

Merck & Co. Inc.  
Form 10-Q  
November 08, 2011

**Table of Contents**

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
FORM 10-Q**

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934**

**For the quarterly period ended September 30, 2011**

**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, 2011: 3,047,921,407

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting  
company

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes

No

**TABLE OF CONTENTS**

Part I Financial Information

Item 1. Financial Statements

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

Item 4. Controls and Procedures

PART II Other Information

Item 1. Legal Proceedings

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

Item 6. Exhibits

Signatures

EXHIBIT INDEX

EX-31.1

EX-31.2

EX-32.1

EX-32.2

EX-101 INSTANCE DOCUMENT

EX-101 SCHEMA DOCUMENT

EX-101 CALCULATION LINKBASE DOCUMENT

EX-101 LABELS LINKBASE DOCUMENT

EX-101 PRESENTATION LINKBASE DOCUMENT

EX-101 DEFINITION LINKBASE DOCUMENT

---

**Table of Contents****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)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Sales	\$ 12,022	\$ 11,125	\$ 35,753	\$ 33,893
Costs, Expenses and Other				
Materials and production	4,352	4,191	12,695	13,956
Marketing and administrative	3,340	3,192	10,029	9,589
Research and development	1,954	2,322	6,048	6,552
Restructuring costs	119	50	773	864
Equity income from affiliates	(161)	(236)	(354)	(417)
Other (income) expense, net	66	1,108	809	995
	9,670	10,627	30,000	31,539
Income Before Taxes	2,352	498	5,753	2,354
Taxes on Income	628	126	904	872
Net Income	\$ 1,724	\$ 372	\$ 4,849	\$ 1,482
Less: Net Income Attributable to Noncontrolling Interests	32	30	89	89
Net Income Attributable to Merck & Co., Inc.	\$ 1,692	\$ 342	\$ 4,760	\$ 1,393
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	\$ 0.55	\$ 0.11	\$ 1.54	\$ 0.45
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	\$ 0.55	\$ 0.11	\$ 1.53	\$ 0.44
Dividends Declared per Common Share	\$ 0.38	\$ 0.38	\$ 1.14	\$ 1.14

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

**Table of Contents**

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

	September 30, 2011	December 31, 2010
<b>Assets</b>		
Current Assets		
Cash and cash equivalents	\$ 14,253	\$ 10,900
Short-term investments	1,323	1,301
Accounts receivable (net of allowance for doubtful accounts of \$129 in 2011 and \$104 in 2010)	8,136	7,344
Inventories (excludes inventories of \$1,382 in 2011 and \$1,194 in 2010 classified in Other assets see Note 6)	6,239	5,868
Deferred income taxes and other current assets	4,158	3,651
Total current assets	34,109	29,064
Investments	2,423	2,175
Property, Plant and Equipment, at cost, net of accumulated depreciation of \$15,674 in 2011 and \$13,481 in 2010	16,383	17,082
Goodwill	12,228	12,378
Other Intangibles, Net	35,822	39,456
Other Assets	5,569	5,626
	\$ 106,534	\$ 105,781
<b>Liabilities and Equity</b>		
Current Liabilities		
Loans payable and current portion of long-term debt	\$ 2,455	\$ 2,400
Trade accounts payable	2,282	2,308
Accrued and other current liabilities	9,228	8,514
Income taxes payable	1,462	1,243
Dividends payable	1,166	1,176
Total current liabilities	16,593	15,641
Long-Term Debt	15,692	15,482
Deferred Income Taxes and Noncurrent Liabilities	16,653	17,853

Merck & Co., Inc. Stockholders' Equity		
Common stock, \$0.50 par value		
Authorized - 6,500,000,000 shares		.
Issued - 3,576,948,356 shares in 2011 and 2010	1,788	1,788
Other paid-in capital	40,717	40,701
Retained earnings	38,763	37,536
Accumulated other comprehensive loss	(2,713)	(3,216)
	78,555	76,809
Less treasury stock, at cost 525,000,622 shares in 2011 and 494,841,533 shares in 2010	23,415	22,433
Total Merck & Co., Inc. stockholders' equity	55,140	54,376
Noncontrolling Interests	2,456	2,429
Total equity	57,596	56,805
	\$ 106,534	\$ 105,781

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

- 3 -

---

**Table of Contents**

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

	Nine Months Ended September 30,	
	2011	2010
<b>Cash Flows from Operating Activities</b>		
Net income	\$ 4,849	\$ 1,482
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	5,566	5,515
Intangible asset impairment charges	461	216
Equity income from affiliates	(354)	(417)
Dividends and distributions from equity affiliates	186	264
Gain on AstraZeneca asset option exercise		(443)
Deferred income taxes	(974)	(743)
Share-based compensation	287	400
Other	(207)	227
Net changes in assets and liabilities	(664)	782
 Net Cash Provided by Operating Activities	 9,150	 7,283
<b>Cash Flows from Investing Activities</b>		
Capital expenditures	(1,120)	(1,018)
Purchases of securities and other investments	(4,686)	(5,826)
Proceeds from sales of securities and other investments	4,740	3,726
Dispositions of businesses, net of cash divested	323	
Acquisitions of businesses, net of cash acquired	(373)	(152)
Proceeds from AstraZeneca option exercise		647
Other	(90)	133
 Net Cash Used in Investing Activities	 (1,206)	 (2,490)
<b>Cash Flows from Financing Activities</b>		
Net change in short-term borrowings	1,356	1,573
Payments on debt	(1,277)	(689)
Purchases of treasury stock	(1,359)	(1,593)
Dividends paid to stockholders	(3,526)	(3,559)
Proceeds from exercise of stock options	194	313
Other	(61)	(191)
 Net Cash Used in Financing Activities	 (4,673)	 (4,146)
 Effect of Exchange Rate Changes on Cash and Cash Equivalents	 82	 (84)

Net Increase in Cash and Cash Equivalents	3,353	563
Cash and Cash Equivalents at Beginning of Year	10,900	9,311
Cash and Cash Equivalents at End of Period	\$ 14,253	\$ 9,874

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

- 4 -

---



**Table of Contents**

**Notes to Consolidated Financial Statements (unaudited)**

**1. Basis of Presentation**

The accompanying unaudited interim consolidated financial statements 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 & Co., Inc.'s Form 10-K filed on February 28, 2011.

On November 3, 2009, Merck & Co., Inc. ( Old Merck ) and Schering-Plough Corporation ( Schering-Plough ) merged (the Merger ). In the Merger, Schering-Plough acquired all of the shares of Old Merck, which became a wholly owned subsidiary of Schering-Plough and was renamed Merck Sharp & Dohme Corp. Schering-Plough continued as the surviving public company and was renamed Merck & Co., Inc. ( New Merck or the Company ). However, for accounting purposes only, the Merger was treated as an acquisition with Old Merck considered the accounting acquirer. References in these financial statements to Merck for periods prior to the Merger refer to Old Merck and for periods after the completion of the Merger to New Merck.

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 October 2009, the Financial Accounting Standards Board ( FASB ) issued new guidance for revenue recognition with multiple deliverables. The Company adopted this guidance prospectively for revenue arrangements entered into or materially modified on or after January 1, 2011. This guidance eliminates the residual method under the current guidance and replaces it with the relative selling price method when allocating revenue in a multiple deliverable arrangement. The selling price for each deliverable shall be determined using vendor specific objective evidence of selling price, if it exists, otherwise third-party evidence of selling price shall be used. If neither exists for a deliverable, the vendor shall use its best estimate of the selling price for that deliverable. The effect of adoption on the Company's financial position and results of operations was not material.

*Recently Issued Accounting Standards*

In June 2011, the FASB issued amended guidance on the presentation of comprehensive income in financial statements. This amendment provides companies the option to present the components of net income and other comprehensive income either as one continuous statement of comprehensive income or as two separate but consecutive statements. It eliminates the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity. The provisions of this new guidance are effective for interim and annual periods beginning in 2012 although earlier adoption is permitted. The adoption of this new guidance will not impact the Company's financial position, results of operations or cash flows.

In September 2011, the FASB issued amended guidance that simplifies how an entity tests goodwill for impairment. The amended guidance will allow companies to first assess qualitative factors to determine if it is more-likely-than-not that the fair value of a reporting unit is less than its carrying value and whether to perform the two-step goodwill impairment test. The updated guidance is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011, with early adoption permitted. On October 1, 2011, the Company early adopted the amended guidance in conjunction with its annual impairment testing.

**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)**2. Restructuring***Merger Restructuring Program*

In February 2010, 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. Additional actions under the program continued during 2010. On July 29, 2011, the Company announced the latest phase of the Merger Restructuring Program during which the Company expects to reduce its workforce measured at the time of the Merger by an additional 12% to 13% across the Company worldwide. A majority of the workforce reductions in this phase of the Merger Restructuring Program relate to manufacturing (including Animal Health), administrative and headquarters organizations. Previously announced workforce reductions of approximately 17% in earlier phases of the program primarily reflect the elimination of positions in sales, administrative and headquarters organizations, as well as from the sale or closure of certain manufacturing and research and development sites and the consolidation of office facilities. The Company will continue to hire employees in strategic growth areas of the business as necessary. The Company will continue to pursue productivity efficiencies and evaluate its manufacturing supply chain capabilities on an ongoing basis which may result in future restructuring actions.

The Company recorded total pretax restructuring costs of \$255 million and \$384 million in the third quarter of 2011 and 2010, respectively, and \$1.2 billion and \$1.5 billion for the first nine months of 2011 and 2010, respectively, related to this program. Since inception of the Merger Restructuring Program through September 30, 2011, Merck has recorded total pretax accumulated costs of approximately \$4.5 billion and eliminated approximately 14,200 positions comprised of employee separations, as well as the elimination of contractors and more than 2,500 positions that were vacant at the time of the Merger. 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 completed by 2015, with the total cumulative pretax costs estimated to be approximately \$5.8 billion to \$6.6 billion. The Company estimates that approximately two-thirds of the cumulative pretax costs relate to cash outlays, primarily related to employee separation expense. Approximately one-third of the cumulative pretax costs are non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested.

*2008 Global Restructuring Program*

In October 2008, Old 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 \$20 million were recorded in the third quarter of 2011 and \$25 million and \$130 million in the first nine months of 2011 and 2010, respectively, related to the 2008 Restructuring Program. Since inception of the 2008 Restructuring Program through September 30, 2011, Merck has recorded total pretax accumulated costs of \$1.6 billion and eliminated approximately 6,090 positions comprised of employee separations and the elimination of contractors and vacant positions. The 2008 Restructuring Program is expected to be completed by the end of 2011, with the exception of certain manufacturing-related actions, 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.

**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)

For segment reporting, restructuring charges are unallocated expenses.

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

(\$ in millions)	Three Months Ended September 30, 2011				Nine Months Ended September 30, 2011			
	Separation Costs	Accelerated Depreciation	Other	Total	Separation Costs	Accelerated Depreciation	Other	Total
<i>Merger Restructuring Program</i>								
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	670		95	765
	63	130	62	255	670	407	99	1,176
<i>2008 Restructuring Program</i>								
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
	\$ 68	\$ 140	\$ 67	\$ 275	\$ 667	\$ 423	\$ 111	\$ 1,201

(\$ in millions)	Three Months Ended September 30, 2010				Nine Months Ended September 30, 2010			
	Separation Costs	Accelerated Depreciation	Other	Total	Separation Costs	Accelerated Depreciation	Other	Total
<i>Merger Restructuring Program</i>								
Materials and production	\$	\$ 13 <sup>(1)</sup>	\$ 41 <sup>(2)</sup>	\$ 54	\$	\$ 188	\$ 62	\$ 250
Marketing and administrative		123 <sup>(1)</sup>	11	134		123	11	134
Research and development		153		153		266	37	303
Restructuring costs	67	(41) <sup>(1)</sup>	17	43	650		160	810
	67	248	69	384	650	577	270	1,497
<i>2008 Restructuring Program</i>								
Materials and production		19	(33) <sup>(2)</sup>	(14)		59	3	62
Marketing and administrative			(4)	(4)			(4)	(4)

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

Research and development		10		10		10		10
Restructuring costs	10		(3)	7	41		21	62
	10	29	(40)	(1)	41	69	20	130
	\$ 77	\$ 277	\$ 29	\$ 383	\$ 691	\$ 646	\$ 290	\$ 1,627

(1) Amounts reflect third quarter reclassifications of certain accelerated depreciation charges, recorded in the second quarter, from Materials and production and Restructuring costs to Marketing and administrative.

(2) Reflects the reclassification of a second quarter \$36 million charge from the 2008 Restructuring Program to the Merger Restructuring Program.

Separation costs are associated with actual headcount reductions, as well as those headcount reductions which were probable and could be reasonably estimated. In the first nine months of 2011, separation costs for the Merger Restructuring Program include a reduction of separation reserves of approximately \$50 million resulting from the Company's decision in the first quarter to retain approximately 380 employees at its Oss, Netherlands research facility that had previously been expected to be separated. In the third quarter of 2011 and 2010, approximately 1,300 positions and 2,175 positions, respectively, were eliminated under the Merger Restructuring Program and approximately 110 positions and 180 positions, respectively, were eliminated under the 2008 Restructuring Program. In the first nine months of 2011 and 2010, approximately 2,635 positions and 9,760 positions, respectively, were eliminated under the Merger Restructuring Program and approximately 290 positions and 955 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.

**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)

Other activity in 2011 and 2010 includes asset abandonment, shut-down and other related costs. Additionally, other activity includes employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans (see Note 12) and share-based compensation costs.

The following table summarizes the charges and spending relating to Merger Restructuring Program and 2008 Restructuring Program activities for the nine months ended September 30, 2011:

<i>(\$ in millions)</i>	Separation Costs	Accelerated Depreciation	Other	Total
<i>Merger Restructuring Program</i>				
Restructuring reserves January 1, 2011	\$ 859	\$	\$ 64	\$ 923
Expense	670	407	99	1,176
(Payments) receipts, net	(417)		(121)	(538)
Non-cash activity		(407)	7	(400)
Restructuring reserves September 30, 2011 <sup>(1)</sup>	\$ 1,112	\$	\$ 49	\$ 1,161
<i>2008 Restructuring Program</i>				
Restructuring reserves January 1, 2011	\$ 196	\$	\$	\$ 196
Expense	(3)	16	12	25
(Payments) receipts, net	(53)		(11)	(64)
Non-cash activity		(16)	(1)	(17)
Restructuring reserves September 30, 2011 <sup>(1)</sup>	\$ 140	\$	\$	\$ 140

<sup>(1)</sup> The cash outlays associated with the Merger Restructuring Program and the 2008 Restructuring Program are expected to be substantially completed by the end of 2013 and 2011, respectively, with the exception of certain actions, principally manufacturing-related, which are expected to be completed by 2015.

*Legacy Schering-Plough Program*

Prior to the Merger, Schering-Plough commenced a Productivity Transformation Program which was designed to reduce and avoid costs and increase productivity. The Company recorded accelerated depreciation costs included in *Materials and production* of \$2 million and \$4 million for the third quarter of 2011 and 2010, respectively, and \$18 million and \$13 million for the first nine months of 2011 and 2010, respectively. In addition, the first nine months of 2010 includes a net gain of \$8 million reflected in *Restructuring costs* primarily related to the sale of a manufacturing facility. The remaining reserve associated with this program was \$30 million at September 30, 2011.

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

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. Certain estimated values are not yet finalized and may be subject to change. The

Company expects to finalize these amounts as soon as possible, but no later than one year from the acquisition date. 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 beginning after 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 leading 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 own all assets of the Merck BioManufacturing Network comprising

- 8 -

---

**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)

facilities located in Research Triangle Park, North Carolina and Billingham, U.K.; and including manufacturing contracts; business support operations and a highly skilled workforce. As part of the agreement with Fujifilm, Merck has committed to certain continued development and manufacturing activities with these two companies. 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, Old 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, Old 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 for *Cozaar* and *Hyzaar* expired in April 2010. In addition, *Cozaar* and *Hyzaar* lost patent protection in a number of major European markets in March 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* (golimumab), 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 ( EU ) following the receipt of pricing and reimbursement approval within the EU. In April 2011, Merck and J&J reached agreement to amend the distribution rights to *Remicade* and *Simponi*. Under the terms of the amended distribution agreement, Merck relinquished exclusive 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 ( Retained Territories ). In addition, beginning July 1, 2011, all profit derived from Merck's exclusive distribution of the two products in the Retained Territories is being equally divided between Merck and J&J. Under the prior terms of the distribution agreement, the contribution income (profit) split, which was at 58% to Merck and 42% percent to J&J, would have declined for Merck and increased for J&J each year until 2014, when it would have been equally divided. J&J also received a one-time payment of \$500 million in April 2011, which the Company recorded as a charge to *Other (income) expense, net* in the first quarter of 2011.

**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)**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*

A significant portion of the Company's revenues are denominated in foreign currencies. The Company has established revenue hedging and balance sheet risk management 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 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 partially hedge 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 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 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 value of the anticipated foreign currency cash flows.

In connection with the Company's revenue hedging program, a purchased collar option strategy may be utilized. With a purchased collar option strategy, the Company writes a local currency call option and purchases a local currency put option. As compared to a purchased put option strategy alone, a purchased collar strategy reduces the upfront costs associated with purchasing puts through the collection of premium by writing call options. If the U.S. dollar weakens relative to the currency of the hedged anticipated sales, the purchased put option value of the collar strategy reduces to zero, but the Company benefits from the increase in the value of its anticipated foreign currency cash flows 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 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.



**Table of Contents**Notes to Consolidated Financial Statements (unaudited) (continued)

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 to *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 that might occur prior to their conversion to U.S. dollars. 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.

Foreign currency denominated monetary assets and liabilities of foreign subsidiaries where the U.S. dollar is the functional currency 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.

When applicable, the Company uses forward contracts to hedge the changes in fair value of certain foreign currency denominated available-for-sale securities attributable to fluctuations in foreign currency exchange rates. These derivative contracts are designated as fair value hedges. Accordingly, changes in the fair value of the hedged securities due to fluctuations in spot rates are recorded in *Other (income) expense, net*, and are offset by the fair value changes in the forward contracts attributable to spot rate fluctuations. Changes in the contracts' fair value due to spot-forward differences are excluded from the designated hedge relationship and recognized in *Other (income) expense, net*. These amounts, as well as hedge ineffectiveness, were not significant. The cash flows from these contracts are reported as operating 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 on the euro-denominated debt instruments are included in foreign currency translation adjustment within *OCI*.

The Company also uses forward exchange contracts to hedge its net investment in foreign operations against adverse 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.



**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)*Interest Rate Risk Management*

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 that mature in the fourth quarter of 2011 with notional amounts of \$125 million each that effectively convert the Company's \$250 million, 5.125% fixed-rate notes due 2011 to floating rate instruments. The interest rate swap contracts are designated hedges of the fair value changes in the notes attributable to changes in the benchmark London Interbank Offered Rate (LIBOR) swap rate. The fair value changes in the notes attributable to changes in the benchmark interest rate are recorded in interest expense and offset by the fair value changes in the swap contracts. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

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

<i>(in millions)</i>	Balance Sheet Caption	September 30, 2011		December 31, 2010	
		Fair Value of Derivative Asset	U.S. Dollar Notional	Fair Value of Derivative Asset	U.S. Dollar Notional
<i>Derivatives Designated as Hedging Instruments</i>					
Foreign exchange contracts (current)	Deferred income taxes and other current assets	\$ 147	\$ 3,115	\$ 167	\$ 2,340
Foreign exchange contracts (non-current)	Other assets	364	4,723	310	3,723
Foreign exchange contracts (current)	Accrued and other current liabilities	121	2,390	18	1,500
Foreign exchange contracts (non-current)	Deferred income taxes and noncurrent liabilities	2	59	6	50
Interest rate swaps (current)	Deferred income taxes and other current assets	6	250		
Interest rate swaps (non-current)	Other assets			56	1,000
Interest rate swaps (non-current)	Deferred income taxes and noncurrent liabilities			7	85
		\$ 517	\$ 123	\$ 533	\$ 31
		\$ 10,537		\$ 9,920	
<i>Derivatives Not Designated as Hedging Instruments</i>					
Foreign exchange contracts (current)	Deferred income taxes and other current assets	\$ 347	\$ 9,496	\$ 95	\$ 6,200

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

foreign exchange contracts (current)	Accrued and other current liabilities	21	2,176	30	4,220		
		\$ 347	\$ 21	\$ 11,672	\$ 95	\$ 30	\$ 10,520
		\$ 864	\$ 144	\$ 22,209	\$ 628	\$ 61	\$ 20,400

- 12 -

---

**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)

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

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
<i>Derivatives designated in fair value hedging relationships</i>				
Interest rate swap contracts				
Amount of gain recognized in <i>Other (income) expense, net</i> on derivatives	\$ (40)	\$ (29)	\$ (203)	\$ (64)
Amount of loss recognized in <i>Other (income) expense, net</i> on hedged item	40	29	203	64
<i>Derivatives designated in foreign currency cash flow hedging relationships</i>				
Foreign exchange contracts				
Amount of loss (gain) reclassified from <i>AOCI</i> to <i>Sales</i>	30	(13)	57	1
Amount of (gain) loss recognized in <i>OCI</i> on derivatives	(70)	234	183	(50)
<i>Derivatives designated in foreign currency net investment hedging relationships</i>				
Foreign exchange contracts				
Amount of gain recognized in <i>Other (income) expense, net</i> on derivatives <sup>(1)</sup>	(1)		(9)	
Amount of loss recognized in <i>OCI</i> on derivatives	124		158	
<i>Derivatives not designated in a hedging relationship</i>				
Foreign exchange contracts				
Amount of (gain) loss recognized in <i>Other (income) expense, net</i> on derivatives <sup>(2)</sup>	(351)	198	(31)	13
Amount of loss (gain) recognized in <i>Sales</i> on hedged item		30		(83)

<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.

