of expert testimony and motions for summary judgment. Following the completion of briefing, the Company expects substantive hearings on those motions to take place in late 2012 or early 2013. 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 September 30, 2012, approximately 265 lawsuits involving a total of approximately 415 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 been filed against Merck. The lawsuits, which are in their early stages, are pending in various federal courts and in state court in New Jersey. The federal lawsuits have been consolidated for pretrial purposes in a federal MDL before Judge John Gleeson of the Eastern District of New York. The matters pending in state court in New Jersey have been consolidated before Judge Jessica Mayer in Middlesex County. The Company intends to defend against these lawsuits.

## Vytorin/Zetia Litigation

As previously disclosed, in April 2008, a Merck shareholder filed a putative class action lawsuit in federal court which has been consolidated in the District of New Jersey with another federal securities lawsuit under the caption *In re Merck & Co., Inc. Vytorin Securities Litigation*. An amended consolidated complaint was filed in October 2008 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, as amended. On March 1, 2012, defendants filed a motion for summary judgment. On September 25, 2012, the court granted lead plaintiffs amended motion for class certification and denied defendants motion for summary judgment. On October 9, 2012, Merck filed a petition for leave to appeal the class certification decision to the Third Circuit Court of Appeals, which lead plaintiffs opposed on October 19, 2012. The petition for interlocutory review is pending before the Third Circuit. A trial date has been set by the district court for March 4, 2013.

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, as amended. 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. On September 25, 2012, the court granted lead plaintiffs amended motion for class certification and denied defendants motions for summary judgment. On October 9, 2012, Schering-Plough and the underwriter defendants filed separate petitions for leave to appeal the class certification decision to the Third Circuit Court of Appeals, which lead plaintiffs opposed on October 19, 2012. The petitions for interlocutory review are pending before the Third Circuit. A trial date has been set by the district court for March 4, 2013.

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 were consolidated under the caption *In re Merck & Co., Inc. Vytorin ERISA Litigation*. A consolidated amended complaint was filed in February 2009, and named as defendants Merck and various current and former members of the Company's Board of Directors. The plaintiffs alleged 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 fairness hearing on final approval of the settlement for September 25, 2012. Following the fairness hearing, the court granted plaintiffs motion for final approval of the settlement agreement on September 28, 2012. On October 26, 2012, the court entered an order and final judgment which, among other things, provides broad releases with prejudice. 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 the plan of allocation approved by the court.

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.

#### **Commercial Litigation**

#### AWP Litigation

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

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

The Company is also appealing the recommendation of a court-appointed Special Master that Merck be reinstated 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 AWPs 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

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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 has filed a petition for certiorari with the U.S. Supreme Court seeking review of the Third Circuit s reversal of summary judgment.

Nexium Anti-Trust Litigation

In September 2012, the Company and certain of its subsidiaries were among the defendants named in a putative class action lawsuit brought on behalf of direct purchasers of Nexium in federal court in New Jersey. The lawsuit alleges violations of federal antitrust law arising from settlements reached by and among the defendants to resolve certain patent litigation relating to the entry of generic esomeprazole on the U.S. market. Specifically, the plaintiffs contend that these settlements had the effect of impermissibly delaying the entry of generic esomeprazole in the United States and extending the monopoly power of Nexium, leading to higher average market prices. The Company denies any wrongdoing and intends to defend the lawsuit, which bears the caption *Value Drug Company and Burlington Drug Co. Inc., et al. v. AstraZeneca PLC, et al.* 

### **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, *Emend* for Injection, *Nasonex*, Nexium, *Vytorin* and *Zetia*. Similar lawsuits defending the Company s patent rights may exist in other countries. The Company intends to vigorously defend its patents, which it believes are valid, against infringement by generic companies attempting to market products prior to the expiration of such patents. As with any litigation, there can be no assurance of the outcomes, which, if adverse, could result in significantly shortened periods of exclusivity for these products and, with respect to products acquired through mergers and acquisitions, potentially significant intangible asset impairment charges.

