

MERCK & CO INC  
Form 10-Q  
November 03, 2008

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**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, 2008**

**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. 1-3305  
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. 22-1109110*

The number of shares of common stock outstanding as of the close of business on September 30, 2008:

Class Number of Shares Outstanding

Common Stock 2,114,186,139

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 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

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2008	2007	2008	2007
Sales	\$5,943.9	\$6,074.1	\$17,817.9	\$17,954.8
Costs, Expenses and Other				
Materials and production	1,477.9	1,517.7	4,112.5	4,595.9
Marketing and administrative	1,730.3	1,951.4	5,515.0	5,837.2
Research and development	1,171.1	1,440.5	3,418.7	3,501.0
Restructuring costs	757.5	49.3	929.4	170.9
Equity income from affiliates	(665.6)	(768.5)	(1,840.7)	(2,180.2)
Other (income) expense, net	61.8	(180.9)	(2,197.4)	(521.2)
	4,533.0	4,009.5	9,937.5	11,403.6
Income Before Taxes	1,410.9	2,064.6	7,880.4	6,551.2
Taxes on Income	318.2	539.1	1,716.8	1,644.9
Net Income	\$1,092.7	\$1,525.5	\$ 6,163.6	\$ 4,906.3
Basic Earnings per Common Share	\$ 0.51	\$ 0.70	\$ 2.87	\$ 2.26
Earnings per Common Share Assuming Dilution	\$ 0.51	\$ 0.70	\$ 2.86	\$ 2.24
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.

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

	September 30, 2008	December 31, 2007
<b>Assets</b>		
Current Assets		
Cash and cash equivalents	\$ 5,720.1	\$ 5,336.1
Short-term investments	1,121.2	2,894.7
Accounts receivable	3,642.6	3,636.2
Inventories (excludes inventories of \$415.6 in 2008 and \$345.2 in 2007 classified in Other assets see Note 5)	2,228.2	1,881.0
Deferred income taxes and other current assets	6,706.4	1,297.4
<b>Total current assets</b>	<b>19,418.5</b>	<b>15,045.4</b>
Investments	6,211.6	7,159.2
Property, Plant and Equipment, at cost, net of allowance for depreciation of \$11,869.1 in 2008 and \$12,457.1 in 2007	12,103.2	12,346.0
Goodwill	1,438.7	1,454.8
Other Intangibles, Net	558.2	713.2
Other Assets	8,815.5	11,632.1
	<b>\$48,545.7</b>	<b>\$48,350.7</b>
<b>Liabilities and Stockholders Equity</b>		
Current Liabilities		
Loans payable and current portion of long-term debt	\$ 2,994.2	\$ 1,823.6
Trade accounts payable	474.7	624.5
Accrued and other current liabilities	9,271.2	8,534.9
Income taxes payable	879.3	444.1
Dividends payable	808.9	831.1
<b>Total current liabilities</b>	<b>14,428.3</b>	<b>12,258.2</b>
Long-Term Debt	3,938.8	3,915.8
Deferred Income Taxes and Noncurrent Liabilities	8,167.9	11,585.3
Minority Interests	2,439.7	2,406.7
Stockholders Equity		

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Common stock, one cent par value		
Authorized - 5,400,000,000 shares		
Issued - 2,983,508,675 shares	29.8	29.8
Other paid-in capital	8,269.5	8,014.9
Retained earnings	42,857.3	39,140.8
Accumulated other comprehensive loss	(1,033.6)	(826.1)
	50,123.0	46,359.4
Less treasury stock, at cost		
869,322,536 shares at September 30, 2008		
811,005,791 shares at December 31, 2007	30,552.0	28,174.7
Total stockholders' equity	19,571.0	18,184.7
	\$48,545.7	\$48,350.7

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

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

	Nine Months Ended September 30,	
	2008	2007
<b>Cash Flows from Operating Activities</b>		
Net income	\$ 6,163.6	\$ 4,906.3
Adjustments to reconcile net income to net cash provided by operating activities:		
Gain on distribution from AstraZeneca LP	(2,222.7)	
Equity income from affiliates	(1,840.7)	(2,180.2)
Dividends and distributions from equity affiliates	3,750.9	1,626.1
Depreciation and amortization	1,157.2	1,489.2
Deferred income taxes	(163.8)	(391.6)
Share-based compensation	285.5	250.8
Acquired research		325.1
Other	461.1	19.8
Taxes paid for Internal Revenue Service settlement		(2,788.1)
Net changes in assets and liabilities	(2,030.2)	1,394.0
<b>Net Cash Provided by Operating Activities</b>	<b>5,560.9</b>	<b>4,651.4</b>
<b>Cash Flows from Investing Activities</b>		
Capital expenditures	(914.3)	(726.3)
Purchases of securities and other investments	(9,154.8)	(7,188.1)
Acquisitions of subsidiaries, net of cash acquired		(1,135.9)
Proceeds from sales of securities and other investments	8,456.8	8,311.9
Distribution from AstraZeneca LP	1,899.3	
Increase in restricted assets	(1,662.3)	(1,224.1)
Other	(8.9)	0.3
<b>Net Cash Used by Investing Activities</b>	<b>(1,384.2)</b>	<b>(1,962.2)</b>
<b>Cash Flows from Financing Activities</b>		
Net change in short-term borrowings	2,553.3	161.1
Payments on debt	(1,391.7)	(1,158.9)
Purchases of treasury stock	(2,515.4)	(574.6)
Dividends paid to stockholders	(2,469.6)	(2,478.1)
Proceeds from exercise of stock options	100.5	473.4
Other	(44.2)	106.1
<b>Net Cash Used by Financing Activities</b>	<b>(3,767.1)</b>	<b>(3,471.0)</b>

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Effect of Exchange Rate Changes on Cash and Cash Equivalents	(25.6)	75.4
Net Increase (Decrease) in Cash and Cash Equivalents	384.0	(706.4)
Cash and Cash Equivalents at Beginning of Year	5,336.1	5,914.7
Cash and Cash Equivalents at End of Period	\$ 5,720.1	\$ 5,208.3

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

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**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. The interim statements should be read in conjunction with the financial statements and notes thereto included in the Company's latest Annual Report on Form 10-K.

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.

On January 1, 2008, the Company adopted Financial Accounting Standards Board ( FASB ) Statement No. 157, *Fair Value Measurements* ( FAS 157 ), which clarifies the definition of fair value, establishes a framework for measuring fair value, and expands the disclosures on fair value measurements. In February 2008, the FASB issued Staff Position 157-2, *Effective Date of FASB Statement No. 157* ( FSP 157-2 ), that deferred the effective date of FAS 157 for one year for nonfinancial assets and liabilities recorded at fair value on a non-recurring basis. The effect of adoption of FAS 157 for financial assets and liabilities recognized at fair value on a recurring basis did not have a material impact on the Company's financial position and results of operations (see Note 4). The Company is assessing the impact of adopting FAS 157 for nonfinancial assets and liabilities. In October 2008, the FASB issued Staff Position 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active* ( FSP 157-3 ), which clarifies the application of FAS 157 in a market that is not active. FSP 157-3 was effective for the Company at September 30, 2008, and the effect of adoption on the Company's financial position and results of operations was not material.

On January 1, 2008, the Company adopted Emerging Issues Task Force ( EITF ) Issue No. 07-3, *Accounting for Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* ( EITF 07-3 ), which is being applied prospectively for new contracts. EITF 07-3 addresses nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities. EITF 07-3 requires these payments be deferred and capitalized and recognized as an expense as the related goods are delivered or the related services are performed. The effect of adoption of EITF 07-3 on the Company's financial position and results of operations was not material.

On January 1, 2008, the Company adopted FASB Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, including an amendment of FASB Statement No. 115* ( FAS 159 ). FAS 159 permits companies to choose an irrevocable election to measure certain financial assets and financial liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings at each subsequent reporting date. The Company did not elect the fair value option under FAS 159 for any of its financial assets or liabilities upon adoption.

In December 2007, the FASB issued Statement No. 141R, *Business Combinations* ( FAS 141R ), and Statement No. 160, *Noncontrolling Interests in Consolidated Financial Statements - an amendment of ARB No. 51* ( FAS 160 ). FAS 141R expands the scope of acquisition accounting to all transactions under which control of a business is obtained. Among other things, FAS 141R requires that contingent consideration as well as contingent assets and liabilities be recorded at fair value on the acquisition date, that acquired in-process research and development be capitalized and recorded as intangible assets at the acquisition date, and also requires transaction costs and costs to restructure the acquired company be expensed. FAS 160 provides guidance for the accounting, reporting and disclosure of noncontrolling interests and requires, among other things, that noncontrolling interests be recorded as

equity in the consolidated financial statements. FAS 141R and FAS 160 are both effective, on a prospective basis, January 1, 2009 with the exception of the presentation and disclosure requirements of FAS 160 which must be applied retrospectively. The Company is assessing the impacts of these standards on its financial position and results of operations.

In December 2007, the FASB ratified the consensus reached by the EITF on Issue No. 07-1 ( EITF 07-1 ), *Accounting for Collaborative Arrangements*. EITF 07-1 is effective for the Company beginning January 1, 2009 and will be applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date. EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. The Company is assessing the impact of adoption of EITF 07-1 on its financial position and results of operations.

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

In March 2008, the FASB issued Statement No. 161, *Disclosures about Derivative Instruments and Hedging Activities* ( FAS 161 ), which is effective January 1, 2009. FAS 161 requires enhanced disclosures about derivative instruments and hedging activities to allow for a better understanding of their effects on an entity's financial position, financial performance, and cash flows. Among other things, FAS 161 requires disclosure of the fair values of derivative instruments and associated gains and losses in a tabular format. Since FAS 161 requires only additional disclosures about the Company's derivatives and hedging activities, the adoption of FAS 161 will not affect the Company's financial position or results of operations.

In May 2008, the FASB issued Statement No. 162, *The Hierarchy of Generally Accepted Accounting Principles* ( FAS 162 ), which is effective in the fourth quarter of 2008. FAS 162 identifies the sources of accounting principles and the framework for selecting the principles used (order of authority) in the preparation of financial statements that are presented in conformity with generally accepted accounting standards in the United States. The Company does not expect the adoption of FAS 162 to have a material impact on its financial statements.

In June 2008, the FASB issued Staff Position EITF 03-6-1, *Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities* ( FSP EITF 03-6-1 ), which is effective January 1, 2009. FSP EITF 03-6-1 clarifies that share-based payment awards that entitle holders to receive nonforfeitable dividends before they vest will be considered participating securities and included in the basic earnings per share calculation. The Company is assessing the impact of adoption of FSP EITF 03-6-1 on its results of operations.

**2. Restructuring****2008 Global Restructuring Program**

In October 2008, the Company announced a global restructuring program (the 2008 Restructuring Program ) which represents the Company's efforts 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 all areas of the Company worldwide by the end of 2011. About 40% of the total reductions will occur in the United States. To streamline management layers across the Company, Merck will reduce its total number of senior and mid-level executives by approximately 25%. Merck will accelerate the rollout of a new, more customer-centric selling model designed to provide Merck with a meaningful competitive advantage and help physicians, patients and payers improve patient outcomes. The Company also will make greater use of outside technology resources, centralize common sales and marketing activities, and consolidate and streamline its operations. Merck's manufacturing division will further focus its capabilities on core products and outsource non-core manufacturing. In addition, Merck is enhancing its research operations to expand access to worldwide external science and incorporate it as a key component of the Company's pipeline, and ensure a more sustainable pipeline by translating basic research productivity into late-stage clinical success. As a result, basic research operations will be organized to consolidate work in support of a given therapeutic area into one of four locations. This will provide a more efficient use of research facilities and result in the closure of three basic research sites in Tsukuba, Japan; Pomezia, Italy; and Seattle by the end of 2009.

Separation costs are accounted for under FASB Statement No. 112, *Employers' Accounting for Postemployment Benefits—an amendment of FASB Statement No. 5 and 43* ( FAS 112 ), and FASB Statement No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* ( FAS 146 ). In connection with the 2008 Restructuring Program, separation costs under the Company's existing severance programs worldwide were accounted for under FAS 112 and recorded in the third quarter of 2008 to the extent such costs were estimable. The costs related to one-time termination benefits offered to employees under the 2008 Restructuring Program will be accrued in the fourth quarter of 2008 as that is when the criteria necessary for accrual under FAS 146 will be met. The Company recorded pretax restructuring costs of \$720 million related to the 2008 Restructuring Program in the third quarter

of 2008 and anticipates that an additional \$250 million to \$450 million will be recorded in the fourth quarter of 2008. The 2008 Restructuring Program is expected to be completed by the end of 2011 with the total pretax costs estimated to be \$1.6 billion to \$2.0 billion. The Company estimates that two-thirds of the cumulative pretax costs will result in future 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)2005 Global Restructuring Program

In November 2005, the Company announced a global restructuring program (the 2005 Restructuring Program) designed to reduce the Company's cost structure, increase efficiency and enhance competitiveness. As part of the 2005 Restructuring Program, Merck has sold or closed five manufacturing sites and two preclinical sites and since inception eliminated 10,400 positions company-wide as of September 30, 2008 comprised of employee separations and the elimination of contractors and vacant positions. The Company also has sold and closed certain other facilities and related assets in connection with the 2005 Restructuring Program. Since inception through September 30, 2008, the Company has recorded total pretax accumulated costs of \$2.5 billion associated with the 2005 Restructuring Program, which is substantially complete.

For segment reporting purposes, restructuring charges are unallocated expenses.

The following table summarizes the charges related to restructuring activities by type of cost:

(\$ in millions)	2008							
	Three Months Ended September 30,				Nine Months Ended September 30,			
	Separation Costs	Accelerated Depreciation	Other	Total	Separation Costs	Accelerated Depreciation	Other	Total
<u>2008 Program</u>								
Materials and production	\$	\$ 3.9	\$30.0	\$ 33.9	\$	\$ 3.9	\$30.0	\$ 33.9
Research and development		31.0		31.0		31.0		31.0
Restructuring costs	631.0		24.1	655.1	631.0		24.1	655.1
	631.0	34.9	54.1	720.0	631.0	34.9	54.1	720.0
<u>2005 Program</u>								
Materials and production	\$	\$ 23.5	\$ 1.4	\$ 24.9	\$	\$ 54.6	\$ 1.3	\$ 55.9
Research and development								
Restructuring costs	74.1		28.3	102.4	251.1		23.2 (1)	274.3
	74.1	23.5	29.7	127.3	251.1	54.6	24.5	330.2
	\$705.1	\$ 58.4	\$ 83.8	\$ 847.3	\$ 882.1	\$ 89.5	\$ 78.6	\$ 1,050.2
2007								
(\$ in millions)	Three Months Ended September 30,				Nine Months Ended September 30,			
	Separation Costs	Accelerated Depreciation	Other	Total	Separation Costs	Accelerated Depreciation	Other	Total
<u>2005 Program</u>								
Materials and production	\$	\$ 127.4	\$ 1.4	\$ 128.8	\$	\$ 363.7	\$ 1.9	\$ 365.6

Research and development							(0.1)	(0.1)
Restructuring costs	36.7		12.6	49.3	121.7		49.2	170.9
	\$36.7	\$127.4	\$14.0	\$178.1	\$121.7	\$363.7	\$51.0	\$536.4

(1) *Includes proceeds from the sales of facilities in connection with the 2005 Restructuring Program.*

Separation costs are associated with actual headcount reductions, as well as those headcount reductions that were probable and could be reasonably estimated. In the third quarter of 2008, approximately 1,700 positions were eliminated and in the third quarter of 2007 approximately 275 positions were eliminated. In the first nine months of 2008, approximately 3,200 positions were eliminated compared with approximately 1,130 positions in the first nine months of 2007. All of these position eliminations were related to the 2005 Restructuring Program.

Accelerated depreciation costs primarily relate to manufacturing and research facilities to be sold or closed as part of the programs.

Other activity of \$83.8 million and \$14.0 million for the third quarter of 2008 and 2007, respectively, and \$78.6 million and \$51.0 million for the first nine months of 2008 and 2007, respectively, reflects costs that include termination charges associated with the Company's pension and other postretirement benefit plans (see Note 10), asset abandonment, shut-down and other related costs. Other activity for the first nine months of 2008 also reflects pretax gains of \$54.4 million resulting from sales of facilities and related assets.