At September 30, 2011, the Company estimates \$50 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.

**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. Entities are required to use 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 that may be used to measure fair value:

*Level 1* - Quoted prices in active markets for identical assets or liabilities. The Company's Level 1 assets include equity securities that are traded in an active exchange market.

*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. The Company's Level 2 assets and liabilities primarily include debt securities with quoted prices that are traded less frequently than exchange-traded instruments, corporate notes and bonds, U.S. and foreign government and agency securities, certain mortgage-backed and asset-backed securities, municipal securities, commercial paper and derivative contracts whose values are determined using pricing models with inputs that are observable in the market or can be derived principally from or corroborated by observable market data.

*Level 3* - Unobservable inputs that are supported by little or no market activity and that are financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation. The Company's Level 3 assets included certain mortgage-backed securities with limited market activity.

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.

- 13 -

---

**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)*Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis*

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

	Fair Value Measurements Using				Fair Value Measurements Using			
	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2) September 30, 2011	Significant Unobservable Inputs (Level 3)	Total	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2) December 31, 2010	Significant Unobservable Inputs (Level 3)	Total
<i>(\$ in millions)</i>								
<b>Assets</b>								
<i>Investments</i>								
Corporate notes and bonds	\$	\$ 1,554	\$	\$ 1,554	\$	\$ 1,133	\$	\$ 1,133
Commercial paper		1,054		1,054		1,046		1,046
U.S. government and agency securities		605		605		500		500
Municipal securities						361		361
Asset-backed securities <sup>(1)</sup>		173		173		171		171
Mortgage-backed securities <sup>(1)</sup>		163		163		99	13	112
Foreign government bonds		51		51		10		10
Equity securities	94	49		143	117	23		140
Other debt securities		3		3		3		3
	94	3,652		3,746	117	3,346	13	3,476
<i>Other assets</i>								
Securities held for employee compensation	184			184	181			181
<i>Derivative assets <sup>(2)</sup></i>								
Purchased currency options		511		511		477		477
Forward exchange contracts		347		347		95		95
Interest rate swaps		6		6		56		56
		864		864		628		628
Total assets	\$ 278	\$ 4,516	\$	\$ 4,794	\$ 298	\$ 3,974	\$ 13	\$ 4,285

**Liabilities***Derivative liabilities <sup>(2)</sup>*

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

Written currency options	\$	\$	4	\$	\$	4	\$	\$	\$
Forward exchange contracts			140			140		54	54
Interest rate swaps								7	7
Total liabilities	\$	\$	144	\$	\$	144	\$	61	\$ 61

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

(2) *The fair value determination of derivatives includes an assessment 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 significant transfers between Level 1 and Level 2 during the third quarter or first nine months of 2011. As of September 30, 2011, *Cash and cash equivalents* of \$14.3 billion included \$13.3 billion of cash equivalents.

*Level 3 Valuation Techniques:*

Financial assets are considered Level 3 when their fair values are determined using pricing models, discounted cash flow methodologies or similar techniques and at least one significant model assumption or input is unobservable. Level 3 financial assets also include certain investment securities for which there is limited market activity such that the determination of fair value requires significant judgment or estimation. The Company's Level 3 investment securities included certain mortgage-backed securities that were valued primarily using pricing models for which management understands the methodologies. These models incorporate transaction details such as contractual terms, maturity, timing and amount of future cash inflows, as well as assumptions about liquidity and credit valuation adjustments of marketplace participants.



**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)

The table below provides a summary of the changes in fair value of all financial assets measured at fair value on a recurring basis using significant unobservable inputs (Level 3):

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Beginning balance	\$	\$ 17	\$ 13	\$ 72
Sales		(2)	(13)	(63)
Settlements				(2)
Total realized and unrealized gains (losses)				
Included in:				
Earnings <sup>(1)</sup>				18
Comprehensive income				(10)
Ending balance	\$	\$ 15	\$	\$ 15
Losses recorded in earnings for Level 3 assets still held at September 30	\$	\$	\$	\$

<sup>(1)</sup> Amounts are recorded in Other (income) expense, net.

**Financial Instruments not Measured at Fair Value**

Some of the Company's financial instruments are not measured at fair value on a recurring basis but are recorded at amounts that approximate fair value due to their liquid or short-term nature, such as cash and cash equivalents, receivables and payables.

The estimated fair value of loans payable and long-term debt (including current portion) at September 30, 2011 was \$19.7 billion compared with a carrying value of \$18.1 billion and at December 31, 2010 was \$18.7 billion compared with a carrying value of \$17.9 billion. Fair value was estimated using quoted dealer prices.

A summary of gross unrealized gains and losses on available-for-sale investments recorded in AOCI is as follows:

(\$ in millions)	September 30, 2011				December 31, 2010			
	Fair Value	Amortized Cost	Gross Unrealized Gains	Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Unrealized Losses
Corporate notes and bonds	\$ 1,554	\$ 1,548	\$ 13	\$ (7)	\$ 1,133	\$ 1,124	\$ 12	\$ (3)
Commercial paper	1,054	1,054			1,046	1,046		
U.S. government and agency securities	605	602	3		500	501	1	(2)
Municipal securities					361	359	4	(2)
Asset-backed securities	173	172	1		171	170	1	
Mortgage-backed securities	163	162	2	(1)	112	108	5	(1)
Foreign government bonds	51	51			10	10		
Other debt securities	3	1	2		3	1	2	

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

Equity securities	327	313	14		321	295	34	(8)
	\$ 3,930	\$ 3,903	\$ 35	\$ (8)	\$ 3,657	\$ 3,614	\$ 59	\$ (16)

Available-for-sale debt securities included in *Short-term investments* totaled \$1.3 billion at September 30, 2011. Of the remaining debt securities, \$2.0 billion mature within five years. At September 30, 2011, there were no debt securities pledged as collateral.

*Concentrations of Credit Risk*

On an ongoing basis, the Company monitors concentrations of credit risk associated with corporate 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 two-thirds of the Company's cash and cash equivalents are invested in three highly-rated money market funds.

The majority of the Company's accounts receivable arise from product sales in the United States and Europe and are primarily due from drug wholesalers and retailers, hospitals, government agencies, managed health

**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)

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 deteriorating 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. The Company does not expect to have write-offs or adjustments to accounts receivable which would have a material adverse impact on its financial position or results of operations. At September 30, 2011, the Company's accounts receivable in Greece, Italy, Spain and Portugal totaled approximately \$1.6 billion of which hospital and public sector receivables were approximately 75%. As of September 30, 2011, the Company's total accounts receivable outstanding for more than one year were approximately \$370 million, of which approximately 90% related to accounts receivable in Greece, Italy, Spain and Portugal, mostly comprised of hospital and public sector receivables.

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. During 2011, the Company sold a portion of these bonds. The Company has recorded impairment charges to reduce the remaining bonds to fair value and as of September 30, 2011, the balance was not material. During 2011, the Company has continued to receive payments on 2011 and 2010 Greek hospital and public sector receivables; these receivables totaled approximately \$100 million as of September 30, 2011.

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, 2011 and December 31, 2010, the Company had received cash collateral of \$378 million and \$157 million, respectively, from various counterparties which is recorded in *Accrued and other current liabilities*. The Company had not advanced any cash collateral to counterparties as of September 30, 2011 or December 31, 2010.

**6. Inventories**

Inventories consisted of:

<i>(\$ in millions)</i>	September 30, 2011	December 31, 2010
Finished goods	\$ 1,640	\$ 1,484
Raw materials and work in process	5,800	5,449
Supplies	293	315
Total (approximates current cost)	7,733	7,248
Reduction to LIFO costs	(112)	(186)
	\$ 7,621	\$ 7,062
Recognized as:		
Inventories	\$ 6,239	\$ 5,868
Other assets	1,382	1,194

As of September 30, 2011 and December 31, 2010, \$155 million and \$225 million, respectively, of purchase accounting adjustments to inventories remained which are recognized as a component of *Materials and production* costs as the related inventories are sold. Amounts recognized as *Other assets* are comprised almost entirely of raw materials and work in process inventories. At September 30, 2011 and December 31, 2010, these amounts included \$1.3 billion and \$1.0 billion, respectively, of inventories not expected to be sold within one year, principally vaccines. In addition, these amounts included \$128 million and \$197 million at September 30, 2011 and December 31, 2010, respectively, of inventories produced in preparation for product launches.

#### **7. Other Intangibles**

At the time of the Merger, the Company measured the fair value of Schering-Plough's marketed products and legacy pipeline programs and capitalized these amounts. 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. Also, during the third quarter and first nine months of 2011, the Company recorded \$22 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 either deemed to have no alternative use in the period or were out-licensed to a third party for consideration that was less than the related asset's carrying value. During the third quarter and first nine months of 2010, the

- 16 -

---

**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)

Company recorded \$189 million and \$216 million, respectively, of IPR&D impairment charges attributable to compounds identified during the Company's pipeline prioritization review that were abandoned and determined to have either no alternative use or were returned to the respective licensor, as well as from expected delays in the launch timing or changes in cash flow assumptions for certain compounds. The Company may recognize additional non-cash impairment charges in the future related to marketed products or for the cancellation of other legacy Schering-Plough pipeline programs 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:

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
AstraZeneca LP	\$ 141	\$ 192	\$ 318	\$ 357
Other <sup>(1)</sup>	20	44	36	60
	\$ 161	\$ 236	\$ 354	\$ 417

<sup>(1)</sup> Primarily reflects results from Sanofi Pasteur MSD, as well as Johnson & Johnson<sup>o</sup>Merck Consumer Pharmaceuticals Company (which was divested in September 2011).

**AstraZeneca LP**

In 1998, Old Merck and Astra completed the restructuring of the ownership and operations of their existing joint venture whereby Old 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 (the AstraZeneca merger ), became the exclusive distributor of the products for which KBI retained rights.

In connection with the 1998 restructuring, Astra purchased an option (the Asset Option ) for a payment of \$443 million, which was recorded as deferred income, to buy Old Merck's interest in the KBI products, excluding the gastrointestinal medicines Nexium and Prilosec (the Non-PPI Products ). In April 2010, AstraZeneca exercised the Asset Option. Merck received \$647 million from AstraZeneca, representing the net present value as of March 31, 2008 of projected future pretax revenue to be received by Old Merck from the Non-PPI Products, which was recorded as a reduction to the Company's investment in AZLP. The Company recognized the \$443 million of deferred income in the second quarter of 2010 as a component of *Other (income) expense, net*. In addition, in 1998, Old Merck granted Astra an option (the Shares Option ) to buy Old Merck's common stock interest in KBI and, therefore, Old Merck's interest in Nexium and Prilosec, exercisable in 2012. The exercise price for the Shares Option will be based on the net present value of estimated future net sales of Nexium and Prilosec as determined at the time of exercise, subject to certain true-up mechanisms. The Company believes that it is likely that AstraZeneca will exercise the Shares Option.

Summarized financial information for AZLP is as follows:

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Sales	\$ 1,124	\$ 1,200	\$ 3,460	\$ 3,790

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

Materials and production costs	464	605	1,524	1,864
Other expense, net	357	224	1,004	679
Income before taxes <sup>(1)</sup>	\$ 303	\$ 371	\$ 932	\$ 1,247

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

- 17 -

---

**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)*Johnson & Johnson<sup>o</sup>Merck Consumer Pharmaceuticals Company*

In September 2011, Merck sold its 50% interest in the Johnson & Johnson<sup>o</sup>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 ( OTC ) 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*. Merck's rights to the *Pepcid* brand outside the United States and Canada were not affected by this transaction. Following the transaction, J&J owns the venture's assets which include the exclusive rights to market OTC *Pepcid*, *Mylanta*, *Mylicon* and other local OTC brands where they are currently sold in the United States and Canada. The partnership assets also included a manufacturing facility.

**9. Contingencies and Environmental Liabilities**

The Company is involved in various claims and legal proceedings of a nature considered normal to its business, including product liability, intellectual property, and commercial litigation, as well as additional matters such as antitrust actions. 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.

***Vioxx* Litigation***Product Liability Lawsuits*

As previously disclosed, individual and putative class actions have been filed against Old Merck in state and federal courts alleging personal injury and/or economic loss with respect to the purchase or use of *Vioxx*. Most of the cases that remain are coordinated in a multidistrict litigation in the U.S. District Court for the Eastern District of Louisiana (the *Vioxx* MDL ) before District Judge Eldon E. Fallon. (All of the actions discussed in this paragraph and in *Other Lawsuits* below are collectively referred to as the *Vioxx* Product Liability Lawsuits. )

Of the plaintiff groups in the *Vioxx* Product Liability Lawsuits described above, the vast majority were dismissed as a result of the *Vioxx* Settlement Program, which has been described previously. As of September 30, 2011, approximately 25 plaintiff groups who were otherwise eligible for the Settlement Program did not participate and their claims remain pending against Old Merck. In addition, the claims of approximately 75 plaintiff groups who were not eligible for the Settlement Program remain pending against Old Merck.

There are no U.S. *Vioxx* Product Liability Lawsuits currently scheduled for trial in 2011. Old Merck has previously disclosed the outcomes of several *Vioxx* Product Liability Lawsuits that were tried prior to 2010. Of the cases that went to trial, there is only one unresolved post-trial appeal: *Ernst v. Merck*. Merck has previously disclosed the details associated with the *Ernst* case and the grounds for Merck's appeal. On August 26, 2011, the Texas Supreme Court reversed the judgment of the Court of Appeals in *Garza*, and rendered judgment for Merck.

**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)*Other Lawsuits*

There are still 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, Old 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 Old Merck's motion in October 2010 and took it under advisement.

In June 2008, a Missouri state court certified a class of Missouri plaintiffs seeking reimbursement for out-of-pocket costs relating to *Vioxx*. Trial is scheduled to begin on May 21, 2012. In addition, in Indiana, plaintiffs have filed a motion to certify a class of Indiana *Vioxx* purchasers in a case pending before the Circuit Court of Marion County, Indiana. In April 2010, a Kentucky state court denied Old Merck's motion for summary judgment and certified a class of Kentucky plaintiffs seeking reimbursement for out-of-pocket costs relating to *Vioxx*. The Kentucky Court of Appeals denied Old Merck's petition for a writ of mandamus, and the Kentucky Supreme Court has affirmed that ruling. The trial court entered an amended class certification order on January 27, 2011, and Merck has appealed that ruling to the Kentucky Court of Appeals. Oral argument on the appeal is currently scheduled for November 14, 2011, although plaintiff has requested a continuance.

Old Merck has also been named as a defendant in several lawsuits brought by, or on behalf of, government entities. Twelve of these suits are being brought by state Attorneys General and one has been brought on behalf of a county. All of these actions, except for a suit brought by the Attorney General of Michigan, are in the *Vioxx* MDL proceeding. The Michigan Attorney General case was remanded to state court. The trial court denied Old Merck's motion to dismiss, but the Court of Appeals reversed that ruling on March 17, 2011, ordering the trial court to dismiss the case. The Michigan Attorney General sought review before the Michigan Supreme Court, but its petition was denied on September 30, 2011. These actions allege that Old Merck misrepresented the safety of *Vioxx*. All but one of these suits seek recovery for expenditures on *Vioxx* by government-funded health care programs such as Medicaid, along with other relief such as penalties and attorneys' fees. An action brought by the Attorney General of Kentucky seeks only penalties for alleged Consumer Fraud Act violations. The Attorney General of Kentucky has moved to remand that case to state court, and the MDL court heard oral argument on the motion on August 31, 2011. The lawsuit brought by the county is a class action filed by Santa Clara County, California on behalf of all similarly situated California counties. Old Merck moved to dismiss the case brought by the Attorney General of Oklahoma in December 2010 and for judgment on the pleadings in the case brought by Santa Clara County in September 2011.

In March 2010, Judge Fallon partially granted and partially denied Old Merck's motion for summary judgment in the Louisiana Attorney General case. A trial on the remaining claims before Judge Fallon was completed in April 2010 and Judge Fallon found in favor of Old Merck in June 2010 dismissing the Louisiana Attorney General's remaining claims with prejudice. The Louisiana Attorney General filed a notice of appeal, and the Fifth Circuit dismissed the appeal without prejudice pursuant to its scheduling rules on October 21, 2011 after the Louisiana Attorney General requested a stay of the appeal.

*Shareholder Lawsuits*

As previously disclosed, in addition to the *Vioxx* Product Liability Lawsuits, various putative class actions and individual lawsuits under federal and state securities laws have been filed against Old Merck and various current and former officers and directors (the *Vioxx* Securities Lawsuits). As previously disclosed, the *Vioxx* Securities Lawsuits have been transferred by the Judicial Panel on Multidistrict Litigation (the JPML) to the U.S. District Court for the District of New Jersey before District Judge Stanley R. Chesler for inclusion in a nationwide MDL (the Shareholder MDL), and have been consolidated for all purposes. In June 2010, Old Merck moved to dismiss the Fifth Amended Class Action Complaint in the consolidated securities action. Oral argument on the motion to dismiss was held on July 12, 2011. On August 8, 2011, Judge Chesler granted in part and denied in part the motion to dismiss. Among other things, the claims based on statements made on or after the voluntary withdrawal of *Vioxx* on September 30, 2004 have been dismissed. On October 7, 2011, defendants answered the Fifth Amended Class Action Complaint.





**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)

As previously disclosed, several individual securities lawsuits filed by foreign institutional investors also are consolidated with the *Vioxx* Securities Lawsuits. By stipulation, defendants were not required to respond to these complaints until the resolution of any motions to dismiss in the consolidated securities class action. On October 7, 2011, the court entered as an order a stipulation previously submitted by the parties requiring plaintiffs to file amended complaints in each of the individual securities lawsuits by October 21, 2011. Under the order, defendants have until January 20, 2012 to file motions to dismiss in one of the individual lawsuits (the *ABP Lawsuit*). The time to move or otherwise respond to the complaints in the remaining individual securities lawsuits is stayed until 45 days after the resolution of any motions to dismiss in the *ABP Lawsuit*.

In addition, as previously disclosed, various putative class actions have been filed in federal court under the Employee Retirement Income Security Act ( *ERISA* ) against Old Merck and certain current and former officers and directors (the *Vioxx ERISA Lawsuits*). Those cases were consolidated in the Shareholder MDL before Judge Chesler. Fact discovery in the *Vioxx ERISA Lawsuits* closed in September 2010 and expert discovery closed in May 2011. In June 2011, Old Merck filed a motion for summary judgment, and plaintiffs filed a motion for partial summary judgment. As previously disclosed, in February 2009, the court denied the motion for class certification as to one count, and granted the motion as to the remaining counts in Consolidated Amended Complaint in the *Vioxx ERISA Lawsuits*. On August 16, 2011, while motions for renewed class certifications and summary judgment were pending but not yet decided, the parties reached an agreement in principle in which Merck would pay \$49.5 million to settle the *Vioxx ERISA Lawsuits*. On August 17, 2011, Merck requested a stay of all proceedings to allow the parties to document and seek approval of the proposed settlement. On August 19, 2011, the court granted the parties' request for a stay, and on August 25, 2011, in light of the proposed settlement, the court dismissed without prejudice all pending motions. On September 20, 2011, plaintiffs filed an unopposed motion for preliminary approval of the settlement and approval of notice plan. On October 6, 2011, the court entered an order preliminarily approving the proposed settlement. The court has scheduled a final approval hearing on the settlement for November 29, 2011.

*International Lawsuits*

As previously disclosed, in addition to the lawsuits discussed above, Old Merck has been named as a defendant in litigation relating to *Vioxx* in Australia, Brazil, Canada, Europe and Israel (collectively, the *Vioxx Foreign Lawsuits*).