AzaSite In May 2011, a patent infringement 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.

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 Teva Parenteral Medicines, Inc. (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, whichever may occur earlier.

Vytorin In December 2009, a patent infringement lawsuit was filed in the United States against Mylan Pharmaceuticals, Inc. (Mylan) in respect of Mylan s application to the FDA seeking pre-patent expiry approval to sell a generic version of Vytorin. A trial against Mylan jointly in respect of Zetia and Vytorin was conducted in December 2011. In April 2012, the court issued a decision finding the patent valid and enforceable. Accordingly, Mylan s ANDA will not be approvable until April 25, 2017. 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. 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. In September 2012, a patent infringement suit was filed in the United States against Sandoz in respect of Sandoz s application to the FDA seeking pre-patent expiry approval to market a generic version of Zetia. The lawsuit automatically stays FDA approval of Sandoz s ANDA until February 2015 or until an adverse court decision, if any, whichever may occur earlier.

### Other Litigation

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

## **Legal Defense Reserves**

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company s legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of September 30, 2012 and December 31, 2011 of approximately \$240 million 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.

# 11. Equity

(\$ and shares in millions)	Comn Shares		tock Value		Other Paid-In Capital	_	Retained Earnings		cumulated Other prehensive Loss	Tre Shares	asur	y Stock Cost	Co	Non- ntrolling nterests		Total
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.	-		-		-		4,760		_	-		-		-		4,760
Cash dividends declared on																
common stock	-		-		-		(3,533)		-	-		-		-		(3,533)
Treasury stock shares purchased	-		-		-		-		-	41		(1,359)		-		(1,359)
Share-based compensation plans																
and other	-		-		16		-		-	(11)		377		-		393
Other comprehensive income	-		-		-		-		503	-		-		-		503
Net income attributable to																
noncontrolling interests	-		-		-		-		-	-		-		89		89
Distributions attributable to																
noncontrolling interests	-		-		-		-		-	-		-		(62)		(62)
Balance September 30, 2011	3,577	\$	1,788	\$	40,717	\$	38,763	\$	(2,713)	525	\$	(23,415)	\$	2,456	\$	57,596
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	3,577	Ψ	1,700	Ψ	10,005	Ψ	50,770	Ψ	(3,132)	330	Ψ	(23,772)	Ψ	2,120	Ψ	50,715
Merck & Co., Inc.	_		_		_		5.261		_	_		_		_		5,261
Cash dividends declared on							,									-,
common stock	_		-		_		(3,861)		_	-		-		_		(3,861)
Treasury stock shares purchased	-		-		-		-		-	36		(1,439)		-		(1,439)
Share-based compensation plans																. , ,
and other	-		-		(192)		-		_	(39)		1,369		-		1,177
					. /					` ′						

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Other comprehensive income	-	-	-	-	92	-	-	-	92
Net income attributable to									
noncontrolling interests	-	-	-	-	-	-	-	89	89
Distributions attributable to									
noncontrolling interests	-	-	-	-	-	-	-	(50)	(50)
Balance September 30, 2012	3,577	\$ 1,788	\$ 40,471	\$ 40,390	\$ (3,040)	533	\$ (23,862)	\$ 2,465	\$ 58,212

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.

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

									Acc	umulated
					Е	mployee	Cu	mulative		Other
						Benefit	Tr	anslation	Compi	ehensive
(\$ in millions)	Deriv	atives	Inves	stments		Plans	Ad	ljustment		Loss
Balance January 1, 2011	\$	41	\$	31	\$	(2,043)	\$	(1,245)	\$	(3,216)
Other comprehensive (loss) income		(77)		(11)		59		532		503
Balance at September 30, 2011	\$	(36)	\$	20	\$	(1,984)	\$	(713)	\$	(2,713)
Balance January 1, 2012	\$	4	\$	21	\$	(2,346)	\$	(811)	\$	(3,132)
Other comprehensive (loss) income		(99)		62		45		84		92
Balance at September 30, 2012	\$	(95)	\$	83	\$	(2,301)	\$	(727)	\$	(3,040)

Included in cumulative translation adjustment are pretax gains of approximately \$393 million for the first nine months of 2011 relating to translation impacts of intangible assets recorded in conjunction with the Merger.