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

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

<i>(\$ in millions)</i>	Separation Costs	Accelerated Depreciation	Other	Total
<i>2008 Program</i>				
Restructuring reserves as of January 1, 2008	\$	\$	\$	\$
Expense	631.0	34.9	54.1	720.0
(Payments) receipts, net			(10.3)	(10.3)
Non-cash activity		(34.9)	(43.8)	(78.7)
Restructuring reserves as of September 30, 2008 (1)	\$ 631.0	\$	\$	\$ 631.0
<i>2005 Program</i>				
Restructuring reserves as of January 1, 2008	\$ 231.5	\$	\$	\$ 231.5
Expense	251.1	54.6	24.5	330.2
(Payments) receipts, net	(307.5)		(12.9) <sup>(2)</sup>	(320.4)
Non-cash activity		(54.6)	(11.6)	(66.2)
Restructuring reserves as of September 30, 2008 (1)	\$ 175.1	\$	\$	\$ 175.1

(1) *The cash outlays associated with the restructuring reserve for the 2008 Restructuring Program are expected to be completed by the end of 2011. The cash outlays associated with the remaining restructuring reserve for the 2005 Restructuring Program are expected to be largely*

*completed by  
the end of 2009.*

- (2) *Includes  
proceeds from  
the sales of  
facilities in  
connection with  
the 2005  
Restructuring  
Program.*

### **3. Research Collaborations**

In September 2008, Merck and Japan Tobacco Inc. ( JT ) signed a worldwide licensing agreement to develop and commercialize JTT-305, an investigational oral osteoanabolic (bone growth stimulating) agent for the treatment of osteoporosis, a disease which reduces bone density and strength and results in an increased risk of bone fractures. JTT-305 is an investigational oral calcium sensing receptor antagonist that is currently being evaluated by JT in Phase II clinical trials in Japan for its effect on increasing bone density and is in Phase I clinical trials outside of Japan. Under the terms of the agreement, Merck gains worldwide rights, except for Japan, to develop and commercialize JTT-305 and certain other related compounds. JT will receive an upfront payment of \$85 million, which the Company will record as Research and development expense upon closing in the fourth quarter of 2008, and is eligible to receive additional cash payments upon achievement of certain milestones associated with the development and approval of a drug candidate covered by this agreement. JT will also be eligible to receive royalties from sales of any drug candidates that receive marketing approval.

The license agreement between Merck and JT will remain in effect until expiration of all royalty and milestone obligations, and may be terminated in the event of an uncured material breach by the other party. The agreement may also be terminated by Merck without cause before initial commercial sale of JTT-305 by giving six months prior notice to JT, and thereafter by giving one year prior notice thereof to JT. The license agreement may also be terminated immediately by Merck if Merck determines due to safety and/or efficacy concerns based on available scientific evidence to cease development of JTT-305 and/or to withdraw JTT-305 from the market on a permanent basis.

### **4. Fair Value Measurements**

On January 1, 2008, the Company adopted FAS 157, which clarifies the definition of fair value, establishes a framework for measuring fair value, and expands the disclosures on fair value measurements. In February 2008, the FASB issued FSP 157-2 that deferred the effective date of FAS 157 for one year for nonfinancial assets and liabilities recorded at fair value on a non-recurring basis. In October 2008, the FASB issued FSP 157-3, which clarifies the application of FAS 157 in a market that is not active. FSP 157-3 was effective for the Company at September 30, 2008, and the effect of adoption on the Company's financial position and results of operations was not material. FAS 157 defines fair value 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. FAS 157 also establishes a fair value hierarchy which requires an entity to



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

maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. FAS 157 describes 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, 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 mainly include mortgage-backed and asset-backed securities, as well as certain corporate notes and bonds with limited market activity. At September 30, 2008, \$183.7 million, or approximately 1.7%, of the Company's investment securities were categorized as Level 3 fair value assets (all of which were pledged under certain collateral arrangements (see Note 12)).

If the inputs used to measure the financial assets and liabilities fall within the different levels described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument. Financial assets and liabilities measured at fair value on a recurring basis as of September 30, 2008 are summarized below:

(\$ in millions)	Quoted Prices In Active Markets for Identical Assets (Level 1)	Fair Value Measurements Using		Total
		Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
<b>Assets</b>				
<i>Investments</i>				
Corporate notes and bonds	\$	\$ 3,081.9	\$	\$ 3,081.9
U.S. government and agency securities		2,620.3		2,620.3
Mortgage-backed securities <sup>(1)</sup>		555.6		555.6
Foreign government bonds		456.4		456.4
Asset-backed securities <sup>(1)</sup>		303.3		303.3
Equity securities	104.6	86.4		191.0
Commercial paper		124.3		124.3
Total investments	104.6	7,228.2		7,332.8
Other assets <sup>(2)</sup>		3,036.9	183.7	3,220.6

Derivative assets		471.7		471.7
Total Assets	104.6	10,736.8	183.7	11,025.1

**Liabilities**

Derivative liabilities	\$	\$ 74.7	\$	\$ 74.7
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(1) *Mortgage-backed securities represent AAA rated securities issued or unconditionally guaranteed as to payment of principal and interest by U.S. government agencies. Substantially 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.*

(2) *Other assets represent a portion of the pledged collateral discussed in Note 7 and Note 12. Level 2 Other assets are comprised primarily of \$1,411.1 million*

*in corporate notes  
and bonds,  
\$750.7 million in  
municipal  
securities,  
\$352.3 million in  
mortgage-backed  
securities,  
\$270.0 million of  
asset-backed  
securities and  
\$227.8 million in  
commercial  
paper.*

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**Table of Contents**Notes to Consolidated Financial Statements (unaudited) (continued)*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 at September 30, 2008, primarily include mortgage-backed and asset-backed securities, as well as certain corporate notes and bonds for which there was a decrease in the observability of market pricing for these investments. These securities 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 at September 30, 2008.

The table below provides a summary of the changes in fair value, including net transfers in and/or out, of all financial assets measured at fair value on a recurring basis using significant unobservable inputs (Level 3):

	Three Months Ended September 30, 2008					Ending Balance September 30	Losses Recorded in Earnings for Level 3 Assets Still Held at September 30
	Beginning Balance July 1	Net Transfers In to Level 3	Purchases, Sales, Settlements, Net	Total Realized and Unrealized Gains/ (Losses) Included in: Earnings (1)	Compre- hensive Income		
(\$ in millions)							
Other assets	\$ 179.5	\$ 32.6	\$ (28.3)	\$ 1.3	\$ (1.4)	\$ 183.7	\$ (0.2)

	Nine Months Ended September 30, 2008					Ending Balance September 30	Losses Recorded in Earnings for Level 3 Assets Still Held at September 30
	Beginning Balance January 1	Net Transfers (Out) of Level 3	Purchases, Sales, Settlements, Net	Total Realized and Unrealized Losses Included in: Earnings (1)	Compre- hensive Income		
(\$ in millions)							
Other assets	\$ 958.6	\$ (712.2)	\$ (52.9)	\$ (6.9)	\$ (2.9)	\$ 183.7	\$ (7.2)
Other debt securities	314.5	(314.5)					
Total	\$ 1,273.1	\$ (1,026.7)	\$ (52.9)	\$ (6.9)	\$ (2.9)	\$ 183.7	\$ (7.2)

(1) *Amounts are recorded in Other (income) expense, net, in the Consolidated Statement of Income.*

On January 1, 2008, the Company had \$1,273.1 million invested in a short-term fixed income fund (the Fund ). Due to market liquidity conditions, cash redemptions from the Fund were restricted. As a result of this restriction on cash redemptions, the Company did not consider the Fund to be traded in an active market with observable pricing on January 1, 2008 and these amounts were categorized as Level 3. On January 7, 2008, the Company elected to be redeemed-in-kind from the Fund and received its share of the underlying securities of the Fund. As a result, \$1,099.7 million of the underlying securities were transferred out of Level 3 as it was determined these securities had observable markets. On September 30, 2008, \$183.7 million of the investment securities associated with the redemption-in-kind were classified in Level 3 as the securities contained at least one significant input which was unobservable.

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**Table of Contents****5. Inventories**

Inventories consisted of:

<i>(\$ in millions)</i>	September 30, 2008	December 31, 2007
Finished goods	\$ 463.6	\$ 382.9
Raw materials and work in process	2,071.9	1,732.2
Supplies	108.3	111.1
Total (approximates current cost)	2,643.8	2,226.2
Reduction to LIFO cost for domestic inventories		
	\$2,643.8	\$2,226.2
Recognized as:		
Inventories	\$2,228.2	\$1,881.0
Other assets	\$ 415.6	\$ 345.2

Amounts recognized as Other assets are comprised entirely of raw materials and work in process inventories, representing inventories for products not expected to be sold within one year, the majority of which are vaccines.

**6. Joint Ventures and Other Equity Method Affiliates**

Equity income from affiliates reflects the performance of the Company's joint ventures and other equity method affiliates and was comprised of the following:

<i>(\$ in millions)</i>	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Merck/Schering-Plough	\$400.2	\$480.9	\$1,158.2	\$1,293.1
AstraZeneca LP	139.1	181.2	331.6	608.3
Other <sup>(1)</sup>	126.3	106.4	350.9	278.8
	\$665.6	\$768.5	\$1,840.7	\$2,180.2

<sup>(1)</sup> Primarily reflects results from Merial Limited, Sanofi Pasteur MSD and Johnson & Johnson<sup>o</sup>Merck Consumer Pharmaceuticals Company.

*Merck/Schering-Plough*

In 2000, the Company and Schering-Plough Corporation ( Schering-Plough ) (collectively the Partners ) entered into agreements to create separate equally-owned partnerships to develop and market in the United States new prescription medicines in the cholesterol-management and respiratory therapeutic areas. These agreements generally provide for equal sharing of development costs and for co-promotion of approved products by each company. In 2001, the cholesterol-management partnership agreements were expanded to include all the countries of the world, excluding Japan. In 2002, ezetimibe, the first in a new class of cholesterol-lowering agents, was launched in the United States as *Zetia* (marketed as *Ezetrol* outside the United States). In 2004, a combination product containing the active ingredients of both *Zetia* and *Zocor* was approved in the United States as *Vytorin* (marketed as *Inegy* outside of the United States).

The cholesterol agreements provide for the sharing of operating income generated by the Merck/Schering-Plough cholesterol partnership (the MSP Partnership ) based upon percentages that vary by product, sales level and country. In the U.S. market, the Partners share profits on *Zetia* and *Vytorin* sales equally, with the exception of the first \$300 million of annual *Zetia* sales on which Schering-Plough receives a greater share of profits. Operating income includes expenses that the Partners have contractually agreed to share, such as a portion of manufacturing costs, specifically identified promotion costs (including direct-to-consumer advertising and direct and identifiable out-of-pocket promotion) and other agreed upon costs for specific services such as on-going clinical research, market support, market research, market expansion, as well as a specialty sales force and physician education programs. Expenses incurred in support of the MSP Partnership but not shared between the Partners, such as marketing and administrative expenses (including certain sales force costs), as well as certain manufacturing costs, are not included in Equity income from affiliates. However, these costs are reflected in the overall results of the Company. Certain

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

research and development expenses are generally shared equally by the Partners, after adjusting for earned milestones.

See Note 8 for information with respect to litigation involving the MSP Partnership and the Partners related to the sale and promotion of *Zetia* and *Vytorin*.

The respiratory therapeutic agreements provided for the joint development and marketing in the United States by the Partners of a once-daily, fixed-combination tablet containing the active ingredients montelukast sodium and loratadine. Montelukast sodium, a leukotriene receptor antagonist, is sold by Merck as *Singulair* and loratadine, an antihistamine, is sold by Schering-Plough as Claritin, both of which are indicated for the relief of symptoms of allergic rhinitis. In April 2008, the Partners announced that they had received a non-approvable letter from the U.S. Food and Drug Administration ( FDA ) for the proposed fixed combination of loratadine/montelukast. In June 2008, the Partners announced the withdrawal of the New Drug Application for the loratadine/montelukast combination tablet. The companies also terminated the respiratory joint venture. This action had no impact on the business of the cholesterol joint venture. As a result of the termination of the respiratory joint venture, the Company was obligated to Schering-Plough in the amount of \$105 million as specified in the joint venture agreements. This resulted in a charge of \$43 million during the second quarter of 2008, included in Equity income from affiliates. The remaining amount is being amortized over the remaining patent life of *Zetia* through 2016.

Summarized financial information for the MSP Partnership is as follows:

(\$ in millions)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2008	2007	2008	2007
Sales	\$1,101.5	\$1,300.0	\$3,486.9	\$3,731.7
Vytorin	567.2	693.0	1,810.5	2,003.2
Zetia	534.3	607.0	1,676.4	1,728.5
Materials and production costs	41.0	60.9	144.6	162.1
Other expense, net	283.5	302.9	929.6	948.9
Income before taxes	\$ 777.0	\$ 936.2	\$2,412.7	\$2,620.7
Merck's share of income before taxes <sup>(1)</sup>	\$ 383.9	\$ 481.9	\$1,124.9	\$1,297.7

(1) Merck's share of the MSP Partnership's income before taxes differs from the equity income recognized from the MSP



*Partnership  
primarily due to  
the timing of  
recognition of  
certain  
transactions  
between the  
Company and  
the MSP  
Partnership,  
including  
milestone  
payments.  
AstraZeneca LP*

As previously disclosed, the 1999 AstraZeneca merger triggered a partial redemption in March 2008 of Merck's limited partnership interest in AstraZeneca LP ( "AZLP" ). Upon this redemption, Merck received \$4.3 billion from AZLP. This amount was based primarily on a multiple of Merck's average annual variable returns derived from sales of the former Astra USA, Inc. products for the three years prior to the redemption (the "Limited Partner Share of Agreed Value" ). Merck recorded a \$1.5 billion pretax gain on the partial redemption in the first quarter of 2008.

Also, as a result of the 1999 AstraZeneca merger, in exchange for Merck's relinquishment of rights to future Astra products with no existing or pending U.S. patents at the time of the merger, Astra paid \$967.4 million (the "Advance Payment" ). The Advance Payment was deferred as it remained subject to a true-up calculation that was directly dependent on the fair market value in March 2008 of the Astra product rights retained by the Company. The calculated True-Up Amount of \$243.7 million was returned to AZLP in March 2008 and Merck recognized a pretax gain of \$723.7 million related to the residual Advance Payment balance.

In 1998, Astra purchased an option (the "Asset Option" ) to buy Merck's interest in the KBI Inc. ( "KBI" ) products, excluding the gastrointestinal medicines *Nexium* and *Prilosec* (the "Non-PPI Products" ), for a payment of \$443.0 million, which was deferred. The Asset Option is exercisable in the first half of 2010 at an exercise price equal to the net present value as of March 31, 2008 of projected future pretax revenue to be received by the Company from the Non-PPI Products (the "Appraised Value" ). Merck also had the right to require Astra to purchase such interest in 2008 at the Appraised Value. In February 2008, the Company advised AZLP that it would not exercise the Asset Option, thus the \$443.0 million remains deferred.

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

The sum of the Limited Partner Share of Agreed Value, the Appraised Value and the True-Up Amount was guaranteed to be a minimum of \$4.7 billion. Distribution of the Limited Partner Share of Agreed Value less payment of the True-Up Amount resulted in cash receipts to Merck of \$4.0 billion and an aggregate pretax gain of \$2.2 billion which is included in Other (income) expense, net. AstraZeneca's purchase of Merck's interest in the Non-PPI Products is contingent upon the exercise of the Asset Option by AstraZeneca in 2010 and, therefore, payment of the Appraised Value may or may not occur. Also, in March 2008, the outstanding loan from Astra in the amount of \$1.38 billion plus interest through the redemption date was settled. As a result of these transactions, the Company received net proceeds from AZLP of \$2.6 billion in the first quarter of 2008.

Summarized financial information for AZLP is as follows:

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Sales	\$ 1,306.2	\$ 1,486.0	\$ 3,983.0	\$ 4,873.1
Materials and production costs	690.2	607.8	2,016.6	2,562.5
Other expense, net	335.0	315.5	1,072.7	870.3
Income before taxes	\$ 281.0	\$ 562.7	\$ 893.7	\$ 1,440.3

**7. Debt and Financial Instruments**

In January and February 2008, the Company terminated four interest rate swap contracts with notional amounts of \$250 million each, and in September 2008 terminated an interest rate swap contract with a notional amount of \$500 million. These swaps had effectively converted its \$1.0 billion, 4.75% fixed-rate notes due 2015 and its \$500 million, 4.375% fixed-rate notes due 2013 to variable rate debt. As a result of the swap terminations, the Company received \$128.3 million in cash, excluding accrued interest which was not material. The corresponding gains related to the basis adjustment of the debt associated with the terminated swap contracts were deferred and are being amortized as a reduction of interest expense over the remaining term of the notes. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

In August 2008, the Company executed a \$4.1 billion letter of credit agreement with a financial institution which satisfied certain conditions set forth in the U.S. *Vioxx* Settlement Agreement (see Note 8). The Company pledged collateral to the financial institution of approximately \$5.1 billion pursuant to the terms of the letter of credit agreement. Although the amount of assets pledged as collateral is set by the letter of credit agreement and such assets are held in custody by a third party, the assets are managed by the Company. The Company considers the assets pledged under the letter of credit agreement to be restricted. As a result, \$2.1 billion and \$1.4 billion of cash and investments, respectively, were classified as restricted current assets and \$1.6 billion of investments were classified as restricted non-current assets. The letter of credit amount and required collateral balances will decline as payments (after the first \$750 million) under the Settlement Agreement are made. (See Note 12 for a discussion of other restricted asset activities.) As of September 30, 2008, \$3.7 billion was recorded within Deferred income taxes and other current assets and \$1.4 billion was classified as Other assets.