Following trial of a representative action in 2009, a first instance judge of the Federal Court in Australia entered orders in 2010 which dismissed all claims against Old Merck. With regard to Old Merck's Australian subsidiary, Merck Sharp & Dohme (Australia) Pty Ltd, the court dismissed certain claims but awarded the applicant, whom the court found suffered a myocardial infarction ( *MI* ) after ingesting *Vioxx* for approximately 33 months, AU \$330,465 based on statutory claims that *Vioxx* was not fit for purpose or of merchantable quality, even though the court rejected the applicant's claim that Old Merck and its Australian subsidiary knew or ought to have known prior to the voluntary withdrawal of *Vioxx* in September 2004 that *Vioxx* materially increased the risk of *MI*. The court also determined which of its findings of fact and law were common to the claims of other group members whose individual claims would proceed with reference to those findings. Old Merck's subsidiary appealed the adverse findings and the Full Federal Court (the *Full Court*) heard the appeal and a cross-appeal in August 2011. In October 2011, the Full Court allowed Old Merck's subsidiary's appeal and set aside the judgment in favor of the applicant and dismissed his action. The Full Court held that *Vioxx* was not proven to be the cause of the applicant's *MI* and that Old Merck's subsidiary is not liable to the applicant for damages in negligence or under the former Trade Practices Act. The Full Court also affirmed the first instance decision in favor of Old Merck's subsidiary on the applicant's statutory defect claim, holding that Old Merck's subsidiary's state of the art defense was proven based on the development of scientific knowledge over time. The effect of this decision upon the claims of the remaining group members remains to be determined.

**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)*Insurance*

The Company has Directors and Officers insurance coverage applicable to the *Vioxx* Securities Lawsuits with remaining stated upper limits of approximately \$175 million. The Company has Fiduciary and other insurance for the *Vioxx* ERISA Lawsuits with stated upper limits of approximately \$275 million. As a result of the previously disclosed insurance arbitration, additional insurance coverage for these claims should also be available, if needed, under upper-level excess policies that provide coverage for a variety of risks. There are disputes with the insurers about the availability of some or all of the Company's insurance coverage for these claims and there are likely to be additional disputes. The amounts actually recovered under the policies discussed in this paragraph may be less than the stated upper limits.

*Investigations*

As previously disclosed, Old Merck has received subpoenas from the Department of Justice ( DOJ ) requesting information related to Old Merck's research, marketing and selling activities with respect to *Vioxx* in a federal health care investigation under criminal statutes. This investigation included subpoenas for witnesses to appear before a grand jury. As previously disclosed, in March 2009, Old 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 the third quarter of 2010, the Company established a \$950 million reserve (the *Vioxx* Liability Reserve ) in connection with the anticipated resolution of the DOJ's investigation. The Company's discussions with the government are ongoing. Until they are concluded, there can be no certainty about a definitive resolution. The Company is cooperating with the DOJ in its investigation (the *Vioxx* Investigation ). The Company cannot predict the outcome of these inquiries; however, they could result in potential civil and/or criminal remedies.

*Reserves*

There are no U.S. *Vioxx* Product Liability Lawsuits currently scheduled for trial in 2011. A trial in the Missouri state court action is scheduled to begin on May 21, 2012. The Company cannot predict the timing of any other trials related to the *Vioxx* Litigation. The Company believes that it has meritorious defenses to the *Vioxx* Product Liability Lawsuits, *Vioxx* Shareholder 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 *Vioxx* Lawsuits not included in the Settlement Program. Unfavorable outcomes in the *Vioxx* Litigation could have a material adverse effect on the Company's financial position, liquidity and results of operations.

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. As of December 31, 2010, the Company had an aggregate reserve of approximately \$76 million (the *Vioxx* Legal Defense Costs Reserve ) solely for future legal defense costs related to the *Vioxx* Litigation.

During the first nine months of 2011, the Company spent approximately \$61 million in the aggregate, including \$24 million in the third quarter, in legal defense costs worldwide related to (i) the *Vioxx* Product Liability Lawsuits, (ii) the *Vioxx* Shareholder Lawsuits, (iii) the *Vioxx* Foreign Lawsuits, and (iv) the *Vioxx* Investigation (collectively, the *Vioxx* Litigation ). In addition, in the first nine months of 2011, the Company recorded charges of \$49 million solely for its future legal defense costs for the *Vioxx* Litigation, including \$30 million in the third quarter. Consequently, as of September 30, 2011, the aggregate amount of the *Vioxx* Legal Defense Costs Reserve was approximately \$64 million, which is solely for future legal defense costs for the *Vioxx* Litigation. Some of the significant factors considered in the review of the *Vioxx* Legal Defense Costs Reserve were 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 the *Vioxx* Litigation, including the Settlement Agreement and the lawsuits that are continuing; 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 *Vioxx* Litigation. The amount of the *Vioxx* Legal Defense Costs Reserve as of September 30, 2011 represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with the remaining aspects of the *Vioxx* Litigation; however, events such as additional trials in the *Vioxx* Litigation and other events that could arise in the course of the

*Vioxx* Litigation could affect the ultimate amount of 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 *Vioxx* Legal Defense Costs Reserve at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

- 21 -

---

**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)**Other Product Liability Litigation***Fosamax*

As previously disclosed, Old Merck is a defendant in product liability lawsuits in the United States involving *Fosamax* (the *Fosamax* Litigation ). As of September 30, 2011, approximately 2,000 cases, which include approximately 2,420 plaintiff groups, had been filed and were pending against Old 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 1,160 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 840 of these actions generally allege that they sustained femur fractures and/or other bone injuries in association with the use of *Fosamax*.

*Cases Alleging ONJ and/or Other Jaw Related Injuries*

In August 2006, the JPML ordered that certain *Fosamax* product liability cases pending in federal courts nationwide should be transferred and consolidated into one multidistrict litigation (the *Fosamax* MDL ) for coordinated pre-trial proceedings. The *Fosamax* MDL has been transferred to Judge John Keenan in the U.S. District Court for the Southern District of New York. As a result of the JPML order, approximately 940 of the cases are before Judge Keenan. Judge Keenan issued a Case Management Order (and various amendments thereto) which set forth a schedule governing the proceedings focused primarily upon resolving the class action certification motions in 2007 and completing fact discovery in an initial group of 25 cases by October 1, 2008. In the first *Fosamax* MDL trial, *Boles v. Merck*, the *Fosamax* MDL court declared a mistrial because the eight person jury could not reach a unanimous verdict. The *Boles* case was retried in June 2010 and resulted in a verdict in favor of the plaintiff in the amount of \$8 million. Merck filed post-trial motions seeking judgment as a matter of law or, in the alternative, a new trial. In October 2010, the court denied Merck's post-trial motions but *sua sponte* ordered a remittitur, reducing the verdict to \$1.5 million. Plaintiff rejected the remittitur ordered by the court and requested a new trial on damages, which is scheduled to take place on March 26, 2012. Merck intends to appeal the verdict in *Boles* after the new trial on damages has concluded.

In the next *Fosamax* MDL trial, *Maley v. Merck*, the jury in May 2010 returned a unanimous verdict in Merck's favor. In February 2010, Judge Keenan selected a new bellwether case, *Judith Graves v. Merck*, to replace the *Flemings v. Merck* bellwether case, which the *Fosamax* MDL court dismissed when it granted summary judgment in favor of Old Merck. In November 2010, the Second Circuit affirmed the court's granting of summary judgment in favor of Old Merck in the *Flemings* case. In *Graves*, the jury returned a unanimous verdict in favor of Old Merck in November 2010. The jury in *Secrest v. Merck* returned a unanimous verdict in favor of Old Merck in October 2011.

The next trial scheduled in the *Fosamax* MDL was *Raber v. Merck*, which was subsequently dismissed. In addition, in February 2011, Judge Keenan ordered that there will be two further bellwether trials conducted in the *Fosamax* MDL: *Spano v. Merck* is scheduled to be tried on September 10, 2012; *Jellema v. Merck* is scheduled to be tried on May 7, 2012, though Jellema's counsel has advised that he will seek to dismiss the case.

Outside the *Fosamax* MDL, a trial in Florida, *Anderson v. Merck*, was scheduled to begin in June 2010 but the Florida state court postponed the trial date and a new date has been set for March 5, 2012. The trial ready date in *Carballo v. Merck* has been continued from August 22, 2011 until April 30, 2012. The *Ward v. Merck* case is scheduled to be tried on June 11, 2012.

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, 2011, approximately 210 ONJ cases were pending against Old 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.

On February 14, 2011, the jury in *Rosenberg v. Merck*, the first trial in the New Jersey coordinated proceeding, returned a verdict in Merck's favor. A trial in the *Rifkin v. Merck*, *Flores v. Merck* and *Sessner v. Merck* cases is scheduled for February 27, 2012.

- 22 -

---

**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)

In California, the parties are reviewing the claims of three 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 mid-2012.

Discovery is ongoing in the *Fosamax* 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 and/or Other Bone Injuries*

As of September 30, 2011, approximately 645 cases alleging femur fractures and/or other bone injuries 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. A Case Management Order setting forth a discovery and motions schedule with respect to these cases is expected but has not yet been entered and no trial dates for any of the New Jersey state femur fracture cases have been set.

In March 2011, Merck submitted a Motion to Transfer to the JPML seeking to have all federal cases alleging femur fractures and other bone injuries 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 or other bone injuries have been or will be transferred to the District of New Jersey where the *Fosamax* MDL is sited. Judge Garrett Brown has been assigned to preside over this second *Fosamax* MDL proceeding. A Case Management Order has been entered by Judge Brown that requires the parties to review 40 cases with a fact discovery deadline of July 31, 2012, an expert discovery deadline of November 28, 2012, and a projected trial date for the first case to be tried sometime after March 1, 2013.

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 Ronald L. Bauer will preside over the coordinated proceedings. No scheduling order has yet been entered.

Additionally, there are three femur fracture cases pending in other state courts. One case is pending in Massachusetts, one is pending in Florida, and one is pending in Alabama.

Discovery is ongoing in the federal and state courts where femur fracture cases are pending and the Company intends to defend against these lawsuits.

*NuvaRing*

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 Schering-Plough 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, 2011, there were approximately 900 *NuvaRing* cases. Of these cases, approximately 775 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 120 are pending in consolidated discovery proceedings in the Bergen County Superior Court of New Jersey before Judge Brian R. Martinotti. Four 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 twenty 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 ten trial pool cases to be prepared for trial. The parties have completed fact discovery in the originally selected trial pool cases in each jurisdiction and the Company anticipates expert discovery to be completed in the Spring of 2012. Certain of the cases in the original trial pool have been voluntarily dismissed and in one case judgment was entered in Merck's favor and, as a result, certain replacement trial pool cases remain in fact discovery.





**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)

The Company anticipates that status conferences will be held in each coordinated proceeding following the completion of expert discovery to determine a methodology for selecting the first cases to be tried. The Company intends to defend against these lawsuits.

*Propecia/Proscar*

Merck has been sued this year in approximately 60 lawsuits involving a total of approximately 100 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*. The lawsuits, which are in their early stages, are pending in federal courts in New Jersey, Washington, Washington D.C. and Florida, and in state court in New Jersey. The Company intends to defend against these lawsuits.

**Governmental Proceedings**

Merck has received a Civil Investigative Demand ( CID ) issued by the DOJ addressed to Inspire Pharmaceuticals, Inc., a company acquired by Merck in May 2011. The CID advises that it relates to a False Claims Act investigation concerning allegations that Inspire caused the submission of false claims to federal health benefits programs for the drug AzaSite by marketing it for the treatment of indications not approved by the U.S. Food and Drug Administration (the FDA ). The Company is cooperating with the government in its investigation and cannot predict the outcome of this inquiry.

The Company has received a subpoena from the DOJ requesting information relating to the Company s marketing and selling activities with respect to *Integrilin* and *Avelox*, from January 2003 to June 2010, in a civil federal health care investigation. The Company is cooperating with the DOJ s investigation.

**Vytorin/Zetia Litigation**

As previously disclosed, in April 2008, an Old Merck shareholder filed a putative class action lawsuit in federal court in the Eastern District of Pennsylvania alleging that Old Merck violated the federal securities laws. This suit has since been withdrawn and re-filed in the District of New Jersey and has been consolidated 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 names as defendants Old Merck; Merck/Schering-Plough Pharmaceuticals, LLC; and certain of the Company s current and former officers and directors. Specifically, the complaint alleges that Old Merck delayed releasing unfavorable results of the ENHANCE clinical trial regarding the efficacy of *Vytorin* and that Old Merck made false and misleading statements about expected earnings, knowing that once the results of the *Vytorin* study were released, sales of *Vytorin* would decline and Old Merck s earnings would suffer. In December 2008, Old 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 issued an opinion and order denying the defendants motion to dismiss this lawsuit and, in October 2009, Old Merck and the other defendants filed an answer to the amended consolidated complaint. 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, LLC; 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 issued an opinion and order denying the defendants motion to dismiss this lawsuit. The defendants filed an answer to the consolidated amended complaint in November 2009.

As previously disclosed, in April 2008, a member of an Old Merck ERISA plan filed a putative class action lawsuit against Old 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 Old Merck in the District of New Jersey, and all of those lawsuits have been consolidated under the caption *In re Merck & Co., Inc. Vytorin ERISA Litigation*. A consolidated amended complaint was filed in February 2009, and names as defendants Old Merck and various current and former members of the Company s Board of Directors. The plaintiffs

allege that the ERISA plans' investment in Old Merck stock was imprudent because Old Merck's earnings are dependent on the commercial success of its cholesterol drug *Vytorin* and that 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. In April 2009, Old 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 issued an opinion and order denying the defendants' motion to dismiss this lawsuit. In November 2009, the plaintiffs moved to strike certain of the defendants' affirmative defenses. That motion was denied in part and granted in part in June 2010, and an amended answer was filed in July 2010.

- 24 -

---

**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)

There is a similar consolidated, putative class action ERISA lawsuit currently pending in the District of New Jersey, filed by a member of a Schering-Plough ERISA plan against Schering-Plough and certain of its current and former officers and directors, alleging they breached their fiduciary duties under ERISA, and under the caption *In re Schering-Plough Corp. ENHANCE ERISA Litigation*. The consolidated amended complaint was filed in October 2009 and names as defendants Schering-Plough, various current and former members of Schering-Plough's Board of Directors and current and former members of committees of Schering-Plough's Board of Directors. In November 2009, the Company and the other defendants filed a motion to dismiss this lawsuit on the grounds that the plaintiffs failed to state a claim for which relief can be granted. The plaintiffs' opposition to the motion to dismiss was filed in December 2009, and the motion was fully briefed in January 2010. That motion was denied in June 2010. In September 2010, defendants filed an answer to the amended complaint in this matter.

In November 2009, a stockholder of the Company filed a shareholder derivative lawsuit, *In re Local No. 38 International Brotherhood of Electrical Workers Pension Fund v. Clark* ( *Local No. 38* ), in the District of New Jersey, on behalf of the nominal defendant, the Company, and all shareholders of the Company, against the Company; certain of the Company's officers, directors and alleged insiders; and certain of the predecessor companies' former officers, directors and alleged insiders for alleged breaches of fiduciary duties, waste, unjust enrichment and gross mismanagement. A similar shareholder derivative lawsuit, *Cain v. Hassan*, was filed by a Schering-Plough stockholder and is currently pending in the District of New Jersey. An amended complaint was filed in May 2008, by the Schering-Plough stockholder on behalf of the nominal defendant, Schering-Plough, and all Schering-Plough shareholders. The lawsuit is against the Company, Schering-Plough's then-current Board of Directors, and certain of Schering-Plough's current and former officers, directors and alleged insiders. The plaintiffs in both *Local No. 38* and *Cain v. Hassan* alleged that the defendants withheld the ENHANCE study results and made false and misleading statements, thereby deceiving and causing harm to the Company and Schering-Plough, respectively, and to the investing public, unjustly enriching insiders and wasting corporate assets. The plaintiff in *Local No. 38* voluntarily dismissed the suit without prejudice in July 2011. The intervenor-plaintiff in *Cain v. Hassan* filed a second amended complaint in July 2011. The defendants moved to dismiss the second amended complaint on October 13, 2011. On October 14, 2011, the parties reached an agreement in principle to settle the case, subject to approval by a committee of Merck's Board of Directors and the court. On October 18, 2011, the court stayed all discovery in the action. In November 2010, a Company shareholder filed a derivative lawsuit in state court in New Jersey. This case, captioned *Rose v. Hassan*, asserts claims that are substantially identical to the claims alleged in *Cain v. Hassan*. On April 29, 2011, the defendants in *Rose v. Hassan* moved to stay the case or to dismiss it without prejudice in favor of the federal derivative action. On August 9, 2011, the New Jersey state court dismissed *Rose v. Hassan* without prejudice. On September 21, 2011, the plaintiff in *Rose v. Hassan* filed a notice of appeal.

Discovery in the federal lawsuits referred to in this section (collectively, the ENHANCE Litigation) has been coordinated. 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 with stated upper limits of approximately \$250 million. The Company has Fiduciary and other insurance for the *Vytorin* ERISA lawsuits with stated upper limits of approximately \$265 million. 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 and Investigations***

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. In September 2010, a jury in the U.S. District Court for the District of Massachusetts found the Company liable on the ground that units of Schering-Plough caused Massachusetts to overpay pharmacists for prescriptions of albuterol. The District Court held that Massachusetts should be awarded approximately \$13.8 million in treble damages and penalties, together with prejudgment interest and attorney s fees. The Company is planning to appeal the verdict and expects Massachusetts to seek substantially higher penalties on appeal.

- 25 -

---

**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)

During 2011, the Company has settled AWP cases brought by the states of Utah, South Carolina, Alaska, Idaho, Kentucky, Pennsylvania, Mississippi, Wisconsin, Iowa, and certain New York counties. The Company and/or certain of its subsidiaries continue to be defendants in cases brought by 11 states.

**Patent Litigation**

From time to time, generic manufacturers of pharmaceutical products file Abbreviated New Drug Applications (ANDAs) with the FDA seeking to market generic forms of the Company's products prior to the expiration of relevant patents owned by the Company. To protect its patent rights the Company may file patent infringement lawsuits against such generic companies. Certain products of the Company (or marketed via agreements with other companies) currently involved in such patent infringement litigation in the United States include: *AzaSite*, *Cancidas*, *Integrilin*, *Nasonex*, *Nexium*, *Noxafil*, *Propecia*, *Temodar*, *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.

**AzaSite** In May 2011, a patent infringement suit was filed in the United States against Sandoz Inc. (Sandoz) in respect of Sandoz's application to the FDA seeking pre-patent expiry approval to market a generic version of *AzaSite*. The lawsuit automatically stays FDA approval of Sandoz's ANDA until October 2013 or until an adverse court decision, if any, whichever may occur earlier.

**Cancidas** In November 2009, a patent infringement lawsuit was filed in the United States against Teva Parenteral Medicines, Inc. (TPM) in respect of TPM's application to the FDA seeking pre-patent expiry approval to sell a generic version of *Cancidas*. That lawsuit has been dismissed with no rights granted to TPM. Also, in March 2010, a patent infringement lawsuit was filed in the United States against Sandoz in respect of Sandoz's application to the FDA seeking pre-patent expiry approval to sell a generic version of *Cancidas*. In June 2011, Sandoz amended its challenge to Merck's *Cancidas* patents stating that it did not seek FDA approval any earlier than the expiry of a patent which occurs on July 26, 2015, but Sandoz did maintain its challenge to a *Cancidas* patent which expires on September 28, 2017. Therefore, the lawsuit will continue, however, the FDA cannot approve Sandoz's application any earlier than July 26, 2015.

**Integrilin** In February 2009, a patent infringement lawsuit was filed (jointly with Millennium Pharmaceuticals, Inc.) in the United States against TPM in respect of TPM's application to the FDA seeking approval to sell a generic version of *Integrilin* prior to the expiry of the last to expire listed patent. In October 2011, the parties entered a settlement agreement allowing TPM to sell a generic version of *Integrilin* beginning June 2, 2015.

**Nasonex** In December 2009, a patent infringement suit was filed in the United States against Apotex Corp. (Apotex) in respect of Apotex's application to the FDA seeking pre-patent expiry approval to market a generic version of *Nasonex*. The lawsuit automatically stays FDA approval of Apotex's ANDA until May 2012 or until an adverse court decision, if any, whichever may occur earlier.

**Nexium** In November 2005, a patent infringement lawsuit was filed (jointly with AstraZeneca) in the United States against Ranbaxy Laboratories Ltd. (Ranbaxy) in respect of Ranbaxy's application to the FDA seeking pre-patent expiry approval to sell a generic version of Nexium. As previously disclosed, AstraZeneca, Merck and Ranbaxy entered into a settlement agreement which provided that Ranbaxy will be entitled to bring its generic esomeprazole product to market in the United States on May 27, 2014. The Company and AstraZeneca each received a Civil Investigative Demand (CID) from the Federal Trade Commission (FTC) in July 2008 regarding the settlement agreement with Ranbaxy. The Company is cooperating with the FTC in responding to this CID. In March 2006, a patent infringement lawsuit was filed (jointly with AstraZeneca) against IVAX Pharmaceuticals, Inc. (IVAX) (later acquired by Teva Pharmaceuticals, Inc. (Teva)), in respect of IVAX's application to the FDA seeking pre-patent expiry approval to sell a generic version of Nexium. In January 2010, AstraZeneca, Merck and Teva/IVAX entered into a settlement agreement which provides that Teva/IVAX will be entitled to bring its generic esomeprazole product to market in the United States on May 27, 2014. Patent infringement lawsuits have also been filed in the United States against Dr. Reddy's Laboratories (Dr. Reddy's), Sandoz and Lupin Ltd. (Lupin) in respect to their respective

applications to the FDA seeking pre-patent expiry approval to sell generic versions of Nexium. In January 2011, AstraZeneca, Merck and Dr. Reddy's entered into a settlement agreement which provides that Dr. Reddy's will be entitled to bring its generic esomeprazole product to market in the United States on May 27, 2014. In June 2011, AstraZeneca, Merck and Sandoz entered into a settlement agreement which provides that

- 26 -

---

**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)

Sandoz will be entitled to bring its generic esomeprazole product to market in the United States on May 27, 2014. The lawsuit against Lupin is ongoing with no trial dates presently scheduled. In February 2011, a patent infringement lawsuit was filed (jointly with AstraZeneca) in the United States against Hamni USA, Inc. ( Hamni ) in respect of Hamni s application to the FDA seeking pre-patent expiry approval to sell a generic version of Nexium. 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. In October 2011, AstraZeneca, Merck and Sun Pharma entered into a settlement 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.