#### 12. 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:

	Th	ree Mor Septem			N	ine Mor Septen		
(\$ in millions)	20	012	20	011	20	012	2	2011
Pretax share-based compensation expense	\$	88	\$	86	\$	257	\$	287
Income tax benefit		(28)		(30)		(81)		(99)
Total share-based compensation expense, net of taxes	\$	60	\$	56	\$	176	\$	188

During the first nine months of 2012 and 2011, the Company granted 7 million RSUs with a weighted-average grant date fair value of \$39.38 per RSU and 8 million RSUs with a weighted-average grant date fair value of \$36.44 per RSU, respectively.

During the first nine months of 2012 and 2011, the Company granted 7 million options with a weighted-average exercise price of \$39.39 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 nine months of 2012 and 2011 was \$5.47 and \$5.37 per option, respectively, and was determined using the following assumptions:

	Nine Mont Septemb	
	2012	2011
	4.40	4.00
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 September 30, 2012, there was \$449 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 1.8 years. For segment reporting, share-based compensation costs are unallocated expenses.

#### 13. 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:

	1	Three Mo	onths En		1	Nine Moi Septen		
(\$ in millions)	20	)12	2	2011	2012		2	2011
Service cost	\$	133	\$	158	\$	416	\$	461
Interest cost		162		182		494		541
Expected return on plan assets		(239)		(243)		(727)		(728)
Net amortization		48		58		144		149
Termination benefits		4		15		13		32
Curtailments		(4)		(6)		(5)		(16)
Settlements		-		_		-		(1)
	\$	104	\$	164	\$	335	\$	438

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:

	Т	nded ,	Nine Months Ended September 30,					
(\$ in millions)	20	12	2	011	20	012	2	011
Service cost	\$	22	\$	27	\$	64	\$	83
Interest cost		31		35		93		106
Expected return on plan assets		(34)		(35)		(102)		(106)
Net amortization		(9)		(4)		(25)		(13)
Termination benefits		5		5		10		11
Curtailments		(2)		(1)		(6)		-
	\$	13	\$	27	\$	34	\$	81

In connection with restructuring actions (see Note 2), termination charges for the three and nine months ended September 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.

The Company expects to contribute approximately \$1.75 billion to its defined benefit pension plans during 2012.

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### 14. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

	Т	Three Mo		Nine Mont Septem		ed
(\$ in millions)	20	012	2011	2012	2	2011
Interest income	\$	(47)	\$ (32)	\$ (177)	\$	(102)
Interest expense		178	176	524		522
Exchange losses		50	59	130		102
Other, net		19	(137)	(31)		287
	\$	200	\$ 66	\$ 446	\$	809

As a result of significant collections of accounts receivable in Spain (see Note 5), the Company recognized incremental interest income of approximately \$35 million in the first nine 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 third quarter and first nine months of 2011 includes a \$136 million gain on the disposition of the Company s interest in the JJMCP joint venture. In addition, Other, net for the first nine 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 nine months ended September 30, 2012 and 2011 was \$583 million and \$261 million, respectively, which excludes commitment fees. Interest paid for the nine months ended September 30, 2011 is net of \$288 million received by the Company from the termination of certain interest rate swap contracts during the period (see Note 5).

# 15. Taxes on Income

The effective tax rates of 20.5% and 27.8% for the third quarter and first nine months of 2012 and 26.7% and 15.7% for the third quarter and first nine 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 third quarter and first nine months of 2012 also reflect the favorable impacts of a tax settlement with the Canada Revenue Agency (the CRA) as discussed below and the realization of foreign tax credits. The effective tax rate for the first nine months of 2011 also reflects the net favorable impact relating to the settlement of Merck s 2002-2005 federal income tax audit as discussed below, 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, as well as the unfavorable impact of the \$500 million charge related to the resolution of the arbitration proceeding with J&J.