Also in March 2008, the Company settled the \$1.38 billion Astra Note due in 2008 (see Note 6).

In April 2008, the Company extended the maturity date of its \$1.5 billion, 5-year revolving credit facility from April 2012 to April 2013. The facility provides backup liquidity for the Company's commercial paper borrowing facility and is to be used for general corporate purposes. The Company has not drawn funding from this facility.

**8. Contingencies**

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.



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

As previously disclosed, individual and putative class actions have been filed against the Company in state and federal courts alleging personal injury and/or economic loss with respect to the purchase or use of *Vioxx*. All such actions filed in federal court are coordinated in a multidistrict litigation in the U.S. District Court for the Eastern District of Louisiana (the MDL ) before District Judge Eldon E. Fallon. A number of such actions filed in state court are coordinated in separate coordinated proceedings in state courts in New Jersey, California and Texas, and the counties of Philadelphia, Pennsylvania and Washoe and Clark Counties, Nevada. As of September 30, 2008, the Company had been served or was aware that it had been named as a defendant in approximately 11,575 lawsuits, which include approximately 29,200 plaintiff groups, alleging personal injuries resulting from the use of *Vioxx*, and in approximately 246 putative class actions alleging personal injuries and/or economic loss. (All of the actions discussed in this paragraph are collectively referred to as the *Vioxx* Product Liability Lawsuits .) Of these lawsuits, approximately 9,000 lawsuits representing approximately 23,400 plaintiff groups are or are slated to be in the federal MDL and approximately 725 lawsuits representing approximately 725 plaintiff groups are included in a coordinated proceeding in New Jersey Superior Court before Judge Carol E. Higbee.

In addition to the *Vioxx* Product Liability Lawsuits discussed above, the claims of over 25,100 plaintiffs had been dismissed as of September 30, 2008. Of these, there have been over 3,650 plaintiffs whose claims were dismissed with prejudice (i.e., they cannot be brought again) either by plaintiffs themselves or by the courts. Over 21,450 additional plaintiffs have had their claims dismissed without prejudice (i.e., subject to the applicable statute of limitations, they can be brought again). Of these, approximately 13,575 plaintiff groups represent plaintiffs who had lawsuits pending in the New Jersey Superior Court at the time of the Settlement Agreement described below and who have expressed an intent to enter the program established by the Settlement Agreement; Judge Higbee has dismissed these cases without prejudice for administrative reasons.

On November 9, 2007, Merck announced that it had entered into an agreement (the Settlement Agreement ) with the law firms that comprise the executive committee of the Plaintiffs Steering Committee ( PSC ) of the federal *Vioxx* MDL as well as representatives of plaintiffs counsel in the Texas, New Jersey and California state coordinated proceedings to resolve state and federal myocardial infarction ( MI ) and ischemic stroke ( IS ) claims filed as of that date in the United States. The Settlement Agreement, which also applies to tolled claims, was signed by the parties after several meetings with three of the four judges overseeing the coordination of more than 95% of the U.S. *Vioxx* Product Liability Lawsuits. The Settlement Agreement applies only to U.S. legal residents and those who allege that their MI or IS occurred in the United States.

Merck will pay a fixed aggregate amount of \$4.85 billion into two funds (\$4.0 billion for MI claims and \$850 million for IS claims) for qualifying claims that enter into the resolution process (the Settlement Program ). Individual claimants will be examined by administrators of the Settlement Program to determine qualification based on objective, documented facts provided by claimants, including records sufficient for a scientific evaluation of independent risk factors. The conditions in the Settlement Agreement require claimants to pass three gates: an injury gate requiring objective, medical proof of an MI or IS (each as defined in the Settlement Agreement), a duration gate based on documented receipt of at least 30 *Vioxx* pills, and a proximity gate requiring receipt of pills in sufficient number and proximity to the event to support a presumption of ingestion of *Vioxx* within 14 days before the claimed injury.

The Settlement Agreement provides that Merck does not admit causation or fault. The Settlement Agreement provided that Merck's payment obligations would be triggered only if, among other conditions, (1) law firms on the

federal and state PSCs and firms that have tried cases in the coordinated proceedings elect to recommend enrollment in the program to 100% of their clients who allege either MI or IS and (2) by June 30, 2008, plaintiffs enroll in the Settlement Program at least 85% of each of all currently pending and tolled (i) MI claims, (ii) IS claims, (iii) eligible MI and IS claims together which involve death, and (iv) eligible MI and IS claims together which allege more than 12 months of use. Under the terms of the Settlement Agreement, Merck could exercise a right to walk away from the Settlement Agreement if the thresholds and other requirements were not met. The Company waived that right as of August 4, 2008. The waiver of that right triggered Merck's obligation to pay a fixed total of \$4.85 billion. Payments will be made in installments into the settlement fund. The first payment of \$500 million was made in August 2008 and an additional payment of \$250 million was made in October 2008. Additional payments will be made on a periodic basis going forward, when and as needed to fund payments of claims and administrative expenses.

Merck's total payment for both funds of \$4.85 billion is a fixed amount to be allocated among qualifying claimants based on their individual evaluation. While at this time the exact number of claimants covered by the Settlement Agreement is unknown, the total dollar amount is fixed. The distribution of interim payments to qualified claimants

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

began in August 2008 and will continue on a rolling basis until all claimants who qualify for an interim payment are paid. Final payments will be made after the examination of all of the eligible claims has been completed.

After the Settlement Agreement was announced on November 9, 2007, judges in the Federal MDL, California, Texas and New Jersey State coordinated proceedings entered a series of orders. The orders: (1) temporarily stayed their respective litigations; (2) required plaintiffs to register their claims by January 15, 2008; (3) required plaintiffs with cases pending as of November 9, 2007 to preserve and produce records and serve expert reports; and (4) required plaintiffs who file thereafter to make similar productions on an accelerated schedule. The Clark County, Nevada and Washoe County, Nevada coordinated proceedings were also generally stayed.

As of October 30, 2008, the last day for enrollment in the Settlement Program, more than 48,100 of the approximately 48,325 individuals who were eligible for the Settlement Program and whose claims are not 1) dismissed, 2) expected to be dismissed in the near future, or 3) tolled claims that appear to have been abandoned have submitted some or all of the materials required for enrollment in the Settlement Program to resolve state and federal MI and IS claims filed against the Company in the United States. If all of these eligible submissions are completed in accordance with the Settlement Agreement, this would represent more than 99% of the eligible MI and IS claims previously registered with the Settlement Program.

On April 14, 2008 and June 3, 2008, two groups of various private insurance companies and health plans filed suit against BrownGreer, the claims administrator for the Settlement Program (the Claims Administrator), and U.S. Bancorp, escrow agent for the Settlement Program (the AvMed and Greater New York Benefit Fund suits). The private insurance companies and health plans claim to have paid healthcare costs on behalf of some of the enrolling claimants and seek to enjoin the Claims Administrator from paying enrolled claimants until their claims for reimbursement from the enrolled claimants are resolved. Each group sought temporary restraining orders and preliminary injunctions. Judge Fallon denied these requests. In AvMed, the defendants moved to sever the claims of the named plaintiffs and, in Greater New York Benefit Fund, to strike the class allegations. Judge Fallon granted these motions. AvMed has appealed both of these decisions. The Fifth Circuit will hear argument on AvMed's appeal on November 4, 2008. Greater New York Benefit Fund has served a notice of appeal.

The Company has previously disclosed the outcomes of several *Vioxx* Product Liability Lawsuits that were tried prior to January 1, 2008.

The following sets forth certain significant rulings that occurred in or after the third quarter of 2008 with respect to the *Vioxx* Product Liability Lawsuits.

On April 19, 2007, Judge Randy Wilson, who presides over the Texas *Vioxx* coordinated proceeding, dismissed the failure to warn claim of plaintiff Ruby Ledbetter, whose case was scheduled to be tried on May 14, 2007. Judge Wilson relied on a Texas statute enacted in 2003 that provides that there can be no failure to warn regarding a prescription medicine if the medicine is distributed with FDA approved labeling. There is an exception in the statute if required, material, and relevant information was withheld from the FDA that would have led to a different decision regarding the approved labeling, but Judge Wilson found that the exception is preempted by federal law unless the FDA finds that such information was withheld. Judge Wilson is currently presiding over approximately 1,000 *Vioxx* suits in Texas in which a principal allegation is failure to warn. Judge Wilson certified the decision for an expedited

appeal to the Texas Court of Civil Appeals. Plaintiffs appealed the decision. On March 20, 2008, plaintiffs moved to dismiss their appeal, seeking instead to vacate the trial court's decision. Merck filed an opposition to plaintiffs' motion. On May 15, 2008, the Court of Appeals issued an order granting plaintiffs' motion to dismiss the appeal, but denying plaintiffs' motion to vacate the order dismissing the claim. On July 25, 2008, the appeal was dismissed by agreement of the parties.

In April 2006, in a trial involving two plaintiffs, Thomas Cona and John McDarby, in Superior Court of New Jersey, Law Division, Atlantic County, the jury returned a split verdict. The jury determined that *Vioxx* did not substantially contribute to the heart attack of Mr. Cona, but did substantially contribute to the heart attack of Mr. McDarby. The jury

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

also concluded that, in each case, Merck violated New Jersey's consumer fraud statute, which allows plaintiffs to receive their expenses for purchasing the drug, trebled, as well as reasonable attorneys' fees. The jury awarded \$4.5 million in compensatory damages to Mr. McDarby and his wife, who also was a plaintiff in that case, as well as punitive damages of \$9 million. On June 8, 2007, Judge Higbee denied Merck's motion for a new trial. On June 15, 2007, Judge Higbee awarded approximately \$4 million in the aggregate in attorneys' fees and costs. The Company appealed the judgments in both cases and the Appellate Division held oral argument on both cases on January 16, 2008. On May 29, 2008, the New Jersey Appellate Division vacated the consumer fraud awards in both cases on the grounds that the Product Liability Act provides the sole remedy for personal injury claims. The Appellate Division also vacated the McDarby punitive damage award on the grounds that it is preempted and vacated the attorney's fees and costs awarded under the Consumer Fraud Act in both cases. The Court upheld the McDarby compensatory award. The Company has filed with the Supreme Court of New Jersey a petition to appeal those parts of the trial court's rulings that the Appellate Division affirmed. Plaintiffs filed a cross-petition to appeal those parts of the trial court's rulings that the Appellate Division reversed. Those petitions are currently pending. On October 8, 2008, the Supreme Court of New Jersey granted Merck's petition for certification of appeal, limited solely to the issue of whether the Federal Food, Drug and Cosmetic Act preempts state law tort claims predicated on the alleged inadequacy of warnings contained in *Vioxx* labeling that was approved by the FDA. The court denied the plaintiff's cross-petition.

As previously reported, in September 2006, Merck filed a notice of appeal of the August 2005 jury verdict in favor of the plaintiff in the Texas state court case, *Ernst v. Merck*. On May 29, 2008, the Texas Court of Appeals reversed the trial court's judgment and issued a judgment in favor of Merck. The Court of Appeals found the evidence to be legally insufficient on the issue of causation. Plaintiffs have filed a motion for rehearing *en banc* in the Court of Appeals. Merck filed a response in October 2008.

As previously reported, in April 2006, in *Garza v. Merck*, a jury in state court in Rio Grande City, Texas returned a verdict in favor of the family of decedent Leonel Garza. The jury awarded a total of \$7 million in compensatory damages to Mr. Garza's widow and three sons. The jury also purported to award \$25 million in punitive damages even though under Texas law, in this case, potential punitive damages were capped at \$750,000. On May 14, 2008, the San Antonio Court of Appeals reversed the judgment and rendered a judgment in favor of Merck. On May 29, 2008, plaintiffs filed a motion for rehearing, which is currently pending.

*Other Lawsuits*

As previously disclosed, on July 29, 2005, a New Jersey state trial court certified a nationwide class of third-party payors (such as unions and health insurance plans) that paid in whole or in part for the *Vioxx* used by their plan members or insureds. The named plaintiff in that case sought recovery of certain *Vioxx* purchase costs (plus penalties) based on allegations that the purported class members paid more for *Vioxx* than they would have had they known of the product's alleged risks. On March 31, 2006, the New Jersey Superior Court, Appellate Division, affirmed the class certification order. On September 6, 2007, the New Jersey Supreme Court reversed the certification of a nationwide class action of third-party payors, finding that the suit does not meet the requirements for a class action. Claims of certain individual third-party payors remain pending in the New Jersey court, and counsel representing various third-party payors have filed additional such actions. Judge Higbee lifted the stay on these cases and the parties are currently discussing discovery issues.

At the parties' request, Judge Higbee has extended the briefing schedule in *Martin-Kleinman v. Merck*, which is a putative consumer class action pending in New Jersey Superior Court. The Court will set a new schedule after resolving certain discovery issues.



There are also pending in various U.S. courts putative class actions purportedly brought on behalf of individual purchasers or users of *Vioxx* claiming either reimbursement of alleged economic loss or an entitlement to medical monitoring. The majority of these cases are at early procedural stages. On June 12, 2008, a Missouri state court certified a class of Missouri plaintiffs seeking reimbursement for out-of-pocket costs relating to *Vioxx*. The plaintiffs do not allege any personal injuries from taking *Vioxx*. The Company filed a petition for interlocutory review on June 23, 2008, which was granted on July 30, 2008. During the pendency of the appeal, discovery is proceeding in the lower court.

Plaintiffs also have filed a class action in California state court seeking class certification of California third-party payors and end-users. The parties are engaged in class certification discovery and briefing.

As previously reported, the Company has also been named as a defendant in separate lawsuits brought by the Attorneys General of nine states, and the City of New York. A Colorado taxpayer has also filed a derivative suit, on behalf of the State of Colorado, naming the Company. These actions allege that the Company misrepresented the safety of *Vioxx* and seek (i) recovery of the cost of *Vioxx* purchased or reimbursed by the state and its agencies; (ii) reimbursement of all sums paid by the state and its agencies for medical services for the treatment of persons injured by *Vioxx*; (iii) damages under various common law theories; and/or (iv) remedies under various state statutory

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

theories, including state consumer fraud and/or fair business practices or Medicaid fraud statutes, including civil penalties.

In addition, the Company has been named in six other lawsuits containing similar allegations filed by (or on behalf of) governmental entities seeking the reimbursement of alleged Medicaid expenditures for *Vioxx* or statutory penalties tied to such expenditures. Those lawsuits are (1) a class action filed by Santa Clara County, California on behalf of all similarly situated California counties, (2) separate actions filed by Erie County, Chautauqua County, and Orange County, New York, (3) a *qui tam* action brought by a resident of the District of Columbia, and (4) a *qui tam* action brought by a resident of Florida. With the exception of a case filed by the Texas Attorney General (which remains in Texas state court and is currently scheduled for trial in September 2009), a case recently filed by the Michigan Attorney General (which has been removed to federal court and will likely be transferred to the federal MDL shortly) and the recently-filed Orange County and Florida cases (which will be removed to federal court and will likely be transferred to the federal MDL), the rest of the actions described in this paragraph have been transferred to the federal MDL and are in the discovery phase.

*Shareholder Lawsuits*

As previously disclosed, in addition to the *Vioxx* Product Liability Lawsuits, the Company and various current and former officers and directors are defendants in various putative class actions and individual lawsuits under the federal securities laws and state securities laws (the *Vioxx* Securities Lawsuits). All of the *Vioxx* Securities Lawsuits pending in federal court have been transferred by the Judicial Panel on Multidistrict Litigation (the JPML) to the United States District Court for the District of New Jersey before District Judge Stanley R. Chesler for inclusion in a nationwide MDL (the Shareholder MDL). Judge Chesler has consolidated the *Vioxx* Securities Lawsuits for all purposes. The putative class action, which requested damages on behalf of purchasers of Company stock between May 21, 1999 and October 29, 2004, alleged that the defendants made false and misleading statements regarding *Vioxx* in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, and sought unspecified compensatory damages and the costs of suit, including attorneys' fees. The complaint also asserted claims under Section 20A of the Securities and Exchange Act against certain defendants relating to their sales of Merck stock and under Sections 11, 12 and 15 of the Securities Act of 1933 against certain defendants based on statements in a registration statement and certain prospectuses filed in connection with the Merck Stock Investment Plan, a dividend reinvestment plan. On April 12, 2007, Judge Chesler granted defendants' motion to dismiss the complaint with prejudice. Plaintiffs appealed Judge Chesler's decision to the United States Court of Appeals for the Third Circuit. On September 9, 2008, the Third Circuit issued an opinion reversing Judge Chesler's order and remanding the case to the district court. On September 23, 2008, Merck filed a petition seeking rehearing *en banc* which was denied.