*Noxafil* In May 2011, a patent infringement suit was filed in the United States against Sandoz in respect of Sandoz s application to the FDA seeking pre-patent expiry approval to market a generic version of *Noxafil*. The lawsuit automatically stays FDA approval of Sandoz s ANDA until September 2013 or until an adverse court decision, if any, whichever may occur earlier.

*Propecia* In December 2010, a patent infringement lawsuit was filed in the United States against Hetero Drugs Limited ( Hetero ) in respect of Hetero s application to the FDA seeking pre-patent expiry approval to sell a generic version of *Propecia*. In March 2011, the Company settled this lawsuit with Hetero by agreeing to allow Hetero to sell a generic 1 mg finasteride product beginning on July 1, 2013.

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

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

*Vytorin* In December 2009, a patent infringement lawsuit was filed in the United States against Mylan Pharmaceuticals, Inc. ( Mylan ) in respect of Mylan s application to the FDA seeking pre-patent expiry approval to sell a generic version of *Vytorin*. The lawsuit automatically stays FDA approval of Mylan s application until May 2012 or until an adverse court decision, if any, whichever may occur earlier. A trial against Mylan jointly in respect of *Zetia* and *Vytorin* is scheduled to begin on December 5, 2011. 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 of Actavis application to the FDA seeking pre-patent expiry approval to sell a generic version of *Vytorin*. The lawsuit automatically stays FDA approval of Actavis application until May 2012 or until an adverse

court decision, if any, whichever may occur earlier.

*Zetia* In March 2007, a patent infringement lawsuit was filed in the United States against Glenmark Pharmaceuticals Inc., USA and its parent corporation (collectively, Glenmark ) in respect of Glenmark s application to the FDA seeking pre-patent expiry approval to sell a generic version of *Zetia*. In May 2010, Glenmark agreed to a settlement by virtue of which Glenmark will be permitted to launch its generic product in the United States on December 12, 2016, subject to receiving final FDA approval. In June 2010, a patent infringement

- 27 -

---



**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)

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*. The lawsuit automatically stays FDA approval of Mylan's application until December 2012 or until an adverse court decision, if any, whichever may occur earlier. A trial against Mylan jointly in respect of *Zetia* and *Vytorin* is scheduled to begin on December 5, 2011. 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.

*NuvaRing* In February 2011, a patent infringement suit was brought against Merck in the International Trade Commission by Femina Pharma Incorporated ( Femina ) in respect of the product *NuvaRing*. The complaint alleges that *NuvaRing* infringes a patent owned by Femina. The lawsuit seeks an exclusion order against the importation of *NuvaRing* into the United States. Trial in the case is expected to be held in the first quarter of 2012.

**Environmental Matters**

As previously disclosed, approximately 2,200 plaintiffs have filed an amended complaint against Old Merck and 12 other defendants in U.S. District Court, Eastern District of California asserting claims under the Clean Water Act, the Resource Conservation and Recovery Act, as well as negligence and nuisance. The suit seeks damages for personal injury, diminution of property value, medical monitoring and other alleged real and personal property damage associated with groundwater, surface water and soil contamination found at the site of a former Old Merck subsidiary in Merced, California. Certain of the other defendants in this suit have settled with plaintiffs regarding some or all aspects of plaintiffs' claims. This lawsuit is proceeding in a phased manner. A jury trial commenced in February 2011 during which a jury was asked to make certain factual findings regarding whether contamination moved off-site to any areas where plaintiffs could have been exposed to such contamination and, if so, when, where and in what amounts. Defendants in this Phase 1 trial included Old Merck and three of the other original 12 defendants. In March 2011, the Phase 1 jury returned a mixed verdict, finding in favor of Old Merck and the other defendants as to some, but not all, of plaintiffs' claims. Specifically, the jury found that contamination from the site did not enter or affect plaintiffs' municipal water supply wells or any private domestic wells. The jury found, however, that plaintiffs could have been exposed to contamination via air emissions prior to 1994, as well as via surface water in the form of storm drainage channeled into an adjacent irrigation canal, including during a flood in April 2006. In response to post-trial motions by Old Merck and other defendants, on September 7, 2011 the court entered an order setting aside a part of the Phase 1 jury's findings that had been in favor of plaintiffs. Specifically, the court held that plaintiffs could not have been exposed to any contamination in surface or flood water during the April 2006 flood or, in fact, at any time later than 1991. Old Merck has moved for reconsideration of the remainder of the jury's Phase 1 verdict that was adverse to Old Merck or, in the alternative, for an opportunity to take an immediate appeal of the remainder of the Phase 1 verdict on the basis that the remainder of the Phase 1 verdict that was adverse to Old Merck was unsupported by the evidence and contrary to established legal principles. In the event any portion of the Phase 1 jury's findings in favor of plaintiffs is not set aside by the trial court or on appeal, it is anticipated that later phases of the litigation would be required to address issues related to liability, causation and damages related to specific plaintiffs.

As previously disclosed, the DOJ and the U.S. Environmental Protection Agency (the EPA) notified the Company that they were pursuing civil penalties against Merck in excess of \$2 million for alleged violations of air, water and waste regulations resulting from the EPA's multi-media inspections of Merck's West Point and Riverside, Pennsylvania facilities in 2006 and Merck's subsequent information submissions to the EPA. A Stipulation settling this matter was filed in the United States District Court for the Middle District of Pennsylvania on September 28, 2011 pursuant to which the Company denied all alleged violations and agreed to a civil penalty in the amount of \$1.5 million.

**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 either individually or in the aggregate.



**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)**10. Equity**

(\$ and shares in millions)	Common Stock		Other	Accumulated		Treasury Stock		Non-	Total
	Shares	Par Value	Paid-In Capital	Retained Earnings	Other Comprehensive Loss	Shares	Cost	Controlling Interests	
Balance January 1, 2010	3,563	\$ 1,781	\$ 39,683	\$ 41,405	\$ (2,767)	454	\$ (21,044)	\$ 2,427	\$ 61,485
Net income attributable to Merck & Co., Inc.				1,393					1,393
Cash dividends declared on common stock				(3,552)					(3,552)
Mandatory conversion of 6% convertible preferred stock	4	2	132						134
Treasury stock shares purchased						47	(1,593)		(1,593)
Share-based compensation plans and other	10	5	742			(4)	129		876
Other comprehensive loss					(723)				(723)
Net income attributable to noncontrolling interests								89	89
Distributions attributable to noncontrolling interests								(61)	(61)
Balance September 30, 2010	3,577	\$ 1,788	\$ 40,557	\$ 39,246	\$ (3,490)	497	\$ (22,508)	\$ 2,455	\$ 58,048
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

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 the Shares Option (see Note 8), this preferred

stock obligation will be settled.

**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)

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

<i>(\$ in millions)</i>	Derivatives	Investments	Employee Benefit Plans	Cumulative Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
Balance January 1, 2010	\$ (42)	\$ 33	\$ (2,469)	\$ (289)	\$ (2,767)
Other comprehensive income (loss)	30	17	142	(912)	(723)
Balance at September 30, 2010	\$ (12)	\$ 50	\$ (2,327)	\$ (1,201)	\$ (3,490)
Balance January 1, 2011	\$ 41	\$ 31	\$ (2,043)	\$ (1,245)	\$ (3,216)
Other comprehensive income (loss)	(77)	(11)	59	532	503
Balance at September 30, 2011	\$ (36)	\$ 20	\$ (1,984)	\$ (713)	\$ (2,713)

Comprehensive income (loss) was \$1.8 billion and \$1.5 billion for the three months ended September 30, 2011 and 2010, respectively, and was \$5.3 billion and \$669 million for the nine months ended September 30, 2011 and 2010, respectively.

Included in the cumulative translation adjustment are pretax (losses) gains of \$(84) million and \$221 million for the first nine months of 2011 and 2010, respectively, from euro-denominated notes which have been designated as, and are effective as, economic hedges of the net investment in a foreign operation. Also included in cumulative translation adjustment are pretax gains (losses) of approximately \$393 million and \$(963) million for the first nine months of 2011 and 2010, respectively, relating to translation impacts of intangible assets recorded in conjunction with the Merger.

**11. Share-Based Compensation Plans**

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

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

<i>(\$ in millions)</i>	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Pretax share-based compensation expense	\$ 86	\$ 125	\$ 287	\$ 400
Income tax benefit	(30)	(42)	(99)	(136)
Total share-based compensation expense, net of taxes	\$ 56	\$ 83	\$ 188	\$ 264

During the first nine months of 2011 and 2010, the Company granted 8 million RSUs with a weighted-average grant date fair value of \$36.44 per RSU and 10 million RSUs with a weighted-average grant date fair value of \$33.90

per RSU, respectively.

- 30 -

---

**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)

During the first nine months of 2011 and 2010, the Company granted 8 million options with a weighted-average exercise price of \$36.55 per option and 7 million options with a weighted-average exercise price of \$34.27 per option, respectively. The weighted-average fair value of options granted for the first nine months of 2011 and 2010 was \$5.37 and \$7.99 per option, respectively, and was determined using the following assumptions:

	Nine Months Ended September 30,	
	2011	2010
Expected dividend yield	4.3%	4.1%
Risk-free interest rate	2.6%	2.8%
Expected volatility	23.2%	33.7%
Expected life (years)	7.0	6.8

At September 30, 2011, there was \$483 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 1.9 years. For segment reporting, share-based compensation costs are unallocated expenses.

**12. Pension and Other Postretirement Benefit Plans**

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

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Service cost	\$ 158	\$ 125	\$ 461	\$ 426
Interest cost	182	158	541	507
Expected return on plan assets	(243)	(225)	(728)	(657)
Net amortization	58	22	149	110
Termination benefits	15	14	32	42
Curtailments	(6)	(3)	(16)	(40)
Settlements			(1)	(7)
	\$ 164	\$ 91	\$ 438	\$ 381

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

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Service cost	\$ 27	\$ 27	\$ 83	\$ 81
Interest cost	35	37	106	111
Expected return on plan assets	(35)	(32)	(106)	(97)
Net amortization	(4)	1	(13)	5
Termination benefits	5	9	11	36

Curtailments	(1)	1		(1)
	\$ 27	\$ 43	\$ 81	\$ 135

In connection with restructuring actions (see Note 2), termination charges for the three and nine months ended September 30, 2011 and 2010 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.



**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)**13. Other (Income) Expense, Net**

Other (income) expense, net, consisted of:

(\$ in millions)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2011	2010	2011	2010
Interest income	\$ (45)	\$ (23)	\$ (137)	\$ (57)
Interest expense	189	173	557	539
Exchange losses	59	8	102	84
Other, net	(137)	950	287	429
	\$ 66	\$ 1,108	\$ 809	\$ 995

Interest income in the third quarter and first nine months of 2011 increased primarily due to higher average investment balances. 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. Other, net for the third quarter and first nine months of 2010 reflects a \$950 million charge for the *Vioxx* Liability Reserve (see Note 9). In addition, Other, net for the first nine months of 2010 also reflects \$443 million of income recognized upon AstraZeneca's asset option exercise and \$102 million of income recognized on the settlement of certain disputed royalties.

Exchange losses for the first nine months of 2010 reflect a Venezuelan currency devaluation in the first quarter of 2010 resulting in the recognition of \$80 million of exchange losses. Effective January 11, 2010, the Venezuelan government devalued its currency from at BsF 2.15 per U.S. dollar to a two-tiered official exchange rate at (1) the essentials rate at BsF 2.60 per U.S. dollar and (2) the non-essentials rate at BsF 4.30 per U.S. dollar. In January 2010, the Company was required to remeasure its local currency operations in Venezuela to U.S. dollars as the Venezuelan economy was determined to be hyperinflationary. Throughout 2010, the Company settled its transactions at the essentials rate and therefore remeasured monetary assets and liabilities using the essentials rate. In December 2010, the Venezuelan government announced it would eliminate the essentials rate and, effective January 1, 2011, all transactions would be settled at the official rate of at BsF 4.30 per U.S. dollar. As a result of this announcement, the Company remeasured its December 31, 2010 monetary assets and liabilities at the new official rate.

Interest paid for the nine months ended September 30, 2011 and 2010 was \$261 million and \$442 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).

**14. Taxes on Income**

The effective tax rates of 26.7% for the third quarter of 2011 and 15.7% for the first nine months of 2011 reflect the impacts of purchase accounting adjustments and restructuring costs, partially offset by the beneficial impact of foreign earnings. In addition, the effective tax rate for the first nine months of 2011 also reflects a net favorable impact relating to the settlement of Old Merck's 2002-2005 federal income tax audit as discussed below, a \$230 million net favorable impact of certain foreign and state tax rate changes that resulted in a reduction of deferred tax liabilities on intangibles established in purchase accounting, and the favorable impact of the \$500 million charge related to the resolution of the arbitration proceeding with J&J. The effective tax rates of 25.3% for the third quarter of 2010 and 37.1% for the first nine months of 2010, as compared with the statutory rate of 35%, reflect a \$380 million tax benefit from a change in a foreign entity's tax rate, which resulted in a reduction in deferred tax liabilities on product intangibles recorded in conjunction with the Merger, as well as the favorable impact of foreign earnings. These

favorable impacts were largely offset by the unfavorable impacts of purchase accounting charges, restructuring charges and the third quarter charge for the *Vioxx* Liability Reserve for which no tax impact was recorded. In addition, the effective tax rate for the first nine months of 2010 reflects the unfavorable impact of a \$147 million charge associated with a change in tax law that requires taxation of the prescription drug subsidy of the Company's retiree health benefit plans which was enacted in the first quarter of 2010 as part of U.S. health care reform legislation, as well as the unfavorable impact of AstraZeneca's asset option exercise.

- 32 -

---

**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)

The Company and Old Merck are both under examination by numerous tax authorities in various jurisdictions globally.

The Company anticipates that its liability for unrecognized tax benefits at December 31, 2010 will be reduced by approximately \$1.3 billion during 2011, as a result of various audit closures, including the Internal Revenue Service ( IRS ) settlement discussed below, other settlements or the expiration of the statute of limitations. The ultimate finalization of the Company s examinations with relevant taxing authorities can include formal administrative and legal proceedings, which could have a significant impact on the timing of the reversal of unrecognized tax benefits. The Company believes that its reserves for uncertain tax positions are adequate to cover existing risks or exposures.

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

As previously disclosed, the Canada Revenue Agency ( CRA ) has proposed adjustments for 1999 and 2000 relating to intercompany pricing matters and, in July 2011, the CRA issued assessments for other miscellaneous audit issues for tax years 2001-2004. These adjustments would increase Canadian tax due by approximately \$330 million (U.S. dollars) plus approximately \$370 million (U.S. dollars) of interest through September 30, 2011. The Company disagrees with the positions taken by the CRA and believes they are without merit. The Company continues to contest the assessments through the CRA appeals process. The CRA is expected to prepare similar adjustments for later years. Management believes that resolution of these matters will not have a material effect on the Company s financial position or liquidity.

In October 2001, IRS auditors asserted that two interest rate swaps that Schering-Plough entered into with an unrelated party should be re-characterized as loans from affiliated companies, resulting in additional tax liability for the 1991 and 1992 tax years. In September 2004, Schering-Plough made payments to the IRS in the amount of \$194 million for income taxes and \$279 million for interest. The Company s tax reserves were adequate to cover these payments. Schering-Plough filed refund claims for the taxes and interest with the IRS in December 2004. Following the IRS s denial of Schering-Plough s claims for a refund, Schering-Plough filed suit in May 2005 in the U.S. District Court for the District of New Jersey for refund of the full amount of taxes and interest. A decision in favor of the government was announced in August 2009. The Company s appeal of the decision was denied by the U.S. Court of Appeals for the Third Circuit in June 2011. The Company s petition for a rehearing was denied.

In 2010, the IRS finalized its examination of Schering-Plough s 2003-2006 tax years. In this audit cycle, the Company reached an agreement with the IRS on an adjustment to income related to intercompany pricing matters. This income adjustment mostly reduced net operating losses ( NOLs ) and other tax credit carryforwards. Additionally, the Company is seeking resolution of one issue raised during this examination through the IRS administrative appeals process. The Company s reserves for uncertain tax positions were adequate to cover all adjustments related to this examination period. The IRS began its examination of the 2007-2009 tax years for the Company in 2010.

**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)**15. Earnings Per Share**

The Company calculates earnings per share pursuant to the two-class method, which is an earnings allocation formula that determines earnings per share for common stock and participating securities according to dividends declared and participation rights in undistributed earnings. Under this method, all earnings (distributed and undistributed) are allocated to common shares and participating securities based on their respective rights to receive dividends. RSUs and certain PSUs granted before December 31, 2009 to certain management level employees participate in dividends on the same basis as common shares and such dividends are nonforfeitable by the holder. As a result, these RSUs and PSUs meet the definition of a participating security. For RSUs and PSUs issued on or after January 1, 2010, dividends declared during the vesting period are payable to the employees only upon vesting and therefore such RSUs and PSUs do not meet the definition of a participating security.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
<i>Basic Earnings per Common Share</i>				
Net income attributable to Merck & Co., Inc.	\$ 1,692	\$ 342	\$ 4,760	\$ 1,393
Less: Income allocated to participating securities	3	2	12	6
Net income allocated to common shareholders	\$ 1,689	\$ 340	\$ 4,748	\$ 1,387
Average common shares outstanding	3,070	3,078	3,079	3,099
	\$ 0.55	\$ 0.11	\$ 1.54	\$ 0.45
<i>Earnings per Common Share Assuming Dilution</i>				
Net income attributable to Merck & Co., Inc.	\$ 1,692	\$ 342	\$ 4,760	\$ 1,393
Less: Income allocated to participating securities	3	2	12	6
Net income allocated to common shareholders	\$ 1,689	\$ 340	\$ 4,748	\$ 1,387
Average common shares outstanding	3,070	3,078	3,079	3,099
Common shares issuable <sup>(1)</sup>	21	24	23	24
Average common shares outstanding assuming dilution	3,091	3,102	3,102	3,123
	\$ 0.55	\$ 0.11	\$ 1.53	\$ 0.44

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

For the three months ended September 30, 2011 and 2010, 170 million and 173 million, respectively, and for the nine months ended 2011 and 2010, 170 million and 177 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.

**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)**16. Segment Reporting**

The Company's operations are principally managed on a products basis and are comprised of four operating segments: Pharmaceutical, Animal Health, Consumer Care and Alliances (which includes revenue and equity income from the Company's relationship with AZLP). The Animal Health, Consumer Care and Alliances segments are not material for separate reporting and are included in all other in the table below. The 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. Segment composition reflects certain managerial changes that have been implemented. Consumer Care product sales outside the United States and Canada, previously included in the Pharmaceutical segment, are now included in the Consumer Care segment. Segment disclosures for prior periods have been recast on a comparable basis with 2011.

Revenues and profits for these segments are as follows:

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Segment revenues:				
Pharmaceutical segment	\$ 10,354	\$ 9,523	\$ 30,534	\$ 28,826
All other segment revenues	1,559	1,453	4,833	4,548
	\$ 11,913	\$ 10,976	\$ 35,367	\$ 33,374
Segment profits:				
Pharmaceutical segment	\$ 6,355	\$ 5,851	\$ 19,014	\$ 17,578
All other segment profits	709	598	2,080	1,945
	\$ 7,064	\$ 6,449	\$ 21,094	\$ 19,523

Segment profits are comprised of segment revenues less certain elements of materials and production costs and operating expenses, including components of equity income or loss from affiliates and depreciation and amortization expenses. For internal management reporting presented to the chief operating decision maker, Merck does not allocate production costs, other than standard costs, research and development expenses or general and administrative expenses, nor the cost of financing these activities. Separate divisions maintain responsibility for monitoring and managing these costs, including depreciation related to fixed assets utilized by these divisions and, therefore, they are not included in segment profits.