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

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.

#### 16. 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.

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

(\$ and shares in millions except per share amounts)	Three Months Ended September 30, 2012 2011					Nine Mor Septen 2012		
Basic Earnings per Common Share								
Net income attributable to Merck & Co., Inc.	\$	1,729	\$	1,692	\$	5,261	\$	4,760
Less: Income allocated to participating securities		-		3		4		12
Net income allocated to common shareholders	\$	1,729	\$	1,689	\$	5,257	\$	4,748
Average common shares outstanding		3,045		3,070		3,043		3,079
	\$	0.57	\$	0.55	\$	1.73	\$	1.54
Earnings per Common Share Assuming Dilution								
Net income attributable to Merck & Co., Inc.	\$	1,729	\$	1,692	\$	5,261	\$	4,760
Less: Income allocated to participating securities		-		3		4		12
Net income allocated to common shareholders	\$	1,729	\$	1,689	\$	5,257	\$	4,748
Average common shares outstanding		3,045		3,070		3,043		3,079
Common shares issuable (1)		34		21		34		23
Average common shares outstanding assuming dilution	¢	3,079	¢	3,091	¢	3,077	¢	3,102
	\$	0.56	\$	0.55	\$	1.71	\$	1.53

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

For the three months ended September 30, 2012 and 2011, 97 million and 170 million, respectively, and for the first nine months of 2012 and 2011, 111 million and 170 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.

#### 17. Segment Reporting

The Company s operations are principally managed on a products basis and are comprised of four operating segments 
Pharmaceutical, Animal Health, Consumer Care and Alliances (which includes revenue and equity income from the Company s relationship with AZLP). The Animal Health, Consumer Care and Alliances segments are not material for separate reporting. The Pharmaceutical segment includes human health pharmaceutical and vaccine products marketed either directly by the Company or through joint ventures. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities. A large component of pediatric and adolescent vaccines is sold to the U.S. Centers for Disease Control and Prevention Vaccines for Children program, which is funded by the U.S. government. Additionally, the Company sells vaccines to the Federal government for placement into vaccine stockpiles. The Company also has animal health operations that discover, develop, manufacture and market animal health products, including vaccines, which the Company sells to veterinarians, distributors and animal producers. Additionally, the Company has consumer care operations that develop, manufacture and market over-the-counter, foot care and sun care products, which are sold through wholesale and retail drug, food chain and mass merchandiser outlets.

Sales of the Company s products were as follows:

	Septer	onths Ended onber 30,	Nine Mon Septem	iber 30,
(\$ in millions)	2012	2011	2012	2011
Primary Care and Women s Health				
Cardiovascular				
Zetia	\$ 645	\$ 614	\$ 1,891	\$ 1,788
Vytorin	423	469	1,312	1,407
Diabetes and Obesity				
Januvia	975	846	2,952	2,364
Janumet	405	350	1,207	977
Respiratory				
Singulair	602	1,336	3,373	4,018
Nasonex	292	266	960	962
Clarinex	64	128	337	492
Asmanex	42	42	141	149
Dulera	52	22	140	59
Women s Health and Endocrine				
Fosamax	152	215	522	644
NuvaRing	156	159	459	455
Follistim AQ	111	129	352	404
Implanon	93	80	254	220
Cerazette	64	74	202	199
Other				
Maxalt	166	156	476	460
Arcoxia	109	108	338	321
Avelox	30	59	146	227
Hospital and Specialty				
Immunology				
Remicade	490	561	1,527	2,156
Simponi	86	74	236	203
Infectious Disease				
Isentress	399	343	1,133	972
PegIntron	165	163	510	482
Cancidas	163	150	474	476
Victrelis	149	31	387	53
Invanz	118	107	329	296
Primaxin	109	124	301	397
Noxafil	66	61		