In October 2005, a Dutch pension fund filed a complaint in the District of New Jersey alleging violations of federal securities laws as well as violations of state law against the Company and certain officers. Pursuant to the Case Management Order governing the Shareholder MDL, the case, which is based on the same allegations as the *Vioxx* Securities Lawsuits, was consolidated with the *Vioxx* Securities Lawsuits. Defendants' motion to dismiss the pension fund's complaint was filed on August 3, 2007. In September 2007, the Dutch pension fund filed an amended complaint rather than responding to defendants' motion to dismiss. In addition in 2007, six new complaints were filed in the District of New Jersey on behalf of various foreign institutional investors also alleging violations of federal securities laws as well as violations of state law against the Company and certain officers.

As previously disclosed, various shareholder derivative actions filed in federal court were transferred to the Shareholder MDL and consolidated for all purposes by Judge Chesler (the *Vioxx* Derivative Lawsuits). On May 5, 2006, Judge Chesler granted defendants' motion to dismiss and denied plaintiffs' request for leave to amend their

complaint. Plaintiffs appealed, arguing that Judge Chesler erred in denying plaintiffs' leave to amend their complaint with materials acquired during discovery. On July 18, 2007, the United States Court of Appeals for the Third Circuit reversed the District Court's decision on the grounds that Judge Chesler should have allowed plaintiffs to make use of the discovery material to try to establish demand futility, and remanded the case for the District Court's consideration of whether, even with the additional materials, plaintiffs' request to amend their complaint would still be futile. Plaintiffs filed their brief in support of their request for leave to amend their complaint in November 2007. The Court denied the motion in June 2008 and closed the case. Plaintiffs have appealed Judge Chesler's decision to the United States Court of Appeals for the Third Circuit.

In addition, as previously disclosed, various putative class actions filed in federal court under the Employee Retirement Income Security Act ( ERISA ) against the Company and certain current and former officers and directors

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(the *Vioxx* ERISA Lawsuits and, together with the *Vioxx* Securities Lawsuits and the *Vioxx* Derivative Lawsuits, the *Vioxx* Shareholder Lawsuits ) have been transferred to the Shareholder MDL and consolidated for all purposes. The consolidated complaint asserts claims on behalf of certain of the Company's current and former employees who are participants in certain of the Company's retirement plans for breach of fiduciary duty. The lawsuits make similar allegations to the allegations contained in the *Vioxx* Securities Lawsuits. On July 11, 2006, Judge Chesler granted in part and denied in part defendants' motion to dismiss the ERISA complaint. In October 2007, plaintiffs moved for certification of a class of individuals who were participants in and beneficiaries of the Company's retirement savings plans at any time between October 1, 1998 and September 30, 2004 and whose plan accounts included investments in the Merck Common Stock Fund and/or Merck common stock. That motion is pending. On October 6, 2008 defendants filed a motion for judgment on the pleadings seeking dismissal of the complaint.

As previously disclosed, on October 29, 2004, two individual shareholders made a demand on the Company's Board to take legal action against Mr. Raymond Gilmartin, former Chairman, President and Chief Executive Officer and other individuals for allegedly causing damage to the Company with respect to the allegedly improper marketing of *Vioxx*. In December 2004, the Special Committee of the Board of Directors retained the Honorable John S. Martin, Jr. of Debevoise & Plimpton LLP to conduct an independent investigation of, among other things, the allegations set forth in the demand. Judge Martin's report was made public in September 2006. Based on the Special Committee's recommendation made after careful consideration of the Martin report and the impact that derivative litigation would have on the Company, the Board rejected the demand. On October 11, 2007, the shareholders filed a lawsuit in state court in Atlantic County, NJ against current and former executives and directors of the Company alleging that the Board's rejection of their demand was unreasonable and improper, and that the defendants breached various duties to the Company in allowing *Vioxx* to be marketed. The current and former executive and director defendants filed motions to dismiss the complaint in June 2008. Those motions are pending.

*International Lawsuits*

As previously disclosed, in addition to the lawsuits discussed above, the Company has been named as a defendant in litigation relating to *Vioxx* in various countries (collectively, the *Vioxx* Foreign Lawsuits ) in Europe, as well as Canada, Brazil, Argentina, Australia, The Philippines, Turkey, and Israel.

On May 30, 2008, the provincial court of Queen's Bench in Saskatchewan, Canada entered an order certifying a class of *Vioxx* users in Canada, except those in Quebec. The class includes individual purchasers who allege inducement to purchase by unfair marketing practices; individuals who allege *Vioxx* was not of acceptable quality, defective or not fit for the purpose of managing pain associated with approved indications; or ingestors who claim *Vioxx* caused or exacerbated a cardiovascular or gastrointestinal condition. On June 17, 2008, the Court of Appeal for Saskatchewan granted the Company leave to appeal the certification order and the appeal is pending before that court. On July 28, 2008, the Superior court in Ontario decided to certify an overlapping class of *Vioxx* users in Canada, except those in Quebec and Saskatchewan, who allege negligence and an entitlement to elect to waive the tort. The Company's motion for leave to appeal that decision is pending before the Ontario Divisional Court. Earlier, in November 2006, the Superior court in Quebec authorized the institution of a class action on behalf of all individuals who, in Québec, consumed *Vioxx* and suffered damages arising out of its ingestion. As of September 30, 2008, the plaintiffs have not instituted an action based upon that authorization.

*Additional Lawsuits*

Based on media reports and other sources, the Company anticipates that additional *Vioxx* Product Liability Lawsuits, *Vioxx* Shareholder Lawsuits and *Vioxx* Foreign Lawsuits (collectively, the *Vioxx* Lawsuits ) will be filed against it and/or certain of its current and former officers and directors in the future.

*Insurance*

As previously disclosed, the Company has product liability insurance for claims brought in the *Vioxx* Product Liability Lawsuits with stated upper limits of approximately \$630 million after deductibles and co-insurance. This insurance provides coverage for legal defense costs and potential damage amounts in connection with the *Vioxx* Product Liability Lawsuits. Through an arbitration proceeding and negotiated settlements, the Company received an aggregate of approximately \$590 million in product liability insurance proceeds relating to the *Vioxx* Product Liability Lawsuits, plus approximately \$45 million in fees and interest payments. The Company has no additional insurance for the *Vioxx* Product Liability Lawsuits. The Company's insurance coverage with respect to the *Vioxx* Lawsuits will not be adequate to cover its defense costs and losses.

The Company also has Directors and Officers insurance coverage applicable to the *Vioxx* Securities Lawsuits and *Vioxx* Derivative Lawsuits with stated upper limits of approximately \$190 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

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arbitration proceeding referenced above, 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, in November 2004, the Company was advised by the staff of the Securities and Exchange Commission ( SEC ) that it was commencing an informal inquiry concerning *Vioxx*. On January 28, 2005, the Company announced that it received notice that the SEC issued a formal notice of investigation. Also, the Company has received subpoenas from the U.S. Department of Justice (the DOJ ) requesting information related to the Company's research, marketing and selling activities with respect to *Vioxx* in a federal health care investigation under criminal statutes. In addition, as previously disclosed, investigations are being conducted by local authorities in certain cities in Europe in order to determine whether any criminal charges should be brought concerning *Vioxx*. The Company is cooperating with these governmental entities in their respective investigations (the *Vioxx* Investigations ). The Company cannot predict the outcome of these inquiries; however, they could result in potential civil and/or criminal dispositions.

As previously disclosed, on May 20, 2008, the Company reached civil settlements with Attorneys General from 29 states and the District of Columbia to fully resolve previously disclosed investigations under state consumer protection laws related to past activities for *Vioxx*. As part of the civil resolution of these investigations, Merck paid a total of \$58 million to be divided among the 29 states and the District of Columbia. In April 2008, Merck announced it had taken a pretax charge in the first quarter of \$55 million in anticipation of this settlement. The agreement also includes compliance measures that supplement policies and procedures previously established by the Company.

In addition, the Company received a subpoena in September 2006 from the State of California Attorney General seeking documents and information related to the placement of *Vioxx* on California's Medi-Cal formulary. The Company is cooperating with the Attorney General in responding to the subpoena.

*Reserves*

As discussed above, on November 9, 2007, Merck entered into the Settlement Agreement with the law firms that comprise the executive committee of the PSC of the federal *Vioxx* MDL as well as representatives of plaintiffs counsel in the Texas, New Jersey and California state coordinated proceedings to resolve state and federal MI and IS claims filed as of that date in the United States. The Settlement Agreement, which also applies to tolled claims, was signed by the parties after several meetings with three of the four judges overseeing the coordination of more than 95% of the U.S. *Vioxx* Product Liability Lawsuits. The Settlement Agreement applies only to U.S. legal residents and those who allege that their MI or IS occurred in the United States. As a result of entering into the Settlement Agreement, the Company recorded a pretax charge of \$4.85 billion in 2007 which represents the fixed aggregate amount to be paid to plaintiffs qualifying for payment under the Settlement Program.

The Company currently anticipates that *Vioxx* Product Liability Lawsuits will be tried in the future. The Company believes that it has meritorious defenses to 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. The Company has not established any reserves for any potential liability relating to the *Vioxx* Lawsuits not included in the Settlement Program or the *Vioxx* Investigations (other than as set forth above), including for those cases in which verdicts or judgments have been entered against the Company, and are now in post-verdict proceedings or on appeal. In each of those cases the Company believes it has strong points to raise on appeal and therefore that unfavorable outcomes in such cases are not probable. Unfavorable outcomes in the *Vioxx* Litigation (as defined below) 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, 2007, the Company had a reserve of \$5.372 billion which represented the aggregate amount to be paid under the Settlement Agreement and its future legal defense costs related to (i) the *Vioxx* Product Liability Lawsuits, (ii) the *Vioxx* Shareholder Lawsuits, (iii) the *Vioxx* Foreign Lawsuits, and (iv) the *Vioxx* Investigations (collectively, the *Vioxx* Litigation). During the first half of 2008, the Company spent approximately \$156 million in the aggregate in legal defense costs related to the *Vioxx* Litigation. In the third quarter of 2008, the Company spent approximately \$66 million in the aggregate in legal defense costs related to the *Vioxx* Litigation. In addition, in the third quarter the Company paid \$500 million into the settlement fund in connection with the Settlement

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Agreement referred to above. Thus, as of September 30, 2008, the Company had a reserve of approximately \$4.649 billion related to the *Vioxx* Litigation.

Some of the significant factors considered in the review of the 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, but that certain lawsuits will continue to be pending; 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* Product Liability Lawsuits. Events such as trials, which may occur in 2009, and the inherent inability to predict the ultimate outcomes of such trials and the disposition of *Vioxx* Product Liability Lawsuits not participating in or not eligible for the Settlement Program, limit the Company's ability to reasonably estimate its legal costs beyond 2009.

The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase its reserves for legal defense costs at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

**Other Product Liability Litigation**

As previously disclosed, the Company is a defendant in product liability lawsuits in the United States involving *Fosamax* (the *Fosamax* Litigation). As of September 30, 2008, approximately 700 cases, which include approximately 1,143 plaintiff groups had been filed and were pending against Merck in either federal or state court, including two cases which seek class action certification, as well as damages and medical monitoring. In these actions, plaintiffs allege, among other things, that they have suffered osteonecrosis of the jaw, generally subsequent to invasive dental procedures such as tooth extraction or dental implants, and/or delayed healing, in association with the use of *Fosamax*. On August 16, 2006, the JPML ordered that the *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 United States District Court for the Southern District of New York. As a result of the JPML order, approximately 583 of the cases are before Judge Keenan. Judge Keenan issued a Case Management Order (and various amendments thereto) setting forth a schedule governing the proceedings which focuses 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. Briefing and argument on plaintiffs' motions for certification of medical monitoring classes were completed in 2007 and Judge Keenan issued an order denying the motions on January 3, 2008. On January 28, 2008, Judge Keenan issued a further order dismissing with prejudice all class claims asserted in the first four class action lawsuits filed against Merck that sought personal injury damages and/or medical monitoring relief on a class wide basis. In October 2008, Judge Keenan issued an order requiring that *Daubert* motions be filed in May 2009 and scheduling trials in the first three cases in the MDL for August 2009, October 2009, and January 2010, respectively.

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. On October 6, 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 osteonecrosis of the jaw, but not solely seeking medical monitoring, be designated as a mass tort for centralized management purposes before Judge Carol Higbee in Atlantic County Superior Court. Judge Higbee has scheduled an initial case management conference in the New Jersey matters for November 14, 2008.



Discovery is ongoing in both the *Fosamax* MDL litigation as well as in various state court cases. The Company intends to defend against these lawsuits.

As of December 31, 2007, the Company had a remaining reserve of approximately \$27 million solely for its future legal defense costs for the *Fosamax* Litigation. During the first half of 2008, the Company spent approximately \$17 million and added \$40 million to its reserve. In the third quarter, the Company spent approximately \$8 million. Consequently, as of September 30, 2008, the Company had a reserve of approximately \$42 million. Some of the significant factors considered in the establishment and ongoing assessment of the reserve for the *Fosamax* Litigation legal defense costs were as follows: the actual costs incurred by the Company thus far; the development of the Company's legal defense strategy and structure in light of the creation of the *Fosamax* MDL; the number of cases being brought against the Company; and the anticipated timing, progression, and related costs of pre-trial activities in the *Fosamax* Litigation. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves. Due to the uncertain nature of litigation, the Company is unable to estimate its costs beyond the

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completion of the first three federal trials discussed above. The Company has not established any reserves for any potential liability relating to the *Fosamax* Litigation. Unfavorable outcomes in the *Fosamax* Litigation could have a material adverse effect on the Company's financial position, liquidity and results of operations.

***Vytorin/Zetia* Litigation**

As previously disclosed, since December 2007, the Company and its joint venture partner, Schering-Plough, have received several letters addressed to both companies from the House Committee on Energy and Commerce, its Subcommittee on Oversight and Investigations ( O&I ), and the Ranking Minority Member of the Senate Finance Committee, collectively seeking a combination of witness interviews, documents and information on a variety of issues related to the ENHANCE clinical trial, the sale and promotion of *Vytorin*, as well as sales of stock by corporate officers. In addition, on August 21 and September 2, 2008, respectively, the companies received additional letters from O&I seeking certain information and documents related to the SEAS clinical trial. As previously disclosed, the companies have each received subpoenas from the New York and New Jersey State Attorneys General Offices and a letter from the Connecticut Attorney General seeking similar information and documents. In addition, the Company has received five Civil Investigative Demands ( CIDs ) from a multistate group of 35 State Attorneys General who are jointly investigating whether the companies violated state consumer protection laws when marketing *Vytorin*. Finally, on September 10, 2008, the Company received a letter from the Civil Division of the U.S. Department of Justice informing it that the DOJ is investigating whether the companies conduct relating to the promotion of *Vytorin* caused false claims to be submitted to federal health care programs. The Company is cooperating with these investigations and working with Schering-Plough to respond to the inquiries. In addition, since mid-January 2008, the Company has become aware of or been served with approximately 140 civil class action lawsuits alleging common law and state consumer fraud claims in connection with the MSP Partnership's sale and promotion of *Vytorin* and *Zetia*. Certain of those lawsuits allege personal injuries and/or seek medical monitoring.

Also, as previously disclosed, on April 3, 2008, a Merck shareholder filed a putative class action lawsuit in federal court in the Eastern District of Pennsylvania alleging that Merck and its Chairman, President and Chief Executive Officer, Richard T. Clark, 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 on October 6, 2008 and names as defendants Merck; Merck/Schering-Plough Pharmaceuticals, LLC; and certain of the Company's officers and directors. Specifically, the complaint alleges that Merck delayed releasing unfavorable results of a clinical study regarding the efficacy of *Vytorin* and that 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 Merck's earnings would suffer. On April 22, 2008, a member of a Merck ERISA plan filed a putative class action lawsuit against the Company and certain of its officers and directors alleging they breached their fiduciary duties under ERISA. Since that time, there have been other similar ERISA lawsuits filed against the Company 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*. Plaintiffs in these suits allege that the ERISA plan's investment in Company stock was imprudent because the Company'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. The Company intends to defend the lawsuits referred to in this section vigorously. Unfavorable outcomes resulting from the government investigations or the civil litigation could have a material adverse effect on the Company's financial position, liquidity and results of operations.

## 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. Generic pharmaceutical manufacturers have submitted ANDAs to the FDA seeking to market in the United States a generic form of *Propecia*, *Prilosec*, *Nexium*, *Singulair* and *Primaxin* prior to the expiration of the Company's (and AstraZeneca's in the case of *Prilosec* and *Nexium*) patents concerning these products. In addition, an ANDA has been submitted to the FDA seeking to market in the United States a generic form of *Zetia* prior to the expiration of Schering-Plough's patent concerning that product. The generic companies' ANDAs generally include allegations of non-infringement, invalidity and unenforceability of the patents. Generic manufacturers have received FDA approval to market a generic form of *Prilosec*. The Company has filed patent infringement suits in federal court against companies filing ANDAs for generic finasteride (*Propecia*), montelukast (*Singulair*), imipenem/cilastatin (*Primaxin*) and AstraZeneca and the Company have filed patent infringement suits in federal court against companies filing ANDAs for generic omeprazole (*Prilosec*) and esomeprazole (*Nexium*). Also, the Company and Schering-Plough have filed a patent infringement suit in federal court against companies filing ANDAs for generic ezetimibe (*Zetia*). Similar patent challenges exist in certain foreign jurisdictions. 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 dates 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.