**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)

Sales of the Company's products were as follows:

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
<b>Pharmaceutical:</b>				
<i>Cardiovascular</i>				
Zetia	\$ 614	\$ 571	\$ 1,788	\$ 1,668
Vytorin	469	485	1,407	1,452
Integrilin	53	63	172	203
<i>Diabetes and Obesity</i>				
Januvia	846	600	2,364	1,710
Janumet	350	247	977	666
<i>Diversified Brands</i>				
Cozaar/Hyzaar	404	423	1,236	1,690
Zocor	110	114	345	347
Propecia	112	109	330	322
Claritin Rx	55	53	240	210
Remeron	65	50	181	160
Vasotec/Vaseretic	57	69	173	191
Proscar	58	58	171	172
<i>Infectious Disease</i>				
Isentress	343	278	972	777
PegIntron	163	168	482	539
Cancidas	150	135	476	437
Primaxin	124	135	397	452
Invanz	107	91	296	249
Avelox	59	59	227	224
Noxafil	61	52	171	150
Crixivan/Stocrin	56	49	151	148
Rebetol	38	55	138	166
Vitreolis	31		53	
<i>Neurosciences and Ophthalmology</i>				
Maxalt	156	133	460	401
Cosopt/Trusopt	124	114	360	353
<i>Oncology</i>				
Temodar	223	254	704	799
Emend	98	91	305	268
Intron A	47	50	143	155
<i>Respiratory and Immunology</i>				
Singulair	1,336	1,215	4,018	3,638
Remicade	561	661	2,156	2,004
Nasonex	266	259	962	917
Clarinex	128	131	492	486
Arcoxia	108	94	321	284
Simponi	74	27	203	55
Asmanex	42	48	149	155

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

Proventil	38	43	117	155
Dulera	22	2	59	2
<i>Vaccines <sup>(1)</sup></i>				
Gardasil	445	316	935	768
ProQuad/M-M-R II/Varivax	391	434	927	1,093
RotaTeq	184	119	457	350
Pneumovax	133	110	276	220
Zostavax	108	23	254	136
<i>Women's Health and Endocrine</i>				
Fosamax	215	220	644	692
NuvaRing	159	134	455	414
Follistim AQ	129	119	404	389
Implanon	80	64	220	165
Cerazette	74	56	199	160
Other pharmaceutical <sup>(2)</sup>	888	942	2,567	2,834
<b>Total Pharmaceutical segment sales</b>	<b>10,354</b>	<b>9,523</b>	<b>30,534</b>	<b>28,826</b>
Other segment sales <sup>(3)</sup>	1,559	1,453	4,833	4,548
<b>Total segment sales</b>	<b>11,913</b>	<b>10,976</b>	<b>35,367</b>	<b>33,374</b>
Other <sup>(4)</sup>	109	149	386	519
	<b>\$ 12,022</b>	<b>\$ 11,125</b>	<b>\$ 35,753</b>	<b>\$ 33,893</b>

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

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

<sup>(3)</sup> *Reflects other non-reportable segments, including Animal Health and Consumer Care, and revenue from the Company's relationship with AZLP primarily relating to sales of Nexium, as well as Prilosec. Revenue from AZLP was \$299 million and \$345 million for the third quarter of 2011 and 2010, respectively, and \$928 million and \$950 million for the first nine months of 2011 and 2010, respectively.*

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



**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)

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

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Segment profits	\$ 7,064	\$ 6,449	\$ 21,094	\$ 19,523
Other profits	31	53	67	168
Adjustments	242	73	718	323
Unallocated:				
Interest income	45	23	137	57
Interest expense	(189)	(173)	(557)	(539)
Equity income from affiliates	47	98	62	98
Depreciation and amortization	(619)	(699)	(1,814)	(1,985)
Research and development	(1,954)	(2,322)	(6,048)	(6,552)
Amortization of purchase accounting adjustments	(1,306)	(1,540)	(4,249)	(5,576)
Restructuring costs	(119)	(50)	(773)	(864)
Arbitration settlement charge			(500)	
Legal reserve		(950)		(950)
Gain on AstraZeneca option exercise				443
Other expenses, net	(890)	(464)	(2,384)	(1,792)
	\$ 2,352	\$ 498	\$ 5,753	\$ 2,354

Other profits are primarily comprised of miscellaneous corporate profits, as well as operating profits related to third-party manufacturing sales, divested products or businesses and other supply sales. Adjustments represent the elimination of the effect of double counting certain items of income and expense. Equity income from affiliates includes taxes paid at the joint venture level and a portion of equity income that is not reported in segment profits. Other expenses, net include expenses from corporate and manufacturing cost centers and other miscellaneous income (expense), net.

**Table of Contents****Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations****Merger**

On November 3, 2009, Merck & Co., Inc. ( Old Merck ) and Schering-Plough Corporation ( Schering-Plough ) merged (the Merger ). In the Merger, Schering-Plough acquired all of the shares of Old Merck, which became a wholly owned subsidiary of Schering-Plough and was renamed Merck Sharp & Dohme Corp. Schering-Plough continued as the surviving public company and was renamed Merck & Co., Inc. ( New Merck or the Company ). However, for accounting purposes only, the Merger was treated as an acquisition with Old Merck considered the accounting acquirer. References in this report and in the accompanying financial statements to Merck for periods prior to the Merger refer to Old Merck and for periods after the completion of the Merger to New Merck.

**Arbitration Settlement**

In April 2011, Merck and Johnson & Johnson ( J&J ) reached agreement to amend the distribution rights to *Remicade* (influximab) and *Simponi* (golimumab). This agreement concluded the arbitration proceeding J&J initiated in May 2009, requesting a ruling related to the distribution agreement following the announcement of the proposed merger between Merck and Schering-Plough. Under the terms of the amended distribution agreement, Merck relinquished exclusive 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 ( Retained Territories ). The Retained Territories represented approximately 70% of Merck's 2010 revenue of \$2.8 billion from *Remicade* and *Simponi*. 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. Under the prior terms of the distribution agreement, the contribution income (profit) split, which was at 58% to Merck and 42% percent to J&J, would have declined for Merck and increased for J&J each year until 2014, when it would have been equally divided. J&J also received a one-time payment from Merck of \$500 million in April 2011.

**U.S. Health Care Reform Legislation**

In 2010, the United States enacted major health care reform legislation. Various insurance market reforms began last year and will continue through full implementation in 2014. The new law is expected to expand access to health care to more than 32 million Americans by the end of the decade that did not previously have regular access to health care.

With respect to the effect of the law on the pharmaceutical industry, beginning in 2010, the law increased the mandated Medicaid rebate from 15.1% to 23.1%, expanded the rebate to Medicaid managed care utilization, and increased the types of entities eligible for the federal 340B drug discount program. The implementation of these provisions reduced revenues by approximately \$44 million and \$43 million in the third quarter of 2011 and 2010, respectively, and by \$129 million and \$120 million for the first nine months of 2011 and 2010, respectively.

Effective in 2011, the law also requires pharmaceutical manufacturers to pay a 50% discount on Medicare Part D utilization by beneficiaries when they are in the Medicare Part D coverage gap (i.e., the so-called donut hole ). Approximately \$39 million and \$109 million was recorded as a reduction to revenue in the third quarter and first nine months of 2011, respectively, related to the estimated impact of this provision of health care reform.

**Table of Contents**

Also, beginning in 2011, pharmaceutical manufacturers are required to pay an annual health care reform fee. The total annual industry fee, which will be \$2.5 billion in 2011, will be assessed on each company in proportion to its share of sales to certain government programs, such as Medicare and Medicaid. The Company's portion of the annual fee is payable no later than September 30 of the applicable calendar year and is not tax deductible. The liability related to the annual fee for 2011 was initially estimated by the Company to be \$167 million and was recorded in full during the first quarter of 2011 with a corresponding offset to a deferred asset. This estimate was refined and revised downward by \$5 million in the third quarter of 2011 to \$162 million. The deferred asset is being amortized to *Marketing and administrative* expenses during 2011 on a straight-line basis (net of any revisions), therefore \$37 million and \$122 million of expense was recognized in the third quarter and first nine months of 2011, respectively. The preliminary invoice for this fee was received and paid by the Company in the third quarter of 2011.

**Acquisition**

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. Certain estimated values are not yet finalized and may be subject to change. The Company expects to finalize these amounts as soon as possible, but no later than one year from the acquisition date. 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 beginning after 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.

**Management Changes**

In August 2011, Merck announced the appointment of Richard R. DeLuca Jr. as executive vice president and president, Merck Animal Health, effective September 15, 2011. In September 2011, Merck announced the appointment of Cuong Viet Do as chief strategy officer, effective October 3, 2011. Both Mr. DeLuca and Mr. Do report to Kenneth C. Frazier, Merck's president and chief executive officer, and serve on the Company's Executive Committee.

In October 2011, Merck announced that Richard T. Clark, chairman, will retire from the Company and the Merck board of directors effective December 1, 2011. The board elected Kenneth C. Frazier, Merck's president and chief executive officer, to serve as chairman following Mr. Clark's retirement.

**Other**

In September 2011, Merck announced that it will launch Merck for Mothers, a long-term effort with global health partners to create a world where no woman has to die from preventable complications of pregnancy and childbirth. The launch includes a 10-year, \$500 million initiative that applies Merck's scientific and business expertise to making proven solutions more widely available, developing new technologies and improving public awareness, policy efforts and private sector engagement for maternal mortality. Merck for Mothers will focus on the two leading causes of maternal mortality (excessive and uncontrolled bleeding after childbirth, known as post-partum hemorrhage, and life-threatening high blood pressure during pregnancy, known as preeclampsia) as well as family planning, which is known to play an important role in reducing maternal mortality.

**Table of Contents****Operating Results**

Segment composition reflects certain managerial changes that have been implemented. Consumer Care product sales outside the United States and Canada, previously included in the Pharmaceutical segment, are now included in the Consumer Care segment. Segment disclosures for prior periods have been recast on a comparable basis with 2011.

*Sales*

Worldwide sales were \$12.0 billion for the third quarter of 2011, an increase of 8% compared with the third quarter of 2010. Foreign exchange favorably affected global sales performance by 5% for the third quarter of 2011. The revenue increase largely reflects higher sales of *Januvia* (sitagliptin) and *Janumet* (sitagliptin/metformin HCl), *Gardasil* [human papillomavirus quadrivalent (types 6, 11, 16 and 18) vaccine, recombinant], *Singulair* (montelukast sodium), *Zostavax* (zoster vaccine live), *RotaTeq* (rotavirus vaccine, live, oral, pentavalent) and *Isentress* (raltegravir). Also contributing to revenue growth in the quarter were higher sales of *Simponi*, *Zetia* (ezetimibe), as well as increased sales of the Company's animal health products. These increases were partially offset by lower sales of *Remicade* due to the relinquishment of marketing rights in certain territories as a result of the arbitration settlement discussed above. Revenue was also negatively affected by lower sales of Caelyx for which the Company no longer has marketing rights, lower sales of *ProQuad* (measles, mumps, rubella and varicella virus vaccine live) and lower revenue from the Company's relationship with AstraZeneca LP (AZLP).

Worldwide sales were \$35.8 billion for the first nine months of 2011, an increase of 5% compared with the same period in 2010. Foreign exchange favorably affected global sales performance by 3% for the first nine months of 2011. The revenue increase largely reflects higher sales of *Januvia* and *Janumet*, *Singulair*, *Isentress*, *Gardasil*, *Remicade*, *Simponi*, *Zetia*, *Zostavax* and *RotaTeq*, as well as increased sales of the Company's animal health products. These increases were partially offset by lower sales of *Cozaar* (losartan potassium) and *Hyzaar* (losartan potassium-hydrochlorothiazide), which lost patent protection in the United States in April 2010 and in a number of major European markets in March 2010, as well as lower sales of Caelyx and Subutex/Suboxone for which the Company no longer has marketing rights, and decreased sales of *Varivax* (varicella virus vaccine live).

While many of the Company's brands are experiencing positive growth trends in the European Union (EU) during 2011, the environment in the EU continues to be challenging. Many countries have announced austerity measures, which include the implementation of pricing actions to reduce prices of generic and patented drugs. While the Company is taking steps to mitigate the impact in the EU, the austerity measures have negatively affected the Company's revenue performance in 2011 and the Company anticipates the austerity measures will continue to negatively affect revenue performance into 2012.

**Table of Contents**

Sales of the Company's products were as follows:

(\$ in millions)	Three Months Ended		Nine Months Ended	
	September 30, 2011	September 30, 2010	September 30, 2011	September 30, 2010
<b>Pharmaceutical:</b>				
<i>Cardiovascular</i>				
Zetia	\$ 614	\$ 571	\$ 1,788	\$ 1,668
Vytorin	469	485	1,407	1,452
Integrilin	53	63	172	203
<i>Diabetes and Obesity</i>				
Januvia	846	600	2,364	1,710
Janumet	350	247	977	666
<i>Diversified Brands</i>				
Cozaar/Hyzaar	404	423	1,236	1,690
Zocor	110	114	345	347
Propecia	112	109	330	322
Claritin Rx	55	53	240	210
Remeron	65	50	181	160
Vasotec/Vaseretic	57	69	173	191
Proscar	58	58	171	172
<i>Infectious Disease</i>				
Isentress	343	278	972	777
PegIntron	163	168	482	539
Cancidas	150	135	476	437
Primaxin	124	135	397	452
Invanz	107	91	296	249
Avelox	59	59	227	224
Noxafil	61	52	171	150
Crixivan/Stocrin	56	49	151	148
Rebetol	38	55	138	166
Vitreolis	31		53	
<i>Neurosciences and Ophthalmology</i>				
Maxalt	156	133	460	401
Cosopt/Trusopt	124	114	360	353
<i>Oncology</i>				
Temodar	223	254	704	799
Emend	98	91	305	268
Intron A	47	50	143	155
<i>Respiratory and Immunology</i>				
Singulair	1,336	1,215	4,018	3,638
Remicade	561	661	2,156	2,004
Nasonex	266	259	962	917
Clarinx	128	131	492	486
Arcoxia	108	94	321	284
Simponi	74	27	203	55
Asmanex	42	48	149	155
Proventil	38	43	117	155

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

Dulera	22	2	59	2
<i>Vaccines</i> <sup>(1)</sup>				
Gardasil	445	316	935	768
ProQuad/M-M-R II/Varivax	391	434	927	1,093
RotaTeq	184	119	457	350
Pneumovax	133	110	276	220
Zostavax	108	23	254	136
<i>Women's Health and Endocrine</i>				
Fosamax	215	220	644	692
NuvaRing	159	134	455	414
Follistim AQ	129	119	404	389
Implanon	80	64	220	165
Cerazette	74	56	199	160
Other pharmaceutical <sup>(2)</sup>	888	942	2,567	2,834
Total Pharmaceutical segment sales	10,354	9,523	30,534	28,826
Other segment sales <sup>(3)</sup>	1,559	1,453	4,833	4,548
Total segment sales	11,913	10,976	35,367	33,374
Other <sup>(4)</sup>	109	149	386	519
	\$ 12,022	\$ 11,125	\$ 35,753	\$ 33,893

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

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

(3) *Reflects other non-reportable segments, including Animal Health and Consumer Care, and revenue from the Company's relationship with AZLP primarily relating to sales of Nexium, as well as Prilosec. Revenue from AZLP was \$299 million and \$345 million for the third quarter of 2011 and 2010, respectively, and was \$928 million and \$950 million for the first nine months of 2011 and 2010, respectively.*

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

**Table of Contents**

The provision for discounts includes indirect customer discounts that occur when a contracted customer purchases directly through an intermediary wholesale purchaser, known as chargebacks, as well as indirectly in the form of rebates owed based upon definitive contractual agreements or legal requirements with private sector and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. These discounts, in the aggregate, reduced revenues by \$1.5 billion and \$1.2 billion for the three months ended September 30, 2011 and 2010, respectively, and \$4.0 billion and \$3.5 billion for the nine months ended September 30, 2011 and 2010, respectively. Inventory levels at key U.S. wholesalers for each of the Company's major pharmaceutical products are generally less than one month.

**Pharmaceutical Segment Revenues***Cardiovascular*

Sales of *Zetia* (also marketed as *Ezetrol* outside the United States), a cholesterol-absorption inhibitor, were \$614 million in the third quarter of 2011, an increase of 8% compared with the third quarter of 2010, and were \$1.8 billion for the first nine months of 2011, an increase of 7% compared with the same period in 2010. These increases reflect favorable pricing in the United States, and higher sales in international markets due in part to the positive impact of foreign exchange, partially offset by volume declines in the United States. Sales of *Vytorin* (ezetimibe/simvastatin) (marketed outside the United States as *Inegy*), a combination product containing the active ingredients of both *Zetia* and *Zocor* (simvastatin), were \$469 million and \$1.4 billion for the third quarter and first nine months of 2011, respectively, representing declines of 3% compared with the same periods in 2010. These results reflect volume declines in the United States, partially offset by sales increases in international markets due in large part to the positive impact of foreign exchange.

Supplemental New Drug Applications ( sNDAs ) for *Vytorin* and *Zetia* have been accepted for standard review by the U.S. Food and Drug Administration (the FDA ). The sNDAs seek indications for *Vytorin*, and for *Zetia* when used in combination with simvastatin, for the prevention of major cardiovascular events in patients with chronic kidney disease. On November 2, 2011, the FDA's Endocrinologic and Metabolic Drugs Advisory Committee unanimously voted to recommend approval of the ezetimibe/simvastatin combination for use in patients with pre-dialysis chronic kidney disease based on the results of the Study of Heart and Renal Protection (SHARP) trial. The Committee's vote was mixed (with the majority not in favor) regarding whether there is sufficient evidence to support approval specifically for patients with end-stage renal disease who are receiving dialysis. The Committee's non-binding recommendation will be considered by the FDA in its assessment of these investigational uses for *Vytorin* and *Zetia*. Currently, the Company's sNDAs remain under review, with FDA action expected in the first quarter of 2012.

As previously disclosed, in early September 2011, Merck was advised that the IMPROVE-IT executive committee has decided to schedule the study's second interim analysis in the first quarter of 2012, rather than as previously anticipated in late 2011. As previously disclosed, the Data Safety Monitoring Board for IMPROVE-IT plans to conduct an interim analysis for efficacy when approximately 75% of the pre-specified (5,250) primary clinical endpoints have occurred. The study is fully enrolled and approximately 70% of its pre-specified events had been reported as of early September 2011.

In July 2011, Merck and Astellas US, LLC ( Astellas ) entered into an agreement under which Merck acquired exclusive rights in Canada, Mexico and the United States to develop and commercialize the investigational intravenous formulation of vernakalant ( vernakalant i.v. ) from Astellas. Under the terms of the agreement, Merck paid Astellas a *de minimis* upfront fee. In addition, Astellas will be eligible for milestone payments associated with (i) development, (ii) regulatory approval as well as (iii) sales thresholds associated with vernakalant i.v. in Canada, Mexico and the United States. Astellas had been granted an exclusive license to develop and commercialize vernakalant i.v. in Canada, Mexico and the United States by Cardiome Pharma Corp ( Cardiome ). Under an agreement with Cardiome in 2009, Merck acquired exclusive rights outside of Canada, Mexico and the United States to vernakalant i.v., as well as exclusive worldwide rights to oral formulations of vernakalant. In September 2010, Merck was granted marketing approval in the EU, Iceland and Norway for vernakalant i.v. (marketed as *Brinavess*) for rapid conversion of recent onset atrial fibrillation to sinus rhythm in adults: for non-surgery patients with atrial fibrillation of seven days or less and for post-cardiac surgery patients with atrial fibrillation of three days or less.

*Diabetes and Obesity*

Global sales of *Januvia*, Merck's dipeptidyl peptidase-4 ( DPP-4 ) inhibitor for the treatment of type 2 diabetes, were \$846 million in the third quarter of 2011 and \$2.4 billion for the first nine months of 2011, representing increases of 41% and 38%, respectively, compared with the same periods of 2010, reflecting growth in the United States, as well as in international markets, particularly in Japan and across Europe. DPP-4 inhibitors represent a class of prescription medications that improve blood sugar control in patients with type 2 diabetes by enhancing a natural body system called the incretin system, which helps to regulate glucose by affecting the beta cells and alpha cells in the pancreas.

Worldwide sales of *Janumet*, Merck's oral antihyperglycemic agent that combines sitagliptin (*Januvia*) with metformin in a single tablet to target all three key defects of type 2 diabetes, were \$350 million for the third



**Table of Contents**

quarter of 2011, an increase of 42% compared with the third quarter of 2010, and were \$977 million for the first nine months of 2011, an increase of 47% compared with the first nine months of 2010, reflecting growth both in the United States and internationally.

In October 2011, the FDA approved *Juvisync* (sitagliptin and simvastatin), a new treatment for type 2 diabetes that combines the glucose-lowering medication sitagliptin, the active component of *Januvia*, with the cholesterol-lowering medication *Zocor*. *Juvisync* is the first treatment option for health care providers to help patients who need the blood sugar-lowering benefits of a DPP-4 inhibitor and the cholesterol-lowering benefits of simvastatin, with the convenience of a single tablet once daily.

In July 2011, the Company received a Complete Response letter from the FDA for *Janumet XR* (MK-0431A XR), the Company's investigational extended-release formulation of *Janumet*, related to the resolution of pre-approval inspection issues. Merck has responded to the questions raised by the FDA and expects a response from the FDA in the first quarter of 2012.

***Diversified Brands***

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

Global sales of *Cozaar* and its companion agent *Hyzaar* (a combination of *Cozaar* and hydrochlorothiazide) for the treatment of hypertension declined 4% in the third quarter of 2011 and 27% in the first nine months of 2011 compared with the same periods in 2010. The patents that provided U.S. market exclusivity for *Cozaar* and *Hyzaar* expired in April 2010. In addition, *Cozaar* and *Hyzaar* lost patent protection in a number of major European markets in March 2010. Accordingly, the Company has experienced significant declines in *Cozaar* and *Hyzaar* sales and the Company expects the declines to continue.

Other products contained in the Diversified Brands franchise include among others, *Zocor*, a statin for modifying cholesterol; *Propecia* (finasteride), a product for the treatment of male pattern hair loss; prescription *Claritin* (loratadine) for the treatment of seasonal outdoor allergies and year-round indoor allergies; *Remeron* (mirtazapine), an antidepressant; *Vasotec* (enalapril maleate) and *Vaseretic* (enalapril maleate-hydrochlorothiazide) for hypertension and/or heart failure; and *Proscar* (finasteride), a urology product for the treatment of symptomatic benign prostate enlargement. *Remeron* lost market exclusivity in the United States in January 2010 and has also lost market exclusivity in most European markets.

***Infectious Disease***

Global sales of *ISENTRESS*, an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-naïve and treatment-experienced adults, were \$343 million in the third quarter of 2011, an increase of 23% compared with the third quarter of 2010, and were \$972 million in the first nine months of 2011, an increase of 25% compared with the first nine months of 2010, reflecting positive performance in the United States and Europe due in part to the impact of foreign exchange. *ISENTRESS* works by inhibiting the insertion of HIV DNA into human DNA by the integrase enzyme. Inhibiting integrase from performing this essential function helps to limit the ability of the virus to replicate and infect new cells.

Worldwide sales of *PegIntron* (peginterferon alpha-2b) for treating chronic hepatitis C were \$163 million for the third quarter of 2011, a decline of 3% compared with the third quarter of 2010, and were \$482 million for the first nine months of 2011, a decrease of 11% compared with the same period in 2010. The Company believes these declines were attributable in part to patient treatment being delayed by health care providers in anticipation of new therapeutic options becoming available.

In May 2011, the FDA approved *Victrelis* (boceprevir), the Company's innovative new oral medicine for the treatment of chronic hepatitis C. *Victrelis* is approved for the treatment of chronic hepatitis C genotype 1 infection, in combination with peginterferon alfa and ribavirin, in adult patients (18 years of age and older) with compensated liver disease, including cirrhosis, who are previously untreated or who have failed previous interferon and ribavirin therapy. *Victrelis* is an antiviral agent designed to interfere with the ability of the hepatitis C virus to replicate by inhibiting a key viral enzyme. In July 2011, the European Commission (EC) approved *Victrelis*. The EC's decision grants a single marketing authorization that is valid in the 27 countries that are members of the EU, as well as unified labeling

applicable to Iceland, Liechtenstein and Norway. *Vitreolis* has been launched in the United States and in 13 international markets: Brazil, Canada and 11 markets in the EU, including France, Germany, the United Kingdom and Spain. Sales of *Vitreolis* were \$31 million for the third quarter of 2011 and were \$53 million for the first nine months of 2011.

**Table of Contents**

Sales of *Primaxin* (imipenem and cilastatin), an anti-bacterial product, were \$124 million in the third quarter of 2011 and \$397 million in the first nine months of 2011, representing declines of 8% and 12% compared with the same periods of 2010, primarily reflecting unfavorable pricing and lower volumes due to competitive pressures. Patents on *Primaxin* have expired worldwide and multiple generics have been launched in Europe. Accordingly, the Company is experiencing a decline in sales of *Primaxin* and the Company expects the decline to continue.

Other products contained in the Infectious Disease franchise include among others, *Cancidas* (caspofungin acetate), an anti-fungal product; *Invanz* (ertapenem) for the treatment of certain infections; *Avelox* (moxifloxacin hydrochloride), a fluoroquinolone antibiotic for the treatment of certain respiratory and skin infections; *Noxafil* (posaconazole) for the prevention of invasive fungal infections; *Crixivan* (indinavir sulfate) and *Stocrin* (efavirenz), antiretroviral therapies for the treatment of HIV infection; and *Rebetol* (ribavirin, USP) for use in combination with *PegIntron* for treating chronic hepatitis C. The compound patent that provides U.S. market exclusivity for *Crixivan* expires in 2012.

*Neurosciences and Ophthalmology*

Global sales of *Maxalt* (rizatriptan benzoate), Merck's tablet for the acute treatment of migraine, were \$156 million for the third quarter of 2011, an increase of 17% compared with the third quarter of 2010, and were \$460 million for the first nine months of 2011, an increase of 15% compared with the first nine months of 2010, reflecting a higher inventory level in the United States. The compound patent for *Maxalt*, together with pediatric exclusivity, provides market exclusivity in the United States until December 2012. In addition, the patent for *Maxalt* will expire in a number of major European markets in 2013. The Company anticipates that sales in the United States and in these European markets will decline significantly after these patent expiries.

Worldwide sales of ophthalmic products *Cosopt* (dorzolamide hydrochloride-timolol maleate) and *Trusopt* (dorzolamide hydrochloride) were \$124 million in the third quarter of 2011, an increase of 9% compared with the third quarter of 2010, and were \$360 million in the first nine months of 2011, an increase of 2% compared with the same period in 2010, reflecting higher sales in Japan partially offset by lower sales in Europe that were mitigated in part by the positive impact of foreign exchange. The patent that provided U.S. market exclusivity for *Cosopt* and *Trusopt* expired in October 2008. *Trusopt* has also lost market exclusivity in a number of major European markets. The patent for *Cosopt* will expire in a number of major European markets in March 2013 and the Company expects sales in those markets to decline significantly thereafter.

In April 2011, the New Drug Application (NDA) for Merck's investigational preservative-free formulation of *Cosopt* ophthalmic solution, containing a combination topical carbonic anhydrase inhibitor and beta-adrenergic receptor blocking agent, was accepted for standard review by the FDA.

*Bridion* (sugammadex), for the reversal of certain muscle relaxants during surgery, is currently approved and has launched in many countries outside of the United States. Sales of *Bridion* were \$52 million and \$141 million for the third quarter and first nine months of 2011, respectively. *Bridion* is in Phase III development in the United States.

In August 2009, the FDA approved *Saphris* (asenapine) for the acute treatment of schizophrenia in adults and for the acute treatment of manic or mixed episodes associated with bipolar I disorder with or without psychotic features in adults. In September 2010, two sNDAs for *Saphris* were approved in the United States to expand the product's indications to the treatment of schizophrenia in adults, as monotherapy for the acute treatment of manic or mixed episodes associated with bipolar I disorder in adults, and as adjunctive therapy with either lithium or valproate for the acute treatment of manic or mixed episodes associated with bipolar I disorder in adults. In September 2010, asenapine, to be sold under the brand name *Sycrest*, received marketing approval in the EU for the treatment of moderate to severe manic episodes associated with bipolar I disorder in adults; the marketing approval did not include an indication for schizophrenia. In October 2010, Merck and H. Lundbeck A/S (Lundbeck) announced a worldwide commercialization agreement for *Sycrest* sublingual tablets (5 mg, 10 mg). Under the terms of the agreement, Lundbeck paid a fee and will make product supply payments in exchange for exclusive commercial rights to *Sycrest* in all markets outside the United States, China and Japan. Merck retained exclusive commercial rights to asenapine in the United States, China and Japan. Concurrently, Merck is continuing to pursue regulatory approval for asenapine in other parts of the world.

Merck continues to focus on building the brand awareness of *Saphris* in the United States and has launched a black cherry flavor of the sublingual tablet to provide an additional taste option. Merck continues to monitor and assess *Saphris/Sycrest* and the related intangible asset. If increasing the brand awareness, the additional flavor

- 44 -

---

**Table of Contents**

option, or Lundbeck's launch of the product in the EU is not successful, the Company may take a non-cash impairment charge with respect to *Saphris/Sycrest*, and such charge could be material.

The Neurosciences and Ophthalmology franchise also included the products Subutex/Suboxone for the treatment of opiate addiction. In 2010, Merck sold the rights to Subutex/Suboxone in nearly all markets back to Reckitt Benckiser Group PLC (Reckitt). The rights to the products in most major markets reverted to Reckitt on July 1, 2010 and the remainder has since reverted to Reckitt during 2011 with the exception of some very small markets. Sales of Subutex/Suboxone were \$110 million for the first nine months of 2010.

**Oncology**

Sales of *Temodar* (temozolomide) (marketed as *Temodal* outside the United States), a treatment for certain types of brain tumors, were \$223 million for the third quarter of 2011, a decline of 12% compared with the third quarter of 2010, and were \$704 million for the first nine months of 2011, a decline of 12% compared with the first nine months of 2010, primarily reflecting generic competition in Europe. *Temodar* lost patent exclusivity in the EU in 2009.

Global sales of *Emend* (aprepitant), a treatment for chemotherapy-induced nausea and vomiting, were \$98 million in the third quarter of 2011, an increase of 8% compared with the third quarter of 2010, and were \$305 million in the first nine months of 2011, an increase of 14% compared with the same period in 2010, reflecting growth in international markets.

Other products in the Oncology franchise include among others, *Intron A* (interferon alpha-2b, recombinant) for treating melanoma. Marketing rights for Caelyx for the treatment of ovarian cancer, metastatic breast cancer and Kaposi's sarcoma transitioned to J&J as of December 31, 2010. Sales of Caelyx were \$70 million and \$209 million in the third quarter and first nine months of 2010, respectively.

In March 2011, the FDA approved *Sylatron* (peginterferon alfa-2b), a once-weekly subcutaneous injection indicated for the adjuvant treatment of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy.

**Respiratory and Immunology**

Worldwide sales for *Singulair*, a once-a-day oral medicine indicated for the chronic treatment of asthma and for the relief of symptoms of allergic rhinitis, were \$1.3 billion for the third quarter of 2011, an increase of 10% compared with the third quarter of 2010 reflecting favorable pricing in the United States and the favorable effect of foreign exchange. Sales for the first nine months of 2011 were \$4.0 billion, an increase of 10% compared with the first nine months of 2010 reflecting favorable pricing in the United States, the favorable effect of foreign exchange and volume growth in Japan, partially offset by volume declines in the United States. *Singulair* continues to be the number one prescribed branded product in the U.S. respiratory market. The patent that provides U.S. market exclusivity for *Singulair* expires in August 2012. The Company expects that within the two years following patent expiration, it will lose substantially all U.S. sales of *Singulair*, with most of those declines coming in the first full year following patent expiration. In addition, the patent for *Singulair* will expire in a number of major European markets in August 2012 and the Company expects sales of *Singulair* in those markets will decline significantly thereafter (although the six month Pediatric Market Exclusivity may extend this date in some markets to February 2013).

Sales of *Remicade*, a treatment for inflammatory diseases, were \$561 million for the third quarter of 2011, a decrease of 15% compared with the third quarter of 2010, and were \$2.2 billion for the first nine months of 2011, an increase of 8% compared with the same period in 2010. Foreign exchange favorably affected sales performance by 11% and 7% in the third quarter and first nine months of 2011, respectively. Prior to July 1, 2011, *Remicade* was marketed by the Company outside of the United States (except in Japan and certain other Asian markets). As a result of the agreement reached in April 2011 to amend the distribution rights to *Remicade* and *Simponi* (see Note 4 to the interim consolidated financial statements), effective July 1, 2011, Merck relinquished marketing rights for these products in certain territories including Canada, Central and South America, the Middle East, Africa and Asia Pacific. The sales performance in the third quarter and first nine months of 2011 as compared with same periods in 2010 reflect these changes. In Merck-retained territories, *Remicade* sales grew 25% in the third quarter and 17% for the first nine months of 2011, which reflect 15% and 9% favorable impacts from foreign exchange, respectively. *Simponi*, a once-monthly subcutaneous treatment for certain inflammatory diseases, was approved by the EC in October 2009. In January 2011, *Simponi* was approved in the EU for use in combination with methotrexate in adults with severe, active

and progressive rheumatoid arthritis not previously treated with methotrexate and for the reduction in the rate of progression of joint damage as measured by X-ray in rheumatoid arthritis patients. Sales of *Simponi* were \$74 million in the third quarter of 2011 compared with \$27 million in the third quarter of 2010 and

- 45 -

---

**Table of Contents**

were \$203 million for the first nine months of 2011 compared with \$55 million for the first nine months of 2010. The revenue increases in both periods were primarily driven by sales growth in the European markets where the Company retained the marketing rights for *Simponi*.

Global sales of *Nasonex* (mometasone furoate monohydrate), an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, were \$266 million for the third quarter of 2011, an increase of 3% compared with the third quarter of 2010 driven by positive performance in emerging markets and the beneficial impact of foreign exchange. Sales of *Nasonex* were \$962 million for the first nine months of 2011, an increase of 5% compared with the same period in 2010, driven largely by volume growth in Japan and Latin America and the positive effect of foreign exchange, partially offset by volume declines in the United States.

Global sales of *Clarinex* (desloratadine) (marketed as *Aerius* in many countries outside the United States), a non-sedating antihistamine, were \$128 million for the third quarter of 2011, a decrease of 2% compared with the third quarter of 2010. Sales of *Clarinex* for the first nine months of 2011 were \$492 million, an increase of 1% compared with the first nine months of 2010.

Other products included in the Respiratory and Immunology franchise include among others, *Arcoxia* (etoricoxib) for the treatment of arthritis and pain; *Asmanex* (mometasone furoate inhalation powder), an inhaled corticosteroid for asthma; *Proventil* (albuterol sulfate) Inhalation Aerosol for the relief of bronchospasm; and *Dulera* (mometasone furoate/formoterol fumarate dihydrate) Inhalation Aerosol for the treatment of asthma. An sNDA for *Dulera* for the treatment of chronic obstructive pulmonary disease ( COPD ) has been accepted for review by the FDA.

***Vaccines***

The following discussion of vaccines does not include sales of vaccines sold in most major European markets through Sanofi Pasteur MSD ( SPMSD ), the Company's joint venture with Sanofi Pasteur, the results of which are reflected in *Equity income from affiliates* (see Selected Joint Venture and Affiliate Information below). Supply sales to SPMSD, however, are included.

Worldwide sales of *Gardasil* recorded by Merck grew 41% in the third quarter of 2011 to \$445 million and increased 22% for the first nine months of 2011 to \$935 million driven by increased vaccination of both females and males and wholesaler purchases in conjunction with the launch in Japan. Sales growth in the year-to-date period was partially offset by lower government orders in Canada. *Gardasil*, the world's top-selling human papillomavirus ( HPV ) vaccine, is indicated for girls and women 9 through 26 years of age for the prevention of cervical, vulvar and vaginal cancers caused by HPV types 16 and 18, precancerous or dysplastic lesions caused by HPV types 6, 11, 16 and 18, and genital warts caused by HPV types 6 and 11. *Gardasil* is also approved in the United States for use in boys and men ages 9 through 26 years of age for the prevention of genital warts caused by HPV types 6 and 11. In December 2010, the FDA approved a new indication for *Gardasil* for the prevention of anal cancer caused by HPV types 16 and 18 and for the prevention of anal intraepithelial neoplasia grades 1, 2 and 3 (anal dysplasias and precancerous lesions) caused by HPV types 6, 11, 16 and 18, in males and females 9 through 26 years of age.

In June 2011, *Gardasil* was approved in Japan for the prevention of cervical cancer (squamous cell cancer and adenocarcinoma) and their precursor lesions (cervical intraepithelial neoplasm grade 1/2/3 and cervical adenocarcinoma in situ), vulvar intraepithelial neoplasia grade 1/2/3, vaginal intraepithelial neoplasia grade 1/2/3 and genital warts caused by HPV types 6, 11, 16 and 18 in females 9 years of age and older.

In October 2011, the U.S. Centers for Disease Control and Prevention's ( CDC ) Advisory Committee on Immunization Practices voted to recommend that boys 11 to 12 years old be vaccinated routinely with *Gardasil* to help prevent anal cancer caused by HPV types 16 and 18, anal dysplasias and precancerous lesions caused by HPV types 6, 11, 16 and 18, and genital warts caused by HPV types 6 and 11. Additionally, the Committee recommended that *Gardasil* be administered to males 13 to 21 years of age who have not previously been vaccinated or have not completed the three-dose series, and that the vaccination series can be started at age 9 years at the discretion of their physicians.

Global sales of *RotaTeq*, a vaccine to help protect against rotavirus gastroenteritis in infants and children, recorded by Merck were \$184 million in the third quarter of 2011, an increase of 55% compared with the third quarter of 2010. Sales for the first nine months of 2011 were \$457 million, an increase of 31% compared with the same period in 2010, reflecting favorable public sector inventory fluctuations.





**Table of Contents**

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

A limited quantity of *ProQuad*, a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, one of the VZV-containing vaccines, became available in the United States for ordering in the second quarter of 2010. Merck's sales of *ProQuad* were \$49 million and \$97 million in the third quarter and first nine months of 2010, respectively. This supply has been exhausted and the Company does not anticipate availability of *ProQuad* for the remainder of 2011. Sales of *ProQuad* were \$37 million in the first quarter of 2011. The Company did not record any sales of *ProQuad* in the second or third quarter of 2011.

Merck's sales of *Varivax*, a vaccine to help prevent chickenpox (varicella), were \$290 million for the third quarter of 2011 compared with \$289 million for the third quarter of 2010 and were \$640 million for the first nine months of 2011 compared with \$740 million for the first nine months of 2010. Sales in the first nine months of 2010 include \$48 million of revenue as a result of government purchases for the CDC's Strategic National Stockpile. Merck's sales of *M-M-R II* (measles, mumps and rubella virus vaccine live), a vaccine to help protect against measles, mumps and rubella, were \$102 million for the third quarter of 2011 compared with \$96 million for the third quarter of 2010 and were \$251 million for the first nine months of 2011 compared with \$256 million for the first nine months of 2010. Sales of *Varivax* and *M-M-R II* in the second and third quarters of 2011 benefited from the unavailability of *ProQuad* as noted above.

Merck's sales of *Zostavax*, a vaccine to help prevent shingles (herpes zoster), were \$108 million for the third quarter of 2011 as compared with \$23 million in the third quarter of 2010 and were \$254 million in the first nine months of 2011 compared with \$136 million in the first nine months of 2010. Supply availability has improved, however the Company anticipates that backorders will continue until inventory levels are sufficient to meet market demand. Due to these supply constraints, no broad international launches or immunization programs are currently planned for 2011 or 2012.

In March 2011, the FDA approved an expanded age indication for *Zostavax* for the prevention of shingles to include adults ages 50 to 59. *Zostavax* is now indicated for the prevention of herpes zoster in individuals 50 years of age and older.

The adult formulation of *Recombivax HB* [hepatitis B vaccine (recombinant)], a vaccine against hepatitis B, is now available.

**Women's Health and Endocrine**

Worldwide sales for *Fosamax* (alendronate sodium) and *Fosamax Plus D* (alendronate sodium/cholecalciferol) (marketed as *Fosavance* throughout the EU and as *Fosamac* in Japan) for the treatment and, in the case of *Fosamax*, prevention of osteoporosis were \$215 million for the third quarter of 2011, representing a decline of 2% over the comparable period of 2010, and were \$644 million for the first nine months of 2011, a decrease of 7% compared with the same period in 2010. These medicines have lost market exclusivity in the United States and have also lost market exclusivity in most major European markets. Accordingly, the Company is experiencing sales declines within the *Fosamax* product franchise and the Company expects the declines to continue.

Worldwide sales of *NuvaRing* (etonogestrel/ethinyl estradiol), a contraceptive product, were \$159 million for the third quarter of 2011, an increase of 18% compared with the third quarter of 2010, and were \$455 million for the first nine months of 2011, an increase of 10% compared with the first nine months of 2010. Global sales of *Follistim AQ* (follitropin beta injection) (marketed in most countries outside the United States as *Puregon*), a biological fertility treatment, were \$129 million for the third quarter of 2011, an increase of 8% compared with the third quarter of 2010, and were \$404 million for the first nine months of 2011, an increase of 4% compared with the first nine months of 2010. The increases in both periods were largely driven by the beneficial impact of foreign exchange, as well as by positive performance in emerging markets. *Puregon* lost market exclusivity in the EU in August 2009.

Other products contained in the Women's Health and Endocrine franchise include among others, *Implanon* (etonogestrel implant), a single-rod subdermal contraceptive implant; and *Cerazette* (desogestrol), a progestin only oral contraceptive.