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

As previously disclosed, in February 2007, the Company received a notice from Teva Pharmaceuticals (Teva), a generic company, indicating that it had filed an ANDA for montelukast and that it is challenging the U.S. patent that is listed for *Singulair*. On April 2, 2007, the Company filed a patent infringement action against Teva. The lawsuit automatically stays FDA approval of Teva's ANDA for 30 months or until an adverse court decision, if any, whichever may occur earlier. A trial in this matter has been scheduled to begin on February 23, 2009.

**Other Litigation**

There are various other legal proceedings, principally product liability and intellectual property suits involving the Company, which are pending. While it is not feasible to predict the outcome of such proceedings or the proceedings discussed in this Note, in the opinion of the Company, all such proceedings are either adequately covered by insurance or, if not so covered, should not ultimately result in any liability that would have a material adverse effect on the financial position, liquidity or results of operations of the Company, other than proceedings for which a separate assessment is provided in this Note.

**9. Share-Based Compensation**

The Company has share-based compensation plans under which employees, non-employee directors and employees of certain of the Company's equity method investees may be granted options to purchase shares of Company common stock at the fair market value at the time of grant. In addition to stock options, the Company grants performance share units (PSUs) and restricted stock units (RSUs) 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:

(\$ in millions)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2008	2007	2008	2007
Pretax share-based compensation expense	\$ 86.8	\$ 72.7	\$285.5	\$250.9
Income tax benefits	(26.7)	(22.8)	(88.8)	(79.1)
Total share-based compensation expense, net of tax	\$ 60.1	\$ 49.9	\$196.7	\$171.8

During the first nine months of 2008 and 2007, the Company granted 34.5 million options and 33.7 million options, respectively, related to its annual grant and other grants. The weighted average fair value of options granted for the first nine months of 2008 and 2007 was \$9.89 and \$9.30 per option, respectively, and was determined using the following assumptions:

	Nine Months Ended	
	September 30,	
	2008	2007
Expected dividend yield	3.5%	3.4%
Risk-free interest rate	2.7%	4.4%

Expected volatility	30.8%	24.5%
Expected life (years)	6.1	5.7

At September 30, 2008, there was \$515.1 million of total pretax unrecognized compensation expense related to nonvested stock options, RSU and PSU awards which will be recognized over a weighted average period of 2.2 years. For segment reporting, share-based compensation costs are unallocated expenses.

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**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)**10. 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,	
	2008	2007	2008	2007
Service cost	\$ 90.1	\$ 90.3	\$ 263.4	\$ 275.3
Interest cost	105.4	99.9	318.8	284.5
Expected return on plan assets	(142.8)	(123.1)	(427.7)	(366.7)
Net amortization	19.3	44.0	62.1	112.5
Termination benefits	24.4	2.5	42.9	18.5
Curtailments	8.1		11.3	
Settlements	2.5		2.5	
	\$ 107.0	\$ 113.6	\$ 273.3	\$ 324.1

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,	
	2008	2007	2008	2007
Service cost	\$ 18.4	\$ 25.8	\$ 55.9	\$ 68.1
Interest cost	28.2	28.8	84.5	80.7
Expected return on plan assets	(33.2)	(37.4)	(97.7)	(98.0)
Net amortization	(5.2)	(7.5)	(16.6)	(12.5)
Termination benefits	2.9	0.2	7.1	3.7
Curtailments	(12.3)		(12.9)	(3.9)
	\$ (1.2)	\$ 9.9	\$ 20.3	\$ 38.1

In connection with restructuring actions (see Note 2), the Company recorded termination charges for the three and nine months ended September 30, 2008 and 2007 on its pension and other postretirement benefit plans related to expanded eligibility for certain employees exiting the Company. Also, in connection with these restructuring actions, the Company recorded net curtailment losses on its pension plans for the three and nine months ended September 30, 2008 and curtailment gains on its other postretirement benefit plans for the three and nine months ended September 30, 2008 and the nine months ended September 30, 2007. In addition, the Company recorded settlement losses on its pension plans for the three and nine months ended September 30, 2008.

**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)**11. Other (Income) Expense, Net**

Other (income) expense, net, consisted of:

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Interest income	\$(171.3)	\$(186.9)	\$ (484.2)	\$(540.9)
Interest expense	71.4	91.5	194.6	297.2
Exchange losses (gains)	52.3	(8.3)	73.6	(39.8)
Minority interests	31.2	30.6	93.9	92.0
Other, net	78.2	(107.8)	(2,075.3)	(329.7)
	\$ 61.8	\$(180.9)	\$(2,197.4)	\$(521.2)

Other, net for the nine months ended September 30, 2008 primarily reflects an aggregate gain from AZLP of \$2.2 billion (see Note 6) and a gain of \$249 million related to the sale of the Company's remaining worldwide rights to *Aggrastat*, partially offset by a \$300 million expense for a contribution to the Merck Company Foundation, recognized losses of \$108 million, including \$88 million of losses in the third quarter, in the Company's investment portfolio and a \$58 million charge related to the resolution of an investigation into whether the Company violated consumer protection laws with respect to the sales and marketing of *Vioxx* (see Note 8). Other, net for the first nine months of 2007 primarily reflects the favorable impact of gains on sales of assets and product divestitures, as well as a net gain on the settlements of certain patent disputes. Interest paid for the nine months ended September 30, 2008 and 2007 was \$181.2 million and \$318.4 million, respectively.

**12. Taxes on Income**

The effective tax rate of 22.6% for the third quarter of 2008 reflects the favorable impact of restructuring charges. The effective tax rate of 21.8% for the first nine months of 2008 reflects a net favorable impact of approximately 2 percentage points which includes favorable impacts relating to second quarter tax settlements that resulted in a reduction of the Company's liability for unrecognized tax benefits of approximately \$200 million, the first quarter realization of foreign tax credits and year-to-date restructuring costs, largely offset by an unfavorable impact resulting from the AZLP gain (see Note 6) being fully taxable in the United States at a combined federal and state tax rate of approximately 36.3%. In the first quarter of 2008, the Company decided to repatriate certain prior years foreign earnings which will result in a utilization of foreign tax credits. These foreign tax credits arose as a result of tax payments made outside of the United States in prior years that became realizable in the first quarter based on a change in the Company's repatriation plans. The effective tax rates of 26.1% for the third quarter of 2007 and 25.1% for the first nine months of 2007 reflect the impact of acquired research expense which is not deductible for tax purposes, as well as the favorable impact of restructuring costs.

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

As previously disclosed, Merck's Canadian tax returns for the years 1998 through 2004 are being examined by the Canada Revenue Agency (CRA). In October 2006, the CRA issued the Company a notice of reassessment containing adjustments related to certain intercompany pricing matters, which result in additional Canadian and provincial tax due of approximately \$1.5 billion (U.S. dollars) plus interest of approximately \$1.0 billion (U.S. dollars). In addition, in July 2007, the CRA proposed additional adjustments for 1999 relating to another intercompany pricing matter. The adjustments would increase Canadian tax due by approximately \$21 million (U.S. dollars) plus \$22 million (U.S. dollars) of interest. It is possible that the CRA will propose similar adjustments for later years. The Company disagrees with the positions taken by the CRA and believes they are without merit. The Company intends to contest the assessments through the CRA appeals process and the courts if necessary. In connection with the appeals process, during 2007, the Company pledged collateral to two financial institutions, one of which provided a guarantee to the CRA and the other to the Quebec Ministry of Revenue representing a portion of the tax and interest assessed. The collateral is included in Other Assets in the Consolidated Balance Sheet and totaled approximately \$1.3 billion at September 30, 2008. During the first nine months of 2008, approximately \$400 million of cash and cash equivalents in the collateral account was transferred out and a corresponding amount of investments was transferred in. The Company has previously established reserves for these matters. While the resolution of these matters may result in liabilities higher or lower than the reserves, management believes that resolution of these matters will not have a material effect on the Company's financial position or liquidity. However, an unfavorable resolution could have a material adverse effect on the Company's results of operations or cash flows in the quarter in which an adjustment is recorded or tax is due.

In July 2007, the CRA notified the Company that it is in the process of proposing a penalty of \$160 million (U.S. dollars) in connection with the 2006 notice. The penalty is for failing to provide information on a timely basis. The Company vigorously disagrees with the penalty and feels it is inapplicable and that appropriate information was provided on a timely basis. The Company is pursuing all appropriate remedies to avoid having the penalty assessed and was notified in early August 2007 that the CRA is holding the imposition of a penalty in abeyance pending a review of the Company's submissions as to the inapplicability of a penalty.

**13. Earnings Per Share**

The weighted average common shares used in the computations of basic earnings per common share and earnings per common share assuming dilution are as follows:

<i>(shares in millions)</i>	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Average common shares outstanding	2,128.5	2,170.5	2,144.4	2,168.2
Common shares issuable <sup>(1)</sup>	7.1	22.3	12.4	19.2
Average common shares outstanding assuming dilution	2,135.6	2,192.8	2,156.8	2,187.4

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

For the three months ended September 30, 2008 and 2007, 227.5 million and 124.5 million, respectively, and for the nine months ended September 30, 2008 and 2007, 202.1 million and 177.1 million, respectively, of common shares issuable under the Company's share-based compensation plans were excluded from the computation of earnings per



common share assuming dilution because the effect would have been antidilutive.

**14. Comprehensive Income**

Comprehensive income was \$994.7 million and \$1,584.5 million for the three months ended September 30, 2008 and 2007, respectively, and was \$5,956.1 million and \$5,017.0 million for the nine months ended September 30, 2008 and 2007, respectively.

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**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)**15. Segment Reporting**

The Company's operations are principally managed on a products basis and are comprised of two reportable segments: the Pharmaceutical segment and the Vaccines and Infectious Diseases segment. Segment composition reflects certain managerial changes that were implemented in early 2008. In addition, in the first quarter of 2008, the Company revised the calculation of segment profits to include a greater allocation of costs to the segments. Segment disclosures for 2007 have been recast on a comparable basis with 2008.

The Pharmaceutical segment includes human health pharmaceutical products marketed either directly or through joint ventures. These products consist of therapeutic and preventive agents, sold by prescription, for the treatment of human disorders. Merck 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. The Vaccines and Infectious Diseases segment includes human health vaccine and infectious disease products marketed either directly or through joint ventures. Vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. Merck 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. Infectious disease products consist of therapeutic agents for the treatment of infection sold primarily to drug wholesalers, retailers, hospitals and government agencies. The Vaccines and Infectious Diseases segment includes the majority of the Company's aggregate vaccine and infectious disease product sales, but excludes sales of these products by non-U.S. subsidiaries which are included in the Pharmaceutical segment.

Other segments include other non-reportable human and animal health segments.

Revenues and profits for these segments are as follows:

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Segment revenues:				
Pharmaceutical segment	\$4,804.6	\$4,765.2	\$14,622.1	\$14,539.0
Vaccines and Infectious Diseases segment	1,085.9	1,236.0	3,098.1	3,213.1
Other segment revenues	21.2	44.9	65.3	125.6
	\$5,911.7	\$6,046.1	\$17,785.5	\$17,877.7
Segment profits: <sup>(1)</sup>				
Pharmaceutical segment	\$3,165.5	\$3,305.1	\$ 9,397.5	\$ 9,977.6
Vaccines and Infectious Diseases segment	772.7	815.7	2,042.9	1,941.1
Other segment profits	98.6	112.9	363.9	395.5
	\$4,036.8	\$4,233.7	\$11,804.3	\$12,314.2

<sup>(1)</sup> Includes the majority of Equity income

*from affiliates.*

**Table of Contents****Notes to Consolidated Financial Statements (unaudited)** (continued)Sales <sup>(1)</sup> of the Company's products were as follows:

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
<i>Pharmaceutical:</i>				
Singulair	\$ 1,029.3	\$ 1,018.1	\$ 3,214.6	\$ 3,111.9
Cozaar/Hyzaar	888.3	813.6	2,676.3	2,458.8
Fosamax	353.9	725.2	1,234.8	2,253.0
Januvia	378.5	184.6	984.4	415.3
Cosopt/Trusopt	208.6	196.8	627.4	575.0
Zocor	157.2	217.8	513.1	654.2
Maxalt	136.4	125.0	388.3	341.5
Propecia	107.9	99.2	320.6	292.8
Arcoxia	96.8	76.1	294.1	245.2
Vasotec/Vaseretic	82.1	119.5	271.5	368.5
Proscar	80.9	89.6	251.9	328.0
Janumet	100.7	18.6	231.5	42.9
Emend	68.2	48.9	193.3	143.6
Other pharmaceutical <sup>(2)</sup>	519.1	575.4	1,734.2	1,980.2
Vaccine and infectious disease product sales included in the Pharmaceutical segment <sup>(3)</sup>	596.7	456.8	1,686.1	1,328.1
Pharmaceutical segment revenues	4,804.6	4,765.2	14,622.1	14,539.0
<i>Vaccines <sup>(4)</sup> and Infectious Diseases:</i>				
Gardasil	401.0	418.4	1,117.1	1,141.3
RotaTeq	134.5	171.3	502.4	375.4
Zostavax	11.2	61.2	150.8	150.7
ProQuad/M-M-R II/Varivax	430.4	428.5	973.8	1,018.1
Hepatitis vaccines	36.2	68.4	107.9	219.5
Other vaccines	80.6	96.5	222.8	284.6
Primaxin	187.6	185.6	591.5	568.4
Cancidas	147.9	135.2	457.4	403.2
Isentress	107.3	5.4	231.1	11.9
Crixivan/Stocrin	68.5	72.3	222.8	229.9
Invanz	71.1	49.5	197.0	137.4
Other infectious disease	6.3	0.5	9.6	0.8
Vaccine and infectious disease product sales included in the Pharmaceutical segment <sup>(3)</sup>	(596.7)	(456.8)	(1,686.1)	(1,328.1)
Vaccines and Infectious Diseases segment revenues	1,085.9	1,236.0	3,098.1	3,213.1
Other segment <sup>(5)</sup>	21.2	44.9	65.3	125.6
Total segment revenues	5,911.7	6,046.1	17,785.5	17,877.7

Other <sup>(6)</sup>	32.2	28.0	32.4	77.1
	\$5,943.9	\$6,074.1	\$17,817.9	\$17,954.8

(1) *Presented net of discounts and returns.*

(2) *Other pharmaceutical primarily includes sales of other human pharmaceutical products and revenue from the Company's relationship with AstraZeneca LP primarily relating to sales of Nexium, as well as Prilosec. Revenue from AstraZeneca LP was \$375.2 million and \$416.3 million for the third quarter of 2008 and 2007, respectively, and was \$1,235.7 million and \$1,438.2 million for the first nine months of 2008 and 2007, respectively.*

(3) *Sales of vaccine and infectious disease products by non-U.S. subsidiaries are included in the*

*Pharmaceutical  
segment.*

- (4) *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.*
- (5) *Includes other non-reportable human and animal health segments.*
- (6) *Other revenues are primarily comprised of miscellaneous corporate revenues, 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,	
	2008	2007	2008	2007
Segment profits	\$ 4,036.8	\$ 4,233.7	\$ 11,804.3	\$ 12,314.2
Other profits	21.1	10.3	(6.8)	40.3
Adjustments	72.1	86.6	271.7	258.7
Unallocated:				
Interest income	171.3	186.9	484.2	540.9
Interest expense	(71.4)	(91.5)	(194.6)	(297.2)
Equity income from affiliates	32.9	47.9	31.7	180.6
Depreciation and amortization	(367.0)	(458.0)	(1,079.4)	(1,388.5)
Research and development	(1,171.1)	(1,440.5)	(3,418.7)	(3,501.0)
Gain on distribution from AstraZeneca LP			2,222.7	
Other expenses, net	(1,313.8)	(510.8)	(2,234.7)	(1,596.8)
	\$ 1,410.9	\$ 2,064.6	\$ 7,880.4	\$ 6,551.2

Segment profits are comprised of segment revenues less certain elements of materials and production costs and operating expenses, including the majority of equity income from affiliates and components of depreciation and amortization expenses. For internal management reporting presented to the chief operating decision maker, the Company does not allocate the vast majority of research and development expenses, general and administrative expenses, depreciation related to fixed assets utilized by nonmanufacturing divisions, as well as the cost of financing these activities. Separate divisions maintain responsibility for monitoring and managing these costs and, therefore, they are not included in segment profits.

Other profits are primarily comprised of miscellaneous corporate profits as well as operating profits related to 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, includes expenses from corporate and manufacturing cost centers and other miscellaneous income (expense), net.

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

*Sales*

Worldwide sales were \$5.94 billion for the third quarter of 2008, a decline of 2% compared with the third quarter of 2007, primarily attributable to a 6% unfavorable effect from volume, partially offset by a 4% favorable effect from foreign exchange. The revenue decline in the third quarter largely reflects lower sales of *Fosamax* for the treatment and prevention of osteoporosis. *Fosamax* and *Fosamax Plus D* lost market exclusivity for substantially all formulations in the United States in February 2008 and April 2008, respectively. Also contributing to the decline were lower sales of vaccines, including *Zostavax*, a vaccine to help prevent shingles (herpes zoster), *RotaTeq*, a vaccine to help protect against rotavirus gastroenteritis in infants and children, and Haemophilus influenzae type b (HIB) and hepatitis vaccines. Revenue was also negatively impacted by lower sales of *Zocor*, the Company's statin for modifying cholesterol which lost U.S. market exclusivity in 2006, and lower revenue from the Company's relationship with AstraZeneca LP (AZLP). These declines were partially offset by higher sales of *Januvia* and *Janumet* for the treatment of type 2 diabetes, *Isentress* for the treatment of HIV infection and *Cozaar/Hyzaar*\* for the treatment of hypertension.

Worldwide sales were \$17.82 billion for the first nine months of 2008, a decline of 1% compared with the first nine months of 2007, primarily attributable to a 4% unfavorable effect from volume and a 1% unfavorable effect from price changes, offset by a 4% favorable effect from foreign exchange. The revenue decline for the first nine months of 2008 reflects lower sales of *Fosamax*, decreased revenues from the Company's relationship with AZLP, lower sales of *Zocor* and lower sales of vaccines, including hepatitis and HIB vaccines. Partially offsetting these declines were higher sales of *Januvia* and *Janumet*, *Isentress*, *Cozaar/Hyzaar*, *RotaTeq* and *Singulair*, a medicine indicated for the chronic treatment of asthma and the relief of symptoms of allergic rhinitis.

\* *Cozaar* and *Hyzaar* are registered trademarks of E.I. duPont de Nemours & Company, Wilmington, Delaware.

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Sales of the Company's products were as follows:

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
<i>Pharmaceutical:</i>				
Singular	\$1,029.3	\$1,018.1	\$ 3,214.6	\$ 3,111.9
Cozaar/Hyzaar	888.3	813.6	2,676.3	2,458.8
Fosamax	353.9	725.2	1,234.8	2,253.0
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Cosopt/Trusopt	208.6	196.8	627.4	575.0
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Vasotec/Vaseretic	82.1	119.5	271.5	368.5
Proscar	80.9	89.6	251.9	328.0
Janumet	100.7	18.6	231.5	42.9
Emend	68.2	48.9	193.3	143.6
Other pharmaceutical <sup>(1)</sup>	519.1	575.4	1,734.2	1,980.2
Vaccine and infectious disease product sales included in the Pharmaceutical segment <sup>(2)</sup>	596.7	456.8	1,686.1	1,328.1
Pharmaceutical segment revenues	4,804.6	4,765.2	14,622.1	14,539.0
<i>Vaccines <sup>(3)</sup> and Infectious Diseases:</i>				
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RotaTeq	134.5	171.3	502.4	375.4
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ProQuad/M-M-R II/Varivax	430.4	428.5	973.8	1,018.1
Hepatitis vaccines	36.2	68.4	107.9	219.5
Other vaccines	80.6	96.5	222.8	284.6
Primaxin	187.6	185.6	591.5	568.4
Candidas	147.9	135.2	457.4	403.2
Isentress	107.3	5.4	231.1	11.9
Crixivan/Stocrin	68.5	72.3	222.8	229.9
Invanz	71.1	49.5	197.0	137.4
Other infectious disease	6.3	0.5	9.6	0.8
Vaccine and infectious disease product sales included in the Pharmaceutical segment <sup>(2)</sup>	(596.7)	(456.8)	(1,686.1)	(1,328.1)
Vaccines and Infectious Diseases segment revenues	1,085.9	1,236.0	3,098.1	3,213.1
Other segment <sup>(4)</sup>	21.2	44.9	65.3	125.6
Total segment revenues	5,911.7	6,046.1	17,785.5	17,877.7

Other <sup>(5)</sup>	32.2	28.0	32.4	77.1
	\$5,943.9	\$6,074.1	\$17,817.9	\$17,954.8

(1) *Other pharmaceutical primarily includes sales of other human pharmaceutical products and revenue from the Company's relationship with AZLP primarily relating to sales of Nexium, as well as Prilosec. Revenue from AZLP was \$375.2 million and \$416.3 million for the third quarter of 2008 and 2007, respectively, and was \$1,235.7 million and \$1,438.2 million for the first nine months of 2008 and 2007, respectively.*

(2) *Sales of vaccine and infectious disease products by non-U.S. subsidiaries are included in the Pharmaceutical segment.*

(3) *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.*

*(4) Includes other non-reportable human and animal health segments.*

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

Sales by product are presented net of discounts and returns. The provision for discounts includes indirect customer discounts that occur when a contracted customer purchases directly through an intermediary wholesale purchaser, known

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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 \$529.7 million and \$492.4 million for the three months ended September 30, 2008 and 2007, respectively, and by \$1,581.7 million and \$1,536.1 million for the nine months ended September 30, 2008 and 2007, respectively. Inventory levels at key wholesalers for each of the Company's major pharmaceutical products are generally less than one month.

*Pharmaceutical Segment Revenues*

Sales of the Pharmaceutical segment increased 1% for both the third quarter and first nine months of 2008 to \$4.80 billion and \$14.62 billion, respectively, compared with the corresponding periods of 2007. These results reflect growth of *Januvia*, *Janumet*, *Isentress* and *Cozaar/Hyzaar*, offset by declines in *Fosamax*, *Zocor* and supply sales to AZLP.

Worldwide sales for *Singulair* were \$1.03 billion for the third quarter of 2008, representing an increase of 1% over the third quarter of 2007. Sales for the first nine months of 2008 reached \$3.21 billion, a 3% increase over the comparable prior year period. Sales in the third quarter and first nine months of 2008 reflect the continued demand for asthma and seasonal and perennial allergic rhinitis medications. Sales performance for the quarter and year-to-date period benefited from higher sales outside the United States, including the positive effect of foreign exchange and volume growth in Europe and Japan. Sales performance in the United States also reflects the impact of the switch of a competing allergic rhinitis product to over-the-counter status in the United States in early 2008, the timing and public reaction to the U.S. Food and Drug Administration (FDA) early communication regarding a very limited number of post-marketing adverse event reports which created uncertainty in the marketplace, and a shorter and milder spring allergy season. *Singulair* continues to be the number one prescribed branded product in the U.S. respiratory market. Global sales of *Cozaar* and *Hyzaar* were \$888.3 million for the third quarter of 2008, an increase of 9% compared with the third quarter of 2007. Sales for the first nine months of 2008 were \$2.68 billion, an increase of 9% compared with the first nine months of 2007. The increase in both periods was driven in part by the positive effect of foreign exchange and strong performance of *Hyzaar* in Japan (marketed as *Preminent*). *Cozaar* and *Hyzaar* are among the leading medicines in the growing angiotensin receptor blocker class.

Global sales for *Fosamax* and *Fosamax Plus D* (marketed as *Fosavance* throughout the European Union (EU) and as *Fosamac* in Japan) were \$353.9 million for the third quarter of 2008 and were \$1.23 billion for the first nine months of 2008, representing declines of 51% and 45%, respectively, over the comparable prior year periods of 2007. Since substantially all formulations of these medicines have lost U.S. market exclusivity, the Company is experiencing a significant decline in sales in the United States within the *Fosamax* franchise and the Company expects such declines to continue.

Global sales of *Januvia*, Merck's dipeptidyl peptidase-4 (DPP-4) inhibitor for the treatment of type 2 diabetes, were \$378.5 million in the third quarter of 2008 compared with \$184.6 million for the third quarter of 2007. Sales for the first nine months of 2008 were \$984.4 million compared with \$415.3 for the first nine months of 2007. *Januvia* was approved by the FDA in October 2006 and by the European Commission (EC) in March 2007. *Januvia* continues to be the second leading branded oral anti-diabetic agent in terms of new prescription share. 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.

In September 2008, new data analyses from five new studies were presented at the 44<sup>th</sup> Annual Meeting of the European Association for the Study of Diabetes. These data showed initial combination therapy with *Januvia* and metformin provided improvements in blood sugar levels as measured by A1C (a measure of a person's average blood glucose over a two-month to three-month period) over two years of treatment and was generally well tolerated. Also presented at the meeting was a separate, new pooled analysis of 6,139 patients that showed that *Januvia* was generally well tolerated in clinical trials up to two years in duration. Three additional studies further demonstrated the safety and efficacy profile of *Januvia* as an add-on to other oral diabetes treatments and efficacy when analyzed based on different baseline characteristics.

Global sales of *Janumet*, Merck's oral antihyperglycemic agent that combines sitagliptin (Merck's DPP-4 inhibitor, *Januvia*) with metformin in a single tablet to target all three key defects of type 2 diabetes, were \$100.7 million for the third quarter of 2008 compared with \$18.6 million for the third quarter of 2007. Sales for the first nine months of 2008 were \$231.5 million compared with \$42.9 million for the same period of 2007. *Janumet*, launched in the United States in April 2007, was approved, as an adjunct to diet and exercise, to improve blood sugar control in adult patients with type 2

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diabetes who are not adequately controlled on metformin or sitagliptin alone, or in patients already being treated with the combination of sitagliptin and metformin. In February 2008, Merck received FDA approval to market *Janumet* as an initial treatment for type 2 diabetes. In July 2008, *Janumet* was approved for marketing in the EU, Iceland and Norway.

Worldwide sales of *Zocor*, Merck's statin for modifying cholesterol, declined 28% in the third quarter of 2008 compared with the third quarter of 2007 and 22% for the first nine months of 2008 over the corresponding period of 2007 reflecting the continuing impact of the loss of U.S. market exclusivity in June 2006.

Other Pharmaceutical segment products experiencing growth in the third quarter and first nine months of 2008 compared with the same periods of 2007 include *Arcoxia* for the treatment of arthritis and pain, *Emend* for the prevention of acute and delayed nausea and vomiting associated with moderately and highly emetogenic cancer chemotherapy, as well as for the treatment of post-operative nausea and vomiting, *Maxalt* to treat migraine pain, *Cosopt* to treat elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension, and *Propecia* for male pattern hair loss.

In September 2008, Merck confirmed that the EC adopted the recommendation of the European Medicines Agency to approve *Arcoxia* 90 mg once daily as a new treatment for ankylosing spondylitis, maintain the 90 mg dose for rheumatoid arthritis, and modify the contraindications and warnings sections of the label for treating and monitoring patients with hypertension. In Europe, *Arcoxia* is indicated for the treatment of osteoarthritis (30 mg or 60 mg), rheumatoid arthritis (90 mg) and acute gouty arthritis (120 mg). National approval procedures to implement the new indication and prescribing information are underway in the 27 member states of the EU. *Arcoxia* is approved and launched in 69 countries in Europe, Latin America and the Asia-Pacific region.

In October 2008, Merck terminated its Phase II/III clinical study evaluating *Zolinza* in combination with paclitaxel and carboplatin in patients with Stage IIIB or Stage IV non-small cell lung cancer. The decision follows the recommendations of an independent Data Safety Monitoring Board (DSMB), which met on October 14, 2008 for a pre-planned interim analysis of the study. The DSMB recommended that the study, which had completed Phase II enrollment, be discontinued due to a lack of improvement in progression-free survival and a higher incidence of serious adverse experiences and discontinuations of therapy in the *Zolinza* plus carboplatin and paclitaxel arm. Merck currently remains blinded to the data and will evaluate the data once it has been fully analyzed. As lung cancer is a leading cause of cancer deaths worldwide, Merck is committed to further researching *Zolinza* in combination with other chemotherapy agents.

Also in October 2008, the patent that provided U.S. market exclusivity for *Trusopt* and *Cosopt* expired. The Company expects significant declines in U.S. sales of these products.

During the first quarter of 2008, Merck divested its remaining ownership of *Aggrastat* in foreign markets to Iroko Pharmaceuticals.

Also during the first quarter of 2008, the Company and AZLP entered into an agreement with Ranbaxy Laboratories Ltd. (Ranbaxy) to settle patent litigation with respect to esomeprazole (*Nexium*) which provides that Ranbaxy will not bring its generic esomeprazole product to market in the United States until May 27, 2014.

***Vaccines and Infectious Diseases Segment Revenues***

Sales of the Vaccines and Infectious Diseases segment declined 12% to \$1.09 billion in the third quarter of 2008 from \$1.24 billion in the third quarter of 2007 primarily due to lower sales of *Zostavax*, *Gardasil*, *RotaTeq*, hepatitis and HIB vaccines, partially offset by sales of *Isentress*. Sales for the first nine months of 2008 declined 4% to \$3.10 billion from \$3.21 billion for the first nine months of 2007 primarily due to lower sales of hepatitis and HIB vaccines, *Gardasil* and other viral vaccines, which include *Varivax*, *M-M-R II* and *ProQuad*, partially offset by sales of *Isentress* and growth in *RotaTeq*.

The following discussion of vaccine and infectious disease product sales includes total vaccine and infectious disease product sales, the aggregate majority of which are included in the Vaccines and Infectious Diseases segment and the remainder, representing sales of these products by non-U.S. subsidiaries, are included in the Pharmaceutical segment. These amounts do not reflect 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 are reflected in

Vaccines and Infectious Diseases segment revenues.

Worldwide sales of the Company's cervical cancer vaccine *Gardasil*, as recorded by Merck, were \$401.0 million for the third quarter of 2008, a decline of 4% compared with the third quarter of 2007 and were \$1.12 billion for the first nine months of 2008, a decline of 2% over the comparable period of 2007. Sales performance reflects lower sales

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domestically, partially offset by growth outside the United States. Sales growth outside the United States was aided by the adoption of school-based programs in all Canadian provinces, which was the primary driver of a \$34 million increase in sales in Canada in the third quarter of 2008 compared with the third quarter of 2007. Based on market research, the third quarter 2008 performance for *Gardasil* in the United States was driven by a generally consistent monthly vaccination rate among 19 to 26 year old women over the past year, and while the annual vaccination rate of the remaining 13 to 18 year olds increased, the overall number of first dose vaccinations declined because of the early success in vaccinating this age group following launch. Also, utilization during the back to school season appears to have been tempered by media coverage over the summer on post-marketing reports. *Gardasil*, the world's top-selling HPV vaccine and only HPV vaccine available for use in the United States, currently is indicated for girls and women nine through 26 years of age for the prevention of cervical, vulvar and vaginal cancers, precancerous or dysplastic lesions, and genital warts caused by HPV types 6, 11, 16 and 18.

In September 2008, the FDA approved *Gardasil* for the prevention of vulvar and vaginal cancers caused by HPV types 16 and 18. The approval is based on data from a combined analysis of three studies that demonstrated the efficacy and safety of *Gardasil* in more than 15,000 patients.

In June 2008, the FDA issued a complete response letter regarding the supplemental biologics license application (sBLA) for the use of *Gardasil* in women ages 27 through 45. The agency issued the letter to advise that it has completed its review of the submission and that there are issues that preclude approval of the supplement within the expected review timeframe. Merck discussed with the FDA their questions related to this application and responded to the agency in July 2008. The agency has informed the Company that the response was a class 2 response, which typically undergo a six month review. The letter does not affect current indications for *Gardasil* in females aged nine through 26. Clinical studies to evaluate the safety and efficacy of *Gardasil* in males 16 to 26 years of age continue and the Company expects to submit to the FDA an application to support an indication for males nine to 26 years of age in 2008.

*RotaTeq*, Merck's vaccine to help protect against rotavirus gastroenteritis in infants and children, achieved worldwide sales as recorded by Merck of \$134.5 million for the third quarter of 2008, a decline of 21% compared with the third quarter of 2007. In the third quarter of 2007, the Company recorded \$51 million in revenue as a result of a government purchase for the U.S. Centers for Disease Control and Prevention (CDC) stockpile. Sales were \$502.4 million for the first nine months of 2008, an increase of 34% compared with the first nine months of 2007. The increase for the year-to-date period was driven largely by the continued uptake in the United States and successful launches around the world. Sales in the first nine months of 2008 included purchases of \$54 million to support the CDC stockpile compared with \$51 million in the first nine months of 2007.

In October 2008, Merck announced that *RotaTeq* has been awarded pre-qualification status by the World Health Organization (WHO). WHO pre-qualification allows for expanded access to *RotaTeq* and provides a greater opportunity to help protect millions of babies from rotavirus gastroenteritis. Because *RotaTeq* is pre-qualified by the WHO, the vaccine is eligible for procurement by the Pan American Health Organization, UNICEF and other United Nations agencies for use in national vaccination programs. *RotaTeq* is the only ready-to-use oral liquid rotavirus vaccine to receive WHO pre-qualification. Merck has committed to providing *RotaTeq* to the Global Alliance for Vaccines and Immunization-eligible countries at prices at which it does not profit.