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

- 47 -

---

**Table of Contents**

In August 2011, *Zoely*, an oral contraceptive (norgestrol acetate 2.5 mg/17 $\beta$ -estradiol 1.5 mg), was granted marketing authorization by the EC for the prevention of pregnancy in women. *Zoely* is a combined oral contraceptive tablet containing a unique monophasic combination of 2 hormones: norgestrol acetate, a highly selective progesterone-derived progestin, and 17 $\beta$ -estradiol, an estrogen that is similar to the one naturally present in a woman's body. The marketing authorization of *Zoely* applies to all 27 EU member states plus Iceland, Liechtenstein and Norway. Teva Pharmaceutical Industries Ltd. holds exclusive marketing rights for *Zoely* in France, Italy, Belgium and Spain.

On November 4, 2011, Merck received a Complete Response letter from the FDA for NOMAC/E2 (MK-8175A), which is being marketed as *Zoely* in the EU. The Company plans to have further discussions with the FDA with regard to the letter.

**Other***Animal Health*

Animal Health includes pharmaceutical and vaccine products for the prevention, treatment and control of disease in all major farm and companion animal species. Animal Health sales are affected by intense competition and the frequent introduction of generic products. Global sales of Animal Health products totaled \$826 million for the third quarter of 2011, an increase of 20% compared with the third quarter of 2010, and were \$2.4 billion for the first nine months of 2011, an increase of 12% compared with the first nine months of 2010. Foreign exchange favorably affected global sales performance by 6% and 5%, respectively, in the third quarter and first nine months of 2011. The increased sales in both periods reflect positive performance in cattle, swine and poultry products.

*Consumer Care*

Consumer Care products include over-the-counter, foot care and sun care products such as *Claritin* non-drowsy antihistamines; *MiraLAX*, a treatment for occasional constipation; *Dr. Scholl's* foot care products; and *Coppertone* sun care products. Global sales of Consumer Care products were \$421 million for the third quarter of 2011, an increase of 3% compared with the third quarter of 2010, reflecting increases in *MiraLAX* and *Zegerid OTC*, a treatment for frequent heartburn, partially offset by declines in *Dr. Scholl's*. Consumer Care sales were \$1.5 billion for the first nine months of 2011, an increase of 3% compared with the first nine months of 2010, reflecting strong performance of *Coppertone*, partially offset by declines in *Dr. Scholl's*. Foreign exchange favorably affected global sales performance by 2% and 1%, respectively, in the third quarter and first nine months of 2011. Consumer Care product sales are affected by competition and consumer spending patterns.

*Alliances*

AstraZeneca has an option to buy Old Merck's interest in Nexium and Prilosec, exercisable in 2012, and the Company believes that it is likely that AstraZeneca will exercise that option (see Selected Joint Venture and Affiliate Information below). If AstraZeneca does exercise the option, the Company will no longer record equity income from AZLP and supply sales to AZLP will decline substantially.

**Costs, Expenses and Other**

In February 2010, 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. Additional actions under the program continued during 2010. On July 29, 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. In addition, the Company has eliminated over 2,500 positions which were vacant at the time of the Merger. The Company will continue to hire employees in strategic growth areas of the business as necessary. The Company will continue to pursue productivity efficiencies and evaluate its manufacturing supply chain capabilities on an ongoing basis which may result in future restructuring actions.

The Company recorded total pretax restructuring costs of \$255 million and \$384 million in the third quarter of 2011 and 2010, respectively, and \$1.2 billion and \$1.5 billion for the first nine months of 2011 and 2010, respectively, related to this program. The restructuring actions under the Merger Restructuring Program are expected to be substantially completed by the end of 2013, with the exception of certain actions, principally manufacturing-related, which are expected to be completed by 2015, with the total cumulative pretax costs estimated to be approximately \$5.8 billion to \$6.6 billion. The Company estimates that approximately two-thirds of the cumulative pretax costs relate to cash outlays, primarily related to employee separation expense. Approximately one-third of the cumulative pretax costs are non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested. The Company expects the Merger Restructuring Program to yield annual savings by the end of 2013 of approximately \$3.5 billion to \$4.0 billion and annual savings upon completion of the program of

**Table of Contents**

approximately \$4.0 billion to \$4.6 billion. These cost savings, which are expected to come from all areas of the Company's pharmaceutical business, are in addition to the previously announced ongoing cost reduction initiatives at both legacy companies. Additional savings will come from non-restructuring-related activities.

In October 2008, Old 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 \$20 million were recorded in the third quarter of 2011 and \$25 million and \$130 million for the first nine months of 2011 and 2010, respectively, related to the 2008 Restructuring Program. The 2008 Restructuring Program is expected to be completed by the end of 2011, with the exception of certain manufacturing-related actions, with the total cumulative pretax costs estimated to be up to \$2.0 billion. The Company estimates that two-thirds of the cumulative pretax costs relate to cash outlays, primarily from employee separation expense. Approximately one-third of the cumulative pretax costs are non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested. Merck expects the 2008 Restructuring Program to yield cumulative pretax savings of \$3.8 billion to \$4.2 billion from 2008 to 2013.

The Company anticipates that total costs associated with restructuring activities in 2011 for the Merger Restructuring Program and the 2008 Restructuring Program will be in the range of \$1.3 billion to \$1.5 billion.

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

Materials and production costs were \$4.4 billion for the third quarter of 2011, an increase of 4% compared with the third quarter of 2010, and were \$12.7 billion for the first nine months of 2011, a decline of 9% compared with the first nine months of 2010. Costs in the third quarter of 2011 and 2010 include \$1.3 billion and \$1.1 billion, respectively, and for the first nine months of 2011 and 2010 include \$3.7 billion and \$3.4 billion, respectively, of expenses for the amortization of intangible assets recognized in connection with mergers and acquisitions. Additionally, expenses for the third quarter and first nine months of 2010 include \$266 million and \$2.1 billion of amortization of purchase accounting adjustments to Schering-Plough's inventories recognized as a result of the Merger. Costs in the first nine months of 2011 include an intangible asset impairment charge of \$118 million. The Company may recognize additional non-cash impairment charges in the future related to product intangibles that were measured at fair value and capitalized in connection with mergers and acquisitions and such charges could be material. Also included in materials and production costs were costs associated with restructuring activities which amounted to \$99 million and \$44 million in the third quarter of 2011 and 2010, respectively, and \$280 million and \$325 million in the first nine months of 2011 and 2010, respectively, including accelerated depreciation and asset write-offs related to the planned sale or closure of manufacturing facilities. Separation costs associated with manufacturing-related headcount reductions have been incurred and are reflected in *Restructuring costs* as discussed below.

Gross margin was 63.8% in the third quarter of 2011 compared with 62.3% in the third quarter of 2010 and was 64.5% for the first nine months of 2011 compared with 58.8% for the first nine months of 2010. The amortization of intangible assets and purchase accounting adjustments to inventories, as well as the restructuring and impairment charges noted above and certain acquisition-related costs had an unfavorable effect on gross margin of 11.5 and 12.6 percentage points for the third quarter of 2011 and 2010, respectively, and 11.8 and 16.8 percentage points for the first nine months of 2011 and 2010, respectively. Excluding these impacts, the gross margin improvements reflect changes in product mix and lower costs due to manufacturing efficiencies.

Marketing and administrative expenses were \$3.3 billion in the third quarter of 2011, an increase of 5% compared with the third quarter of 2010, and were \$10.0 billion for the first nine months of 2011, an increase of 5% compared with the first nine months of 2010. The increases were due in part to the unfavorable effect of foreign exchange and strategic investments made in emerging markets. Expenses for the third quarter and first nine months of 2011 included restructuring costs of \$31 million and \$77 million, respectively, primarily related to accelerated depreciation for facilities to be closed or divested. Expenses for the third quarter and first nine months of 2010 included \$130 million of such costs. Separation costs associated with sales force reductions have been incurred and are reflected in *Restructuring costs* as discussed below. Marketing and administrative expenses included \$57 million and \$64 million

of acquisition-related costs in the third quarter of 2011 and 2010, respectively, and \$192 million and \$219 million for the first nine months of 2011 and 2010, respectively, consisting largely of integration costs related to the Merger, and for the first nine months of 2011 also consist of severance costs associated with the acquisition of Inspire which are not part of

**Table of Contents**

the Company's formal restructuring programs. Additionally, marketing and administrative expenses in the third quarter and first nine months of 2011 include \$37 million and \$122 million, respectively, of expenses for the estimated annual health care reform fee which the Company was required to pay beginning in 2011 as part of U.S. health care reform legislation. The Company is amortizing the estimated cost for 2011 on a straight-line basis, net of any revisions to the estimate.

Research and development expenses were \$2.0 billion for the third quarter of 2011, a decline of 16% compared with the third quarter of 2010, and were \$6.0 billion for the first nine months of 2011, a decrease of 8% compared with the first nine months of 2010. Research and development expenses are comprised of the costs associated within Merck Research Labs ( MRL ), the Company's research and development division that focuses on human health-related activities, certain costs from operating segments, including Pharmaceutical, Animal Health and Consumer Care, as well as from other divisions responsible for production, general and administrative and depreciation. Research and development expenses also include in-process research and development impairment charges and research and development related restructuring charges. Research and development expenses in 2011 were favorably affected by cost savings resulting from restructuring activities.

Expenses incurred by MRL were approximately \$1.1 billion and \$1.2 billion for the third quarter of 2011 and 2010, respectively, and \$3.4 billion and \$3.6 billion for the first nine months of 2011, respectively. Research costs incurred by other divisions were approximately \$800 million and \$750 million for the third quarter of 2011 and 2010, respectively, and \$2.3 billion and \$2.5 billion for the first nine months of 2011 and 2010, respectively. In addition, during the third quarter and first nine months of 2011, the Company recorded \$22 million and \$343 million, respectively, of in-process research and development ( IPR&D ) impairment charges primarily for programs that had previously been deprioritized and were either deemed to have no alternative use during the period or were out-licensed to a third party for consideration that was less than the related asset's carrying value. During the third quarter and first nine months of 2010, the Company recorded \$189 million and \$216 million, respectively, of IPR&D impairment charges attributable to compounds identified during the Company's pipeline prioritization review that were abandoned and determined to have either no alternative use or were returned to the respective licensor, as well as from expected delays in the launch timing or changes in cash flow assumptions for certain compounds. The Company may recognize additional non-cash impairment charges in the future for the cancellation of other pipeline programs that were measured at fair value and capitalized in connection with mergers and acquisitions and such charges could be material. Also, research and development expenses in the third quarter of 2011 and 2010 reflect \$28 million and \$163 million, respectively, and for the first nine months of 2011 and 2010 reflect \$89 million and \$313 million, respectively, of accelerated depreciation and asset abandonment costs associated with restructuring activities.

Restructuring costs, primarily representing separation and other related costs associated with restructuring activities, were \$119 million and \$773 million for the third quarter and first nine months of 2011, respectively, a substantial majority of which related to the Merger Restructuring Program. Costs for the first nine months of 2011 reflect a reduction of separation reserves of approximately \$50 million resulting from the Company's decision in the first quarter to retain approximately 380 employees at its Oss, Netherlands research facility that had previously been expected to be separated. Restructuring costs were \$50 million and \$864 million for the third quarter and first nine months of 2010, respectively, of which \$43 million and \$810 million, respectively, related to the Merger Restructuring Program, \$7 million and \$62 million, respectively, related to the 2008 Restructuring Program and the remaining activity related to the legacy Schering-Plough Productivity Transformation Program. Separation costs were incurred associated with actual headcount reductions, as well as estimated expenses under existing severance programs for headcount reductions that were probable and could be reasonably estimated. Merck eliminated approximately 1,510 positions in the third quarter of 2011 of which 1,300 related to the Merger Restructuring Program, 110 related to the 2008 Restructuring Program and 100 related to the legacy Schering-Plough Productivity Transformation Program. During the first nine months of 2011, Merck eliminated approximately 3,025 positions of which 2,635 related to the Merger Restructuring Program, 290 related to the 2008 Restructuring Program and 100 related to the legacy Schering-Plough program. For the third quarter of 2010, Merck eliminated 2,385 positions of which 2,175 related to the Merger Restructuring Program, 180 related to the 2008 Restructuring Program and the remainder to the legacy Schering-Plough Productivity Transformation Program. Merck eliminated 10,820 positions in

the first nine months of 2010, of which 9,760 related to the Merger Restructuring Program, 955 related to the 2008 Restructuring Program and the remainder to the legacy Schering-Plough program. These position eliminations are comprised of actual headcount reductions, and the elimination of contractors and vacant positions. Also included in restructuring costs are curtailment, settlement and termination charges associated with pension and other postretirement benefit plans, share-based compensation and shutdown costs. For segment reporting, restructuring costs are unallocated expenses. Additional costs associated with the Company s

- 50 -

---



**Table of Contents**

restructuring activities are included in *Materials and production, Marketing and administrative* and *Research and development*. (See Note 2 to the interim consolidated financial statements.)

Equity income from affiliates, which reflects the performance of the Company's joint ventures and other equity method affiliates, primarily AZLP, was \$161 million and \$236 million in the third quarter of 2011 and 2010, respectively, and was \$354 million and \$417 million in the first nine months of 2011 and 2010, respectively. During the third quarter of 2011, the Company divested its interest in the Johnson & Johnson<sup>o</sup> Merck Consumer Pharmaceuticals Company ( JJMCP ) joint venture. (See Selected Joint Venture and Affiliate Information below.)

Other (income) expense, net was \$66 million of expense in the third quarter of 2011 compared with \$1.1 billion of expense in the third quarter of 2010. The third quarter of 2011 includes a \$136 million gain on the disposition of the Company's interest in the JJMCP joint venture (see Note 8 to the interim consolidated financial statements). The third quarter of 2010 reflects a \$950 million charge for the *Vioxx* Liability Reserve (see Note 9 to the interim consolidated financial statements). Other (income) expense, net was \$809 million of expense in the first nine months of 2011 compared with \$995 million of expense in the first nine months 2010. Included in other (income) expense, net during the first nine months of 2011 was a \$500 million charge related to the resolution of the arbitration proceeding involving the Company's rights to market *Remicade* and *Simponi* (see Note 4 to the interim consolidated financial statements), a gain of \$136 million related to the divestiture of the JJMCP joint venture noted above, and a \$127 million gain on the sale of certain manufacturing facilities and related assets. Included in other (income) expense, net in the first nine months of 2010 was the \$950 million legal charge for the *Vioxx* Liability Reserve noted above, \$443 million of income recognized upon AstraZeneca's exercise of the asset option (see Note 8 to the interim consolidated financial statements) and \$102 million of income on the settlement of certain disputed royalties. Additionally, during the first nine months of 2010, the Company recognized exchange losses of \$80 million related to a Venezuelan currency devaluation. Effective January 11, 2010, the Venezuelan government devalued its currency from at BsF 2.15 per U.S. dollar to a two-tiered official exchange rate at (1) the essentials rate at BsF 2.60 per U.S. dollar and (2) the non-essentials rate at BsF 4.30 per U.S. dollar. In January 2010, Merck was required to remeasure its local currency operations in Venezuela to U.S. dollars as the Venezuelan economy was determined to be hyperinflationary. Throughout 2010, the Company settled its transactions at the essentials rate and therefore remeasured monetary assets and liabilities using the essentials rate. In December 2010, the Venezuelan government announced it would eliminate the essentials rate and, effective January 1, 2011, all transactions would be settled at the official rate of at BsF 4.30 per U.S. dollar. As a result of this announcement, the Company remeasured its December 31, 2010 monetary assets and liabilities at the new official rate.

*Segment Profits*

(\$ in millions)	Three Months Ended		Nine Months Ended	
	September 30, 2011	September 30, 2010	September 30, 2011	September 30, 2010
Pharmaceutical segment profits	\$ 6,355	\$ 5,851	\$ 19,014	\$ 17,578
Other non-reportable segment profits	709	598	2,080	1,945
Other	(4,712)	(5,951)	(15,341)	(17,169)
Income before income taxes	\$ 2,352	\$ 498	\$ 5,753	\$ 2,354

Segment profits are comprised of segment revenues less certain elements of materials and production costs and operating expenses, including components of equity income or loss from affiliates and depreciation and amortization expenses. For internal management reporting presented to the chief operating decision maker, Merck does not allocate production costs, other than standard costs, research and development expenses or general and administrative expenses, nor the cost of financing these activities. Separate divisions maintain responsibility for monitoring and managing these costs, including depreciation related to fixed assets utilized by these divisions and, therefore, they are not included in segment profits. Also excluded from the determination of segment profits are the arbitration settlement

charge and the gain on the divestiture of the JJMCP joint venture recorded in 2011, the charge for the *Vioxx* Liability Reserve and the gain on AstraZeneca's asset option exercise both recognized in 2010, the amortization of purchase accounting adjustments, intangible asset impairment charges, acquisition-related costs, restructuring costs, taxes paid at the joint venture level and a portion of equity income. Additionally, segment profits do not reflect other expenses from corporate and manufacturing cost centers and other miscellaneous income or expense. These unallocated items are reflected in *Other* in the above table. Also included in *Other* are miscellaneous corporate profits, operating profits related to third-party manufacturing sales, divested products or businesses, as well as other supply sales and adjustments to eliminate the effect of double counting certain items of income and expense.

- 51 -

---

**Table of Contents**

Pharmaceutical segment profits rose 9% and 8%, respectively, in the third quarter and first nine months of 2011 driven largely by the increase in sales and the gross margin improvement discussed above.

The effective tax rates of 26.7% for the third quarter of 2011 and 15.7% for the first nine months of 2011 reflect the impacts of purchase accounting adjustments and restructuring costs, partially offset by the beneficial impact of foreign earnings. In addition, the effective tax rate for the first nine months of 2011 also reflects a net favorable impact of approximately \$700 million relating to the settlement of Old Merck's 2002-2005 federal income tax audit, 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, and the favorable impact of the \$500 million charge related to the resolution of the arbitration proceeding with J&J. The effective tax rates of 25.3% for the third quarter of 2010 and 37.1% for the first nine months of 2010, as compared with the statutory rate of 35%, reflect a \$380 million tax benefit from a change in a foreign entity's tax rate, which resulted in a reduction in deferred tax liabilities on product intangibles recorded in conjunction with the Merger, as well as the favorable impact of foreign earnings. These favorable impacts were largely offset by the unfavorable impacts of purchase accounting charges, restructuring charges and the third quarter charge for the *Vioxx* Liability Reserve for which no tax impact was recorded. In addition, the effective tax rate for the first nine months of 2010 reflects the unfavorable impact of a \$147 million charge associated with a change in tax law that requires taxation of the prescription drug subsidy of the Company's retiree health benefit plans which was enacted in the first quarter of 2010 as part of U.S. health care reform legislation, as well as the unfavorable impact of AstraZeneca's asset option exercise.

Net income attributable to Merck & Co., Inc. was \$1.7 billion for the third quarter of 2011 compared with \$342 million for the third quarter of 2010 and was \$4.8 billion for the first nine months of 2011 compared with \$1.4 billion for the first nine months of 2010. Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders (EPS) for the third quarter of 2011 were \$0.55 compared with \$0.11 in the third quarter of 2010 and were \$1.53 in the first nine months of 2011 compared with \$0.44 in the first nine months of 2010. The increases in net income and EPS in the third quarter and first nine months of 2011 were primarily due to lower amortization of inventory step-up, lower legal reserves and restructuring costs and, for the year-to-date period, the favorable impact of the tax settlement noted above. For the year-to-date period, the positive impact of these items on net income and EPS was partially offset by the arbitration settlement charge recorded in 2011 and the income recognized in 2010 on AstraZeneca's asset option exercise.

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

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

**Table of Contents**

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
<i>(\$ in millions, except per share amounts)</i>	2011	2010	2011	2010
Pretax income as reported under GAAP	\$ 2,352	\$ 498	\$ 5,753	\$ 2,354
Increase (decrease) for excluded items:				
Acquisition-related costs	1,363	1,604	4,460	5,812
Costs related to restructuring programs	277	387	1,219	1,632
Other items:				
Gain on disposition of interest in JJMCP joint venture and other	(137)		(137)	
Arbitration settlement charge			500	
Gain on sale of manufacturing facilities and related assets			(127)	
Vioxx Liability Reserve		950		950
Gain on AstraZeneca asset option exercise				(443)
	3,855	3,439	11,668	10,305
Taxes on income as reported under GAAP	628	126	904	872
Estimated tax benefit on excluded items	287	258	1,025	1,151
Tax benefit from settlement of federal income tax audit			700	
Tax benefit from foreign and state tax rate changes		380	230	380
Tax charge related to U.S. health care reform legislation				(147)
	915	764	2,859	2,256
Non-GAAP net income	2,940	2,675	8,809	8,049
Less: Net income attributable to noncontrolling interests	32	30	89	89
Non-GAAP net income attributable to Merck & Co., Inc.	\$ 2,908	\$ 2,645	\$ 8,720	\$ 7,960
EPS assuming dilution as reported under GAAP	\$ 0.55	\$ 0.11	\$ 1.53	\$ 0.44
EPS difference <sup>(1)</sup>	0.39	0.74	1.27	2.10
Non-GAAP EPS assuming dilution	\$ 0.94	\$ 0.85	\$ 2.80	\$ 2.54

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

Acquisition-Related Costs

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

*Restructuring Costs*

Non-GAAP income and non-GAAP EPS exclude costs related to restructuring actions, including restructuring activities related to the Merger (see Note 2 to the interim consolidated financial statements). These amounts include employee separation costs and accelerated depreciation associated with facilities to be closed or divested. Accelerated depreciation costs represent the difference between the depreciation expense to be recognized over the revised useful life of the site, based upon the anticipated date the site will be closed or divested, and depreciation expense as determined utilizing the useful life prior to the restructuring actions. The Company has undertaken restructurings of different types during the covered periods and therefore these charges should not be considered non-recurring; however, management excludes these amounts from non-GAAP income and non-GAAP EPS because it believes it is helpful for understanding the performance of the continuing business.