Also in October 2008, data on *RotaTeq* were presented at the 48th Interscience Conference on Antimicrobial Agents and Chemotherapy / Infectious Diseases Society of America 46th Annual Meeting in Washington, D.C. that showed *RotaTeq* reduced rotavirus-related hospitalizations and emergency room visits combined by 100% during the 2007 and 2008 rotavirus seasons (January through May of each year) in an observational study in the United States. The large, national, post-licensure observational study was based on a review of health insurance claims data from approximately 61,000 infants in the United States.

Additionally, in October 2008, the CDC Advisory Committee on Immunization Practices (ACIP) voted unanimously to recommend that adults ages 19 to 64 with asthma receive pneumococcal polysaccharide vaccine (PPSV23), known as *Pneumovax 23* (Pneumococcal Vaccine Polyvalent). Merck is the sole supplier of *Pneumovax 23* in the United States. The ACIP based this recommendation on study data that showed an increased risk of pneumococcal disease



among people with asthma. Pneumococcal diseases are caused by common bacteria and can lead to potentially serious bacterial infections of the lungs (pneumonia), lining of the brain (meningitis) and blood (bacteremia). The ACIP also voted to recommend that people aged 19 through 64 years who smoke cigarettes should receive PPSV23 as well as smoking-cessation counseling. This recommendation is the first time the ACIP has recommended a vaccine specifically for people who smoke.

As previously disclosed, the Company has resolved an issue related to the bulk manufacturing process for the Company's varicella zoster virus ( VZV )-containing vaccines. The Company is manufacturing bulk varicella and is producing doses of *Varivax* and *Zostavax*. The Company has received regulatory approvals in the United States and certain other markets

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to increase its manufacturing capacity for VZV-containing vaccines. *ProQuad*, the Company's combination vaccine that helps protect against measles, mumps, rubella and chickenpox, one of the VZV-containing vaccines, is currently not available for ordering; however, orders have been transitioned, as appropriate, to *M-M-R II* and *Varivax*. Total sales as recorded by Merck for *ProQuad* were \$259.9 million for the first nine months of 2007.

Merck's sales of *Varivax*, the Company's vaccine for the prevention of chickenpox (varicella), were \$336.7 million for the third quarter of 2008 compared with \$284.3 million for the third quarter of 2007 and were \$710.6 million for the first nine months of 2008 compared with \$585.1 million for the first nine months of 2007. *Varivax* is currently the only vaccine available in the United States to help protect against chickenpox due to the unavailability of *ProQuad*. Merck's sales of *M-M-R II*, a vaccine to help protect against measles, mumps, and rubella, were \$93.9 million for the third quarter of 2008 compared with \$75.3 million for the third quarter of 2007 and were \$253.7 million for the first nine months of 2008 compared with \$173.1 million for the first nine months of 2007. Sales of *Varivax* and *M-M-R II* were affected by the unavailability of *ProQuad*. Combined sales of *ProQuad*, *M-M-R II* and *Varivax* in the third quarter of 2008 were comparable with sales for the third quarter of 2007 and declined in the first nine months of 2008 compared with the corresponding period of 2007.

Sales of *Zostavax*, the Company's vaccine to help prevent shingles (herpes zoster), as recorded by Merck were \$11.2 million for the third quarter of 2008 as compared with \$61.2 million in the third quarter of 2007. Sales in the quarter were impacted by bulk vaccine supply issues that caused delays in the fulfillment of customer orders. Merck expects to fill the customer back orders that existed at the end of the third quarter by the end of 2008. Sales of *Zostavax* for the first nine months of 2008 of \$150.8 million were comparable with sales for same period a year ago. The Company currently anticipates launching *Zostavax* outside the United States beyond 2009.

The Company has been working to resolve manufacturing issues related to its HIB-containing vaccines, *PedvaxHIB* and *Comvax* since December 2007. The Company has resolved the original issue related to equipment sterilization, but has identified another unrelated manufacturing process change that will require a regulatory filing. Merck anticipates that *PedvaxHIB* and *Comvax* will return to the U.S. market in mid-2009. Additionally, Merck anticipates the pediatric formulation of *Vaqta* will be available in the fourth quarter of 2008 and the adult formulation in the first quarter of 2009.

In October 2007, the FDA granted *Isentress* accelerated approval for use in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-experienced adult patients who have evidence of viral replication and HIV-1 strains resistant to multiple antiretroviral agents. *Isentress* is the first medicine to be approved in the class of antiretroviral drugs called integrase inhibitors. *Isentress* works by inhibiting the insertion of HIV DNA into human DNA by the integrase enzyme. Inhibiting integrase from performing this essential function limits the ability of the virus to replicate and infect new cells. Merck is also conducting Phase III clinical trials of *Isentress* in the treatment-naïve (previously untreated) HIV population. Sales for *Isentress* were \$107.3 million in the third quarter of 2008 and were \$231.1 million for the first nine months of 2008.

In October 2008, the Company presented results from a Phase III study that compared Merck's HIV integrase inhibitor *Isentress* (raltegravir) to efavirenz (one of the leading antiretrovirals prescribed for previously untreated (treatment-naïve) HIV-infected patients. In the study, *Isentress* reduced HIV viral load to undetectable levels in 86% of patients compared to 82% of patients treated with efavirenz in previously untreated HIV patients at week 48. Both medicines were taken in combination with tenofovir/emtricitabine. Patients taking *Isentress* had a greater increase in CD4 cell counts. In addition, drug-related adverse events of any severity occurred in fewer patients treated with *Isentress*. The use of *Isentress* in treatment-naïve patients is investigational. These 48 week findings were presented at the joint 48th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy / Infectious Diseases Society of America 46th Annual Meeting in Washington, D.C.

Other Vaccines and Infectious Diseases segment products experiencing growth in the third quarter and first nine months of 2008 compared with the same periods of 2007 include *Invanz* for the treatment of selected moderate to severe infection in adults and *Candidas*, an anti-fungal product.

In August 2008, Merck announced that the FDA approved an expanded label for *Candidas*, which makes it the first and only echinocandin therapy approved in the United States for the treatment of pediatric patients aged three months to 17 years with indicated fungal infections.

*Costs, Expenses and Other*

In October 2008, the Company announced a global restructuring program (the 2008 Restructuring Program ) which represents the Company s efforts 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

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employees and 400 vacancies across all areas of the Company worldwide by the end of 2011. About 40% of the total reductions will occur in the United States. To streamline management layers across the Company, Merck will reduce its total number of senior and mid-level executives by approximately 25%. For example, Merck will accelerate the rollout of a new, more customer-centric selling model designed to provide Merck with a meaningful competitive advantage and help physicians, patients and payers improve patient outcomes. The Company also will make greater use of outside technology resources, centralize common sales and marketing activities, and consolidate and streamline its operations. Merck's manufacturing division will further focus its capabilities on core products and outsource non-core manufacturing. In addition, Merck is enhancing its research operations to expand access to worldwide external science and incorporate it as a key component of the Company's pipeline, and ensure a more sustainable pipeline by translating basic research productivity into late-stage clinical success. As a result, basic research operations will be organized to consolidate work in support of a given therapeutic area into one of four locations. This will provide a more efficient use of research facilities and result in the closure of three basic research sites in Tsukuba, Japan; Pomezia, Italy; and Seattle by the end of 2009.

Separation costs are accounted for under FASB Statement No. 112, *Employers' Accounting for Postemployment Benefits* (an amendment of FASB Statement No. 5 and 43 (FAS 112)), and FASB Statement No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* (FAS 146). In connection with the 2008 Restructuring Program, separation costs under the Company's existing severance programs worldwide were accounted for under FAS 112 and recorded in the third quarter of 2008 to the extent such costs were estimable. The costs related to one-time termination benefits offered to employees under the 2008 Restructuring Program will be accrued in the fourth quarter of 2008 as that is when the criteria necessary for accrual under FAS 146 will be met. The Company recorded pretax restructuring costs of \$720 million related to the 2008 Restructuring Program in the third quarter of 2008 and anticipates that an additional \$250 million to \$450 million will be recorded in the fourth quarter of 2008. The 2008 Restructuring Program is expected to be completed by the end of 2011 with the total pretax costs estimated to be \$1.6 billion to \$2.0 billion. The Company estimates that two-thirds of the cumulative pretax costs will result in future 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.

In November 2005, the Company announced a global restructuring program (the 2005 Restructuring Program) designed to reduce the Company's cost structure, increase efficiency, and enhance competitiveness. As part of the 2005 Restructuring Program, Merck has sold or closed five manufacturing sites and two preclinical sites and eliminated 10,400 positions company-wide as of September 30, 2008. The Company also has sold and closed certain other facilities and related assets in connection with the 2005 Restructuring Program. Since inception through September 30, 2008, the Company recorded total pretax accumulated costs of \$2.5 billion associated with the 2005 Restructuring Program, which is substantially complete. The Company remains on track to achieving cumulative pretax savings of \$4.5 billion to \$5.0 billion at the end of the 2005-2010 period.

The Company recorded total pretax restructuring costs of \$847.3 million (\$612.3 million after-tax) and \$178.1 million (\$117.2 million after-tax) for the three months ended September 30, 2008 and 2007, respectively, related to both the 2008 and 2005 Restructuring Programs. The Company recorded pretax restructuring costs of \$1.05 billion (\$745.7 million after-tax) and \$536.4 million (\$350.9 million after-tax) for the nine months ended September 30, 2008 and 2007, respectively. These costs were comprised primarily of accelerated depreciation and separation costs recorded in Materials and production, Research and development and Restructuring costs (see Note 2 to the consolidated financial statements).

Materials and production costs were \$1.48 billion for the third quarter of 2008, a decline of 3% compared with the third quarter of 2007. Included in the third quarter of 2008 and 2007 were costs associated with restructuring activities, primarily accelerated depreciation of \$58.8 million and \$128.8 million, respectively. For the first nine months of 2008, materials and production costs were \$4.11 billion, a decline of 11% compared with the same period of last year. Included in the first nine months of 2008 and 2007 were costs associated with restructuring activities of \$89.8 million and \$365.6 million, respectively. (See Note 2 to the consolidated financial statements).

Gross margin was 75.1% in the third quarter of 2008 compared with 75.0% in the third quarter of 2007, which reflect 1.0 and 2.1 percentage point unfavorable impacts, respectively, relating to costs associated with restructuring activities. Gross margin was 76.9% for the first nine months of 2008 compared with 74.4% for the first nine months of 2007, which reflect 0.5 and 2.0 percentage point unfavorable impacts, respectively, relating to costs associated with restructuring activities. Gross margins in the third quarter of 2008 as compared with 2007 reflect changes in product mix and discards, primarily related to vaccines. Gross margins for the first nine months of 2008 reflect changes in product mix and manufacturing efficiencies.

Marketing and administrative expenses were \$1.73 billion for the third quarter of 2008, a decline of 11% compared with the third quarter of 2007. For the first nine months of 2008, marketing and administrative expenses were \$5.51 billion, a

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decrease of 6% compared with the first nine months of 2007. Expenses for the first nine months of 2008 include the impact of reserving an additional \$40 million in the first quarter solely for future legal defense costs for *Fosamax* litigation. Expenses for the third quarter and first nine months of 2007 include \$70 million and \$280 million, respectively, of additional reserves solely for future legal defense costs for *Vioxx* litigation (see Note 8 to the consolidated financial statements). In addition to lower expenses for future legal defense costs, the declines in marketing and administrative expenses reflect the Company's efforts to reduce its cost base.

Research and development expenses were \$1.17 billion and \$3.42 billion for the third quarter and first nine months of 2008, respectively, compared with \$1.44 billion and \$3.50 billion for the corresponding periods of 2007. Expenses in the third quarter and first nine months of 2008 reflect \$31.0 million of accelerated depreciation costs related to the 2008 Restructuring Program. The third quarter and first nine months of 2007 reflect \$325.1 million of acquired research expense related to the NovaCardia Inc. acquisition. Research and development expenses in 2008 compared with 2007 reflect an increase in development spending in support of the continued advancement of the research pipeline.

In October 2008, Merck announced it will not seek regulatory approval for taranabant, an investigational medicine, to treat obesity and is discontinuing its Phase III clinical development program for taranabant for obesity. Available Phase III data showed that both efficacy and adverse events were dose related, with greater efficacy and more adverse events in the higher doses. Therefore, after careful consideration, the Company determined that the overall profile of taranabant does not support further development for obesity.

In August 2008, Dynavax Technologies Corporation ( Dynavax ) and Merck announced top-line immunogenicity results from a Phase III clinical trial comparing V270, an investigational hepatitis B virus ( HBV ) vaccine, to a currently marketed HBV vaccine, Engerix-B (Engerix-B is a registered trademark of GlaxoSmith Kline). V270 is being jointly developed by Dynavax and Merck for use in adults and in patients with end stage renal disease. The study, called PHAST (Phase III HeplisAv Short-regimen Trial), evaluated a two-dose regimen of V270 administered at 0 and 1 month compared to a three-dose regimen of Engerix-B administered at 0, 1 and 6 months. The primary endpoint was the proportion of subjects who developed protective antibodies to hepatitis B after administration. The study achieved its primary endpoint. In PHAST, 95.1% of subjects who received two doses of V270 developed protective antibodies to hepatitis B when measured at 12 weeks versus 81.1% of subjects who received three doses of Engerix-B when measured at 28 weeks. The multi-center study evaluated 2,427 subjects from 11 to 55 years of age in Canada and Germany. Results of additional analyses from this trial will be presented in the future.

In October 2008, Merck and Dynavax received communication from the FDA regarding the two companies' response to the agency's request for safety information relating to the clinical hold on the two Investigational New Drug ( IND ) Applications for V270. In issuing the clinical hold in March 2008, the FDA requested a review of clinical and safety data including all available information about a single case of Wegener's granulomatosis, an uncommon disease in which the blood vessels are inflamed, reported in a Phase III clinical trial. Dynavax and Merck had previously provided a response to the FDA in September 2008. In its October 2008 correspondence, the FDA advised the companies that the balance of risk versus potential benefit no longer favors continued clinical evaluation of V270 in healthy adults and children. The FDA has also advised the companies that there may be potential for an acceptable risk versus benefit profile for V270 in patients with renal failure, and requested additional information from the companies before considering further pursuit of clinical studies in those patients. Dynavax and Merck are evaluating the FDA's response in considering next steps. In the meantime, the clinical hold on the two U.S. IND applications for V270 remains in effect.

In September 2008, at the 30<sup>th</sup> Annual Meeting of the American Society for Bone and Mineral Research, two-year data from a Phase IIB study of odanacatib (formerly MK-0822), an investigational, selective cathepsin K inhibitor in development for the treatment of osteoporosis, were reported which demonstrated dose-dependent increases in bone mineral density ( BMD ) at the total hip, lumbar spine and femoral neck fracture sites and decreased indices of bone resorption compared to placebo in postmenopausal women with low BMD. Osteoporosis is a disease which reduces bone density and strength and results in an increased risk of bone fractures. Odanacatib selectively inhibits the cathepsin K enzyme believed to play a central role in osteoclastic bone resorption, particularly in the degradation of the protein component of bone. Inhibition of cathepsin K is a novel approach to the treatment of osteoporosis that

differs from those of currently approved treatments. The multi-center, double-blind, randomized, placebo-controlled study evaluated doses of 3, 10, 25 or 50 mg of odanacatib administered orally, once-weekly and without regard to the timing of meals or the patient's physical position in postmenopausal women with low BMD for 24 months. The number of patients experiencing a drug-related adverse experience was similar between the 50 mg odanacatib group and placebo. The effect of odanacatib 50 mg on vertebral, hip and non-vertebral fractures is currently being evaluated in a large, global Phase III study.

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Also, in September 2008, Merck announced that in a Phase III clinical trial telcagepant (formerly known as MK-0974), an investigational oral calcitonin gene-related peptide ( CGRP ) receptor antagonist, significantly relieved moderate-to-severe migraine attacks, including migraine pain and migraine-associated symptoms, compared to placebo. The data were presented in London, England at the European Headache/Migraine Trust International Congress. The reported findings are from a worldwide, multicenter, randomized, placebo-controlled clinical trial in adult patients with acute migraine. Telcagepant is a novel, oral CGRP receptor antagonist without direct vasoconstriction in development for treatment of acute migraine. It is an antagonist of the receptor for CGRP, a potent neuropeptide thought to play a central role in the underlying pathophysiology of migraine. Merck continues to anticipate filing a New Drug Application ( NDA ) for telcagepant with the FDA in 2009.