- 53 -

---

**Table of Contents***Certain Other Items*

Non-GAAP income and non-GAAP EPS exclude certain other items. These items represent substantive, unusual items that are evaluated on an individual basis. Such evaluation considers both the quantitative and the qualitative aspect of their unusual nature and generally represent items that, either as a result of their nature or magnitude, management would not anticipate that they would occur as part of the Company's normal business on a regular basis. Certain other items are comprised of the gain on the divestiture of the Company's interest in the JJMCP joint venture (see Note 8 to the interim consolidated financial statements), the charge related to the arbitration settlement (see Note 4 to the interim consolidated financial statements) and the gain associated with the sale of certain manufacturing facilities and related assets recorded in 2011, as well as the gain recognized upon AstraZeneca's asset option exercise in 2010 (see Note 8 to the interim consolidated financial statements). Also excluded from non-GAAP income and non-GAAP EPS are the tax benefits from the settlement of a federal income tax audit, the favorable impact of certain foreign and state tax rate changes that resulted in a net reduction of deferred tax liabilities on intangibles established in purchase accounting, and the tax charge related to U.S. health care reform legislation (see Note 14 to the interim consolidated financial statements).

**Research and Development Update**

In October 2011, the FDA approved *Juvisync* (sitagliptin and simvastatin), a new treatment for type 2 diabetes that combines the glucose-lowering medication sitagliptin, the active component of *Januvia*, with the cholesterol-lowering medication *Zocor*. *Juvisync* is the first treatment option for health care providers to help patients who need the blood sugar-lowering benefits of a DPP-4 inhibitor and the cholesterol-lowering benefits of simvastatin, with the convenience of a single tablet once daily.

In August 2011, *Zoely*, a new oral contraceptive (norgestrel acetate 2.5 mg/17 $\beta$ -estradiol 1.5 mg), was granted marketing authorization by the EC for the prevention of pregnancy in women. *Zoely* is a combined oral contraceptive tablet containing a unique monophasic combination of 2 hormones: norgestrel acetate, a highly selective progesterone-derived progestin, and 17 $\beta$ -estradiol, an estrogen that is similar to the one naturally present in a woman's body. The marketing authorization of *Zoely* applies to all 27 EU member states plus Iceland, Liechtenstein and Norway. Teva Pharmaceutical Industries Ltd. holds exclusive marketing rights for *Zoely* in France, Italy, Belgium and Spain.

On November 4, 2011, Merck received a Complete Response letter from the FDA for NOMAC/E2 (MK-8175A), which is being marketed as *Zoely* in the EU. The Company plans to have further discussions with the FDA with regard to the letter.

On November 7, 2011, Merck received a Complete Response letter from the FDA for tafluprost (MK-2452). The Company plans to have further discussions with the FDA with regard to the letter.

In September 2011, the FDA accepted for filing and review the NDA for ridaforolimus, an investigational oral mTOR inhibitor under development for the treatment of metastatic soft-tissue or bone sarcomas in patients who had a favorable response to chemotherapy. The FDA assigned a Standard review classification to this application. In August 2011, the European Medicines Agency accepted the marketing authorization application for ridaforolimus. As part of an exclusive license agreement with ARIAD, Merck is responsible for the development and worldwide commercialization of ridaforolimus in oncology. ARIAD intends to co-promote ridaforolimus in the United States.

MK-0653C, *Zetia* (ezetimibe) combined with atorvastatin was accepted for standard review by the FDA for the treatment of primary or mixed hyperlipidemia. In response to notice of the Company's filing, Pfizer Inc. (Pfizer) filed a patent infringement lawsuit in U.S. District Court against the Company asserting certain Pfizer patent rights in respect of atorvastatin. This lawsuit has the potential to bar FDA approval of the Company's NDA for up to 30 months (until January 6, 2014) subject to being shortened or lengthened by a court decision, or shortened by an agreement between the parties.

The Company is discontinuing the clinical development program for MK-0431C, a combination of sitagliptin and pioglitazone, for the treatment of diabetes. The decision is based on a review of the regulatory and commercial prospects for the combination drug candidate.

**Table of Contents**

The chart below reflects the Company's research pipeline as of November 4, 2011. Candidates shown in Phase III include specific products and the date such candidate entered into Phase III development. Candidates shown in Phase II include the most advanced compound with a specific mechanism or, if listed compounds have the same mechanism, they are each currently intended for commercialization in a given therapeutic area. Small molecules and biologics are given MK-number designations and vaccine candidates are given V-number designations. Candidates in Phase I, additional indications in the same therapeutic area and additional claims, line extensions or formulations for in-line products are not shown.

<b>Phase II</b>	<b>Phase III (Phase III entry date)</b>	<b>Under Review</b>
<b>Allergy</b> MK-8237, Immunotherapy <sup>(1)</sup>	<b>Allergy</b> MK-7243, Grass pollen <sup>(1)</sup> (March 2008)	<b>Atherosclerosis</b> MK-0653C (ezetimibe/atorvastatin) (U.S.)
<b>Cancer</b> MK-0646 (dalotuzumab) MK-1775 MK-2206 MK-7965 (dinaciclib)	MK-3641, Ragweed <sup>(1)</sup> (September 2009)	<b>Contraception</b> MK-8175A (NOMAC/E2) <sup>(4)</sup> (U.S.)
<b>Contraception, Medicated IUS</b> MK-8342	<b>Atherosclerosis</b> MK-0524A (extended-release niacin/laropiprant) (U.S.) (December 2005)	<b>Diabetes Mellitus</b> MK-0431A XR ( <i>Janumet XR</i> ) (sitagliptin/extended-release metformin) (U.S.)
<b>Diabetes Mellitus</b> MK-3102	MK-0524B (extended-release niacin/laropiprant/simvastatin) (July 2007)	<b>Glaucoma</b> MK-2452 (tafluprost) <sup>(5)</sup> (U.S.)
<b>Hepatitis C</b> MK-5172	MK-0859 (anacetrapib) (May 2008)	<b>Sarcoma</b> MK-8669 (ridaforolimus) (U.S.) (EU)
<b>Insomnia</b> MK-3697 MK-6096	<b>Atrial Fibrillation</b> MK-6621 (vernakalant I.V.) (U.S.) (August 2003) <sup>(2)</sup>	
<b>Overactive Bladder</b> MK-4618	<b>Clostridium difficile Infection</b> MK-3415A (November 2011)	
<b>Pneumoconjugate Vaccine</b> V114	<b>COPD</b> MK-0887A ( <i>Zenhale</i> ) (EU) (August 2006)	
<b>Psoriasis</b> MK-3222	<b>Diabetes and Atherosclerosis</b> MK-0431E (sitagliptin/atorvastatin) (October 2011)	<b>Footnotes:</b>
	<b>Fertility</b> MK-8962 (corifollitropin alfa for injection) (U.S.) (July 2006)	<sup>(1)</sup> North American rights only.
	<b>Hepatitis C</b> MK-7009 (vaniprevir) <sup>(3)</sup> (June 2011)	<sup>(2)</sup> Vernakalant I.V. for atrial fibrillation started Phase III clinical trials in August 2003 sponsored by Cardiome in collaboration with Astellas.
	<b>Herpes Zoster</b> V212 (inactivated VZV vaccine) (December 2010)	<sup>(3)</sup> For development in Japan only.
	<b>HPV-Related Cancers</b> V503 (HPV vaccine (9 valent)) (September 2008)	<sup>(4)</sup> On November 4, 2011, Merck received a Complete Response letter from the FDA for NOMAC/E2 (MK-8175A). The Company plans to have further discussions with the FDA with regard to the letter.
	<b>Insomnia</b> MK-4305 (suvorexant) (December 2009)	<sup>(5)</sup> On November 7, 2011, Merck received a Complete Response letter from the FDA for tafluprost
	<b>Neuromuscular Blockade Reversal</b>	

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

**Osteoporosis**

MK-0822 (odanacatib)  
(September 2007)

**Parkinson s Disease**

MK-3814 (preladenant) (July 2010)

**Pediatric Hexavalent Combination**

**Vaccine**

V419 (April 2011)

**Thrombosis**

MK-5348 (vorapaxar)  
(September 2007)

(MK-2452). The Company plans to have further discussions with the FDA with regard to the letter.



**Table of Contents****Selected Joint Venture and Affiliate Information***AstraZeneca LP*

In 1998, Old Merck and Astra completed the restructuring of the ownership and operations of their existing joint venture whereby Old 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 (the AstraZeneca merger ), became the exclusive distributor of the products for which KBI retained rights.

In connection with the 1998 restructuring, Astra purchased an option (the Asset Option ) for a payment of \$443 million, which was recorded as deferred income, to buy Old Merck's interest in the KBI products, excluding the gastrointestinal medicines Nexium and Prilosec (the Non-PPI Products ). In April 2010, AstraZeneca exercised the Asset Option. Merck received \$647 million from AstraZeneca, representing the net present value as of March 31, 2008 of projected future pretax revenue to be received by Old Merck from the Non-PPI Products, which was recorded as a reduction to the Company's investment in AZLP. The Company recognized the \$443 million of deferred income in the second quarter of 2010 as a component of *Other (income) expense, net*. In addition, in 1998, Old Merck granted Astra an option (the Shares Option ) to buy Old Merck's common stock interest in KBI and, therefore, Old Merck's interest in Nexium and Prilosec, exercisable in 2012. The exercise price for the Shares Option will be based on the net present value of estimated future net sales of Nexium and Prilosec as determined at the time of exercise, subject to certain true-up mechanisms. The Company believes that it is likely that AstraZeneca will exercise the Shares Option. If AstraZeneca does exercise the Shares Option, the Company will no longer record equity income from AZLP and supply sales to AZLP will decline substantially.

*Sanofi Pasteur MSD*

In 1994, Old Merck and Pasteur Mérieux Connaught (now Sanofi Pasteur S.A.) established an equally-owned joint venture to market vaccines in Europe and to collaborate in the development of combination vaccines for distribution in Europe. Total vaccine sales reported by SPMSD were \$375 million and \$382 million in the third quarter of 2011 and 2010, respectively, and were \$805 million and \$871 million for the first nine months of 2011 and 2010, respectively. The decline for the year-to-date period reflects in part lower sales of *Gardasil*. SPMSD sales of *Gardasil* were \$59 million and \$79 million for the third quarter of 2011 and 2010, respectively, and were \$183 million and \$244 million for the first nine months of 2011 and 2010, respectively.

*Johnson & Johnson<sup>o</sup>Merck Consumer Pharmaceuticals Company*

In September 2011, Merck sold its 50% interest in the 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 ( OTC ) consumer products in the United States and Canada. Under the agreement, 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*. Merck's rights to the *Pepcid* brand outside the United States and Canada were not affected by this transaction. Following the transaction, J&J owns the venture's assets which include the exclusive rights to market OTC *Pepcid*, Mylanta, Mylicon and other local OTC brands where they are currently sold in the United States and Canada. The partnership assets also included a manufacturing facility.

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

**Liquidity and Capital Resources**

	September 30, 2011	December 31, 2010
<i>(\$ in millions)</i>		
Cash and investments	\$ 17,999	\$ 14,376
Working capital	17,516	13,423
Total debt to total liabilities and equity	17.0%	16.9%

During the first nine months of 2011, cash provided by operating activities was \$9.2 billion compared with \$7.3 billion in the first nine months of 2010. Cash provided by operating activities during the first nine months of 2011 reflects the \$500 million payment made to J&J as a result of the arbitration settlement, as well as payments to the Internal Revenue Service ( IRS ) as a result of the settlement discussed below. On an ongoing basis, cash

- 56 -

---

**Table of Contents**

provided by operations will continue to be the Company's primary source of funds to finance operating needs and capital expenditures. The global economic downturn and the sovereign debt issues, among other factors, have caused foreign receivables to deteriorate in certain European countries. While the Company continues to receive payment on these receivables, these conditions have resulted in an increase in the average length of time it takes to collect accounts receivable outstanding thereby adversely affecting cash provided by operating activities.

Cash used in investing activities was \$1.2 billion in the first nine months of 2011 compared with \$2.5 billion in the first nine months of 2010 primarily reflecting lower purchases of securities and other investments and higher proceeds from the sales of securities and other investments. In addition, the Company received proceeds from the disposition of businesses in the first nine months of 2011. In 2010, the Company received proceeds from AstraZeneca's asset option exercise. Additionally, the Company had a greater use of cash for acquisitions of businesses and higher capital expenditures in the first nine months of 2011 as compared with the same period in 2010. Cash used in financing activities in the first nine months of 2011 was \$4.7 billion compared with \$4.1 billion in the first nine months of 2010. The higher use of cash in financing activities was primarily driven by higher payments on debt, a decrease in short-term borrowings and lower proceeds from the exercise of stock options, partially offset by lower purchases of treasury stock.

At September 30, 2011, the total of worldwide cash and investments was \$18.0 billion, including \$15.6 billion of cash, cash equivalents and short-term investments and \$2.4 billion of long-term investments. A substantial majority of these cash and investments is held by foreign subsidiaries and would be subject to significant tax payments if such cash and investments were repatriated. However, cash provided by operating activities in the United States continues to be the Company's primary source of funds to finance domestic operating needs, capital expenditures, treasury stock purchases and dividends paid to shareholders.

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

As previously disclosed, the Canada Revenue Agency (CRA) has proposed adjustments for 1999 and 2000 relating to intercompany pricing matters and, in July 2011, the CRA issued assessments for other miscellaneous audit issues for tax years 2001-2004. These adjustments would increase Canadian tax due by approximately \$330 million (U.S. dollars) plus approximately \$370 million (U.S. dollars) of interest through September 30, 2011. The Company disagrees with the positions taken by the CRA and believes they are without merit. The Company continues to contest the assessments through the CRA appeals process. The CRA is expected to prepare similar adjustments for later years. Management believes that resolution of these matters will not have a material effect on the Company's financial position or liquidity.

Capital expenditures totaled \$1.1 billion and \$1.0 billion for the first nine months of 2011 and 2010, respectively. Capital expenditures for full year 2011 are estimated to be \$1.8 billion.

Dividends paid to stockholders were \$3.5 billion and \$3.6 billion for the first nine months of 2011 and 2010, respectively. In May and July 2011, the Board of Directors declared a quarterly dividend of \$0.38 per share on the Company's common stock for the third and fourth quarters of 2011.

In April 2011, Merck announced that its Board of Directors approved additional purchases of up to \$5 billion of Merck's common stock for its treasury. The Company purchased \$1.4 billion of its common stock (41 million shares) for its treasury during the first nine months of 2011. The Company has approximately \$5.0 billion remaining under this program and the previous November 2009 treasury stock purchase authorization. The treasury stock purchases have no time limit and will be made over time on the open market, in block transactions or in privately negotiated transactions.

In May 2011, the Company entered into a new \$2.0 billion, 364-day credit facility and a new \$2.0 billion four-year credit facility maturing in May 2015. The Company terminated its existing \$2.0 billion, 364-day credit facility which expired in May 2011 and its \$2.0 billion revolving credit facility that was scheduled to mature in

- 57 -

---

**Table of Contents**

August 2012. Both outstanding facilities provide backup liquidity for the Company's commercial paper borrowing facility and are to be used for general corporate purposes. The Company has not drawn funding from either facility.

During the third quarter of 2011, the Company entered into a transaction which will require the Company to make future bulk supply purchases of \$150 million in the aggregate through 2016, although this period may be extended in certain circumstances.

**Critical Accounting Policies**

The Company's significant accounting policies, which include management's best estimates and judgments, are included in Note 2 to the consolidated financial statements for the year ended December 31, 2010 included in Merck's Form 10-K filed on February 28, 2011. Certain of these accounting policies are considered critical as disclosed in the Critical Accounting Policies and Other Matters section of Management's Discussion and Analysis of Financial Condition and Results of Operations included in Merck's Form 10-K because of the potential for a significant impact on the financial statements due to the inherent uncertainty in such estimates. There have been no significant changes in the Company's critical accounting policies since December 31, 2010 other than with respect to guidance on revenue recognition adopted on January 1, 2011 as discussed in Note 1 to the interim consolidated financial statements.

**Item 4. Controls and Procedures**

Management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures over financial reporting for the period covered by this Form 10-Q. Based on this assessment, the Company's Chief Executive Officer and Chief Financial Officer have concluded that as of September 30, 2011, the Company's disclosure controls and procedures are effective. As previously disclosed, the Company is continuing its plans for integration of its business operations and the implementation of an enterprise wide resource planning system (SAP). These process modifications, which included several of the Company's major European markets during 2011, affect the design and operation of controls over financial reporting. With each implementation, the Company continues to monitor the status of the business and financial operations and believes that an effective control environment has been maintained post-implementation.

**CAUTIONARY FACTORS THAT MAY AFFECT FUTURE RESULTS**

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

The Company does not assume the obligation to update any forward-looking statement. One should carefully evaluate such statements in light of factors, including risk factors, described in the Company's filings with the Securities and Exchange Commission, especially on Forms 10-K, 10-Q and 8-K. In Item 1A. Risk Factors of the Company's Annual Report on Form 10-K for the year ended December 31, 2010, as filed on February 28, 2011, the Company discusses in more detail various important risk factors that could cause actual results to differ from expected or historic results. The Company notes these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. One should understand that it is not possible to predict or identify all such factors. Consequently, the reader should not consider any such list to be a complete statement of all potential risks or uncertainties.

**Table of Contents****PART II Other Information****Item 1. Legal Proceedings**

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

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

Issuer purchases of equity securities for the three months ended September 30, 2011 were as follows:

**ISSUER PURCHASES OF EQUITY SECURITIES**

	Total Number of Shares Purchased <sup>(1)</sup>	Average Price Paid Per Share	(\$ in millions) Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs <sup>(1)</sup>
Period			
July 1 - July 31	2,991,702	\$ 35.70	\$ 5,985
August 1 - August 31	15,000,293	\$ 31.69	\$ 5,510
September 1 - September 30	14,410,264	\$ 32.13	\$ 5,047
Total	32,402,259	\$ 32.25	\$ 5,047

<sup>(1)</sup> All shares purchased during the period were made as part of plans approved by the Board of Directors in November 2009 to purchase up to \$3 billion in Merck shares and in April 2011 to purchase up to \$5 billion in Merck shares.

**Table of Contents**

**Item 6. Exhibits**

Number	Description
3.1	Restated Certificate of Incorporation of Merck & Co., Inc. (November 3, 2009) Incorporated by reference to Current Report on Form 8-K filed on November 4, 2009
3.2	By-Laws of Merck & Co., Inc. (effective November 3, 2009) Incorporated by reference to Current Report on Form 8-K filed November 4, 2009
31.1	Rule 13a 14(a)/15d 14(a) Certification of Chief Executive Officer
31.2	Rule 13a 14(a)/15d 14(a) Certification of Chief Financial Officer
32.1	Section 1350 Certification of Chief Executive Officer
32.2	Section 1350 Certification of Chief Financial Officer
101	The following materials from Merck & Co., Inc. s Quarterly Report on Form 10-Q for the quarter ended September 30, 2011, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Statement of Income, (ii) the Consolidated Balance Sheet, (iii) the Consolidated Statement of Cash Flows, and (iv) Notes to Consolidated Financial Statements.

- 60 -

---

**Table of Contents**

**Signatures**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

MERCK & CO., INC.

Date: November 8, 2011

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

Date: November 8, 2011

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

- 61 -

---



**Table of Contents**

**EXHIBIT INDEX**

Number	Description
3.1	Restated Certificate of Incorporation of Merck & Co., Inc. (November 3, 2009) Incorporated by reference to Current Report on Form 8-K filed on November 4, 2009
3.2	By-Laws of Merck & Co., Inc. (effective November 3, 2009) Incorporated by reference to Current Report on Form 8-K filed November 4, 2009
31.1	Rule 13a 14(a)/15d 14(a) Certification of Chief Executive Officer
31.2	Rule 13a 14(a)/15d 14(a) Certification of Chief Financial Officer
32.1	Section 1350 Certification of Chief Executive Officer
32.2	Section 1350 Certification of Chief Financial Officer
101	The following materials from Merck & Co., Inc. s Quarterly Report on Form 10-Q for the quarter ended September 30, 2011, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Statement of Income, (ii) the Consolidated Balance Sheet, (iii) the Consolidated Statement of Cash Flows, and (iv) Notes to Consolidated Financial Statements.

- 62 -