In July 2008, the Company announced that *Tredaptive* (also known as MK-0524A) (extended-release ( ER ) niacin/laropiprant) modified-release tablets, a new lipid-modifying therapy for patients with dyslipidemia and primary hypercholesterolemia, has been approved for marketing in the 27 countries of the EU, Iceland and Norway. *Tredaptive* combines nicotinic acid (niacin) and laropiprant, a novel flushing pathway inhibitor. In clinical studies involving more than 4,700 patients, *Tredaptive* reduced LDL-cholesterol (LDL-C, or bad cholesterol) levels, raised HDL-cholesterol (HDL-C, or good cholesterol) levels and decreased triglycerides (a type of fat in the blood). High LDL-C, low HDL-C and elevated triglycerides are risk factors associated with heart attacks and strokes. *Tredaptive* is approved for the treatment of dyslipidemia, particularly in patients with combined mixed dyslipidemia (characterized by elevated levels of LDL-C and triglycerides and low HDL-C) and in patients with primary hypercholesterolemia (heterozygous familial and non-familial). *Tredaptive* should be used in patients in combination with statins, when the cholesterol lowering effects of statin monotherapy is inadequate. *Tredaptive* can be used as monotherapy only in patients in whom statins are considered inappropriate or not tolerated. The launch of *Tredaptive* in Europe and other markets will be delayed due to a manufacturing-related issue. Merck is committed to quickly resolving the issue and to making *Tredaptive* available in Europe as soon as possible.

In June 2008, Merck provided an update on the regulatory status in the United States of its investigational medicines MK-0524A and MK-0524B (ER niacin/laropiprant/simvastatin) for the treatment of primary hypercholesterolemia or mixed dyslipidemia. Merck met with the FDA to discuss the non-approvable action letter it received on April 28, 2008 in response to its NDA for MK-0524A. At the meeting, the FDA stated that additional efficacy and safety data were required and suggested that the Company wait for the results of the HPS2-THRIVE (Treatment of HDL to Reduce the Incidence of Vascular Events) cardiovascular outcomes study, which is expected to be completed in January 2013. The Company intends to continue to discuss with the FDA whether data can be provided prior to the completion of the HPS2-THRIVE study that would address the issues raised by the agency and allow for an earlier filing. In that event, the earliest Merck would file a complete response to the FDA action letter would be 2010. In October 2008, Oxford University issued a press release announcing that it expects to enroll an additional 5,000 patients in the HPS2-THRIVE study to increase the total study population size to 25,000 patients. The study was initially expected to be complete in 2013; the addition of the 5,000 patients may allow the study to be completed earlier. In addition, Merck will not seek approval for MK-0524B in the United States until it files its complete response relating to MK-0524A. The clinical development program for MK-0524A continues, including the HPS2-THRIVE study. Also, in the FDA's April 2008 letter, the agency rejected the proposed trade name *Cordaptive* for MK-0524A. At the appropriate time, the Company expects to pursue the alternative trade name *Tredaptive* for use in the United States. In other countries around the world, Merck continues to pursue regulatory approvals for MK-0524A.

Merck continues to remain focused on augmenting its internal efforts by capitalizing on growth opportunities ranging from targeted acquisitions to research collaborations, licensing pre-clinical and clinical compounds and technology transactions to drive both near- and long-term growth.

In September 2008, Merck and Japan Tobacco Inc. ( JT ) signed a worldwide licensing agreement to develop and commercialize JTT-305, an investigational oral osteoanabolic (bone growth stimulating) agent for the treatment of osteoporosis. JTT-305 is an investigational oral calcium sensing receptor antagonist that is currently being evaluated by JT in Phase II clinical trials in Japan for its effect on increasing bone density and is in Phase I clinical trials outside of Japan. Under the terms of the agreement, Merck gains worldwide rights, except for Japan, to develop and commercialize JTT-305 and certain other related compounds. JT will receive an upfront payment of \$85 million,



which the Company will record as Research and development expense upon closing in the fourth quarter of 2008, and is eligible to receive additional cash payments upon achievement of certain milestones associated with the development and approval of a drug candidate covered by this agreement. JT will also be eligible to receive royalties from sales of any drug candidates that receive marketing approval.

Restructuring costs, primarily representing separation and other related costs associated with the 2008 and 2005 Restructuring Programs, were \$757.5 million and \$929.4 million for the three and nine months ended September 30,

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2008. The Company recorded \$655.1 million of costs associated with the 2008 Restructuring Program for the three and nine months ended September 30, 2008. The remaining restructuring costs were associated with the 2005 Restructuring Program. Amounts for the first nine months of 2008 were reduced by gains on sales of facilities and related assets of \$54.4 million. (See Note 2 to the consolidated financial statements.) Amounts included in Restructuring costs for the three and nine months ended September 30, 2007 were \$49.3 million and \$170.9 million, respectively.

Equity income from affiliates, which reflects the performance of the Company's joint ventures and other equity method affiliates, was \$665.6 million and \$768.5 million for the third quarter of 2008 and 2007, respectively, and was \$1.84 billion and \$2.18 billion for the first nine months of 2008 and 2007, respectively. These results reflect lower partnership returns from AZLP and decreased equity income from the Merck/Schering-Plough partnership, partially offset by higher equity income from SPMSD. The lower partnership returns from AZLP are primarily attributable to the first quarter 2008 partial redemption of Merck's limited partnership interest in AZLP, which resulted in a reduction of the priority return and the variable returns which were based, in part, upon sales of certain former Astra USA, Inc. products. The decrease in equity income from the Merck/Schering-Plough joint venture is a result of lower revenues of *Zetia* and *Vytorin* related to the ENHANCE and SEAS clinical trial results. In addition, as a result of the termination of the respiratory joint venture, the Company was obligated to Schering-Plough Corporation (Schering-Plough) in the amount of \$105 million as specified in the joint venture agreements. This resulted in a charge of \$43 million during the second quarter of 2008, included in Equity income from affiliates. The remaining amount will be amortized over the remaining patent life of *Zetia* through 2016. The increase in equity income from SPMSD is largely attributable to higher sales of *Gardasil*. (See Note 6 to the consolidated financial statements and Selected Joint Venture and Affiliate Information below.)

Other (income) expense, net in the first nine months of 2008 primarily reflects an aggregate gain from AZLP of \$2.2 billion (see Note 6 to the consolidated financial statements) and a gain of \$249 million related to the sale of the Company's remaining worldwide rights to *Aggrastat*, partially offset by a \$300 million expense for a contribution to the Merck Company Foundation, recognized losses of \$108 million, including \$88 million of losses in the third quarter, in the Company's investment portfolio and a \$58 million charge related to the resolution of a previously disclosed investigation into whether the Company violated state consumer protection laws with respect to the sales and marketing of *Vioxx* (see Note 8 to the consolidated financial statements). Other (income) expense, net in the first nine months of 2007 primarily reflects the favorable impact of gains on sales of assets and product divestitures, as well as a net gain on the settlements of certain patent disputes.

*Segment Profits*

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Pharmaceutical segment	\$ 3,165.5	\$ 3,305.1	\$ 9,397.5	\$ 9,977.6
Vaccines and Infectious Diseases segment	772.7	815.7	2,042.9	1,941.1
Other segment	98.6	112.9	363.9	395.5
Other	(2,625.9)	(2,169.1)	(3,923.9)	(5,763.0)
Income before income taxes	\$ 1,410.9	\$ 2,064.6	\$ 7,880.4	\$ 6,551.2

Segment profits are comprised of segment revenues less certain elements of materials and production costs and operating expenses, including the majority of equity income from affiliates and components of depreciation and amortization expenses. For internal management reporting presented to the chief operating decision maker, the Company does not allocate the vast majority of research and development expenses, general and administrative expenses, depreciation related to fixed assets utilized by nonmanufacturing divisions, as well as the cost of financing these activities. Separate divisions maintain responsibility for monitoring and managing these costs and, therefore,

they are not included in segment profits. Also excluded from the determination of segment profits are 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 (expense). These unallocated items are reflected in Other in the above table. Also included in Other are miscellaneous corporate profits, operating profits related to divested products or businesses, other supply sales and adjustments to eliminate the effect of double counting certain items of income and expense.

Pharmaceutical segment profits decreased 4% in the third quarter of 2008 and declined 6% for the first nine months of 2008 compared with the corresponding periods of 2007 largely driven by declines in *Fosamax*, *Nexium* supply sales, *Zocor* and lower equity income from AZLP and the Merck/Schering-Plough joint venture.

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Vaccines and Infectious Diseases segment profits decreased 5% in the third quarter of 2008 compared with the third quarter of 2007, largely driven by lower sales of *Zostavax*, *RotaTeq* and hepatitis vaccines. Vaccines and infectious diseases segment profits increased 5% in the first nine months of 2008 compared with the same period of 2007 primarily driven by the successful launch of *Isentress* and the strong performance of *RotaTeq*, as well as higher equity income from SPMSD.

The effective tax rate of 22.6% for the third quarter of 2008 reflects the favorable impact of restructuring charges. The effective tax rate of 21.8% for the first nine months of 2008 reflects a net favorable impact of approximately 2 percentage points which includes favorable impacts relating to second quarter tax settlements that resulted in a reduction of the Company's liability for unrecognized tax benefits of approximately \$200 million, the first quarter realization of foreign tax credits and year-to-date restructuring costs, largely offset by an unfavorable impact resulting from the AZLP gain being fully taxable in the United States at a combined federal and state tax rate of approximately 36.3%. In the first quarter of 2008, the Company decided to repatriate certain prior years' foreign earnings which will result in a utilization of foreign tax credits. These foreign tax credits arose as a result of tax payments made outside of the United States in prior years that became realizable in the first quarter based on a change in the Company's repatriation plans. The effective tax rates of 26.1% for the third quarter of 2007 and 25.1% for the first nine months of 2007 reflect the impact of acquired research expense which is not deductible for tax purposes, as well as the favorable impact of restructuring costs.

Net income was \$1.09 billion for the third quarter of 2008 compared with \$1.53 billion for the third quarter of 2007 and was \$6.16 billion for the first nine months of 2008 compared with \$4.91 billion for the first nine months of 2007. Earnings per common share assuming dilution (EPS) for the third quarter of 2008 were \$0.51 compared with \$0.70 in the third quarter of 2007 and were \$2.86 for the first nine months of 2008 compared with \$2.24 in the first nine months of 2007. The decrease in net income and EPS for the third quarter of 2008 was largely attributable to higher restructuring charges and increased expenses within other (income) expense, net, partially offset by a decline in acquired research expense and marketing and administrative expenses. For the first nine months of 2008, the increases are primarily attributable to the impact of the gain on distribution from AZLP as discussed above. In addition, the increases reflect the positive impact of tax settlements and the realization of foreign tax credits, lower acquired research costs and a lower reserve for legal defense costs, partially offset by higher restructuring costs and a decline in equity income from affiliates.

**Selected Joint Venture and Affiliate Information***Merck/Schering-Plough Partnership*

The Merck/Schering-Plough partnership (the MSP Partnership) reported combined global sales of *Zetia* and *Vytorin* of \$1.1 billion for the third quarter of 2008, representing a decline of 15% over the third quarter of 2007, and a sequential decline of 4% compared with the second quarter of 2008. Sales for the first nine months of 2008 were \$3.49 billion, a decline of 7% over the first nine months of 2007. Global sales of *Zetia*, the cholesterol-absorption inhibitor also marketed as *Ezetrol* outside the United States, were \$534.3 million in the third quarter of 2008, a decline of 12% compared with the third quarter of 2007, and a sequential decline of 5% compared with the second quarter of 2008. Global sales of *Zetia* for the first nine months of 2008 were \$1.68 billion, a decrease of 3% compared with the same period of 2007. Global sales of *Vytorin*, marketed outside the United States as *Inegy*, were \$567.2 million in the third quarter of 2008, a decline of 18% compared with the third quarter of 2007, and a sequential decline of 4% compared with the second quarter of 2008. Global sales of *Vytorin* for the first nine months of 2008 were \$1.81 billion, a decline of 10% compared with the same period of 2007. Sales declines in the United States were partially offset by growth outside the United States.

As previously disclosed, in January 2008, the Company announced the results of ENHANCE, an imaging trial in 720 patients with heterozygous familial hypercholesterolemia, a rare genetic condition that causes very high levels of LDL bad cholesterol and greatly increases the risk for premature coronary artery disease. As previously reported, despite the fact that ezetimibe/simvastatin 10/80 mg (*Vytorin*) significantly lowered LDL bad cholesterol more than simvastatin 80 mg alone, there was no significant difference between treatment with ezetimibe/simvastatin and simvastatin alone on the pre-specified primary endpoint, a change in the thickness of carotid artery walls over two

years as measured by ultrasound. There also were no significant differences between treatment with ezetimibe/simvastatin and simvastatin on the four pre-specified key secondary endpoints: percent of patients manifesting regression in the average carotid artery intima-media thickness ( CA IMT ); proportion of patients developing new carotid artery plaques >1.3 mm; changes in the average maximum CA IMT; and changes in the average CA IMT plus in the average common femoral artery IMT. In ENHANCE, when compared to simvastatin alone, ezetimibe/simvastatin significantly lowered LDL bad cholesterol, as well as triglycerides and C-reactive protein ( CRP ). Ezetimibe/simvastatin is not indicated for the reduction of CRP. In the ENHANCE study, the overall safety profile of ezetimibe/simvastatin in the study was generally consistent with the product label. The ENHANCE study was not designed nor powered to evaluate cardiovascular clinical events. IMPROVE-IT is underway and is designed to provide cardiovascular outcomes data for ezetimibe/simvastatin in patients with acute coronary syndrome. No incremental benefit of ezetimibe/simvastatin on cardiovascular morbidity and mortality over and

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above that demonstrated for simvastatin has been established. In March 2008, the results of ENHANCE were reported at the annual Scientific Session of the American College of Cardiology.

On July 21, 2008, efficacy and safety results from the Simvastatin and Ezetimibe in Aortic Stenosis ( SEAS ) study were announced. SEAS was designed to evaluate whether intensive lipid lowering with *Vytorin* (ezetimibe/simvastatin) 10/40 mg would reduce the need for aortic valve replacement and the risk of cardiovascular morbidity and mortality versus placebo in patients with asymptomatic mild to moderate aortic stenosis who had no indication for statin therapy. *Vytorin* failed to meet its primary end point for the reduction of major cardiovascular events. There also was no significant difference in the key secondary end point of aortic valve events; however, there was a reduction in the group of patients taking *Vytorin* compared to placebo in the key secondary end point of ischemic cardiovascular events. *Vytorin* is not indicated for the treatment of aortic stenosis. *Vytorin* contains two active ingredients: ezetimibe and simvastatin. No incremental benefit of *Vytorin* on cardiovascular morbidity and mortality over and above that demonstrated for simvastatin has been established. In the study, patients in the group who took *Vytorin* 10/40 mg had a higher incidence of cancer than the group who took placebo. There was also a nonsignificant increase in deaths from cancer in patients in the group who took *Vytorin* versus those who took placebo. Cancer and cancer deaths were distributed across all major organ systems. The Company believes the cancer finding in SEAS is likely to be an anomaly that, taken in light of all the available data, does not support an association with *Vytorin*. The Company, through the MSP Partnership, is committed to working with regulatory agencies to further evaluate the available data and interpretations of those data; however, the Company does not believe that changes in the clinical use of *Vytorin* are warranted.

See Note 8 to the consolidated financial statements for information with respect to litigation involving Merck and Schering-Plough (the Partners ) and the MSP Partnership related to the sale and promotion of *Zetia* and *Vytorin*. On April 25, 2008, the Partners announced that they had received a non-approvable letter from the FDA for the proposed fixed combination of loratadine/montelukast. Montelukast sodium, a leukotriene receptor antagonist, is sold by Merck as *Singulair* and loratadine, an antihistamine, is sold by Schering-Plough as Claritin, both of which are indicated for the relief of symptoms of allergic rhinitis. In June 2008, the Partners announced the withdrawal of the NDA for the loratadine/montelukast combination tablet. The companies also terminated the respiratory joint venture. This action had no impact on the business of the cholesterol joint venture. As a result of the termination of the respiratory joint venture, the Company was obligated to Schering-Plough in the amount of \$105 million as specified in the joint venture agreements. This resulted in a charge of \$43 million during the second quarter of 2008, included in Equity income from affiliates. The remaining amount is being amortized over the remaining patent life of *Zetia* through 2016.

***AstraZeneca LP***

As previously disclosed, the 1999 AstraZeneca merger triggered a partial redemption in March 2008 of Merck's limited partnership interest in AZLP. Upon this redemption, Merck received \$4.3 billion from AZLP. This amount was based primarily on a multiple of Merck's average annual variable returns derived from sales of the former Astra USA, Inc. products for the three years prior to the redemption (the Limited Partner Share of Agreed Value ). Merck recorded a \$1.5 billion pretax gain on the partial redemption in the first quarter of 2008. As a result of the partial redemption of Merck's limited partnership interest, the Company will have lower Partnership returns (which are recorded in Equity income from affiliates) on a prospective basis resulting from a reduction of the priority return and the variable returns which were based, in part, upon sales of certain former Astra USA, Inc. products.

Also, as a result of the 1999 AstraZeneca merger, in exchange for Merck's relinquishment of rights to future Astra products with no existing or pending U.S. patents at the time of the merger, Astra paid \$967.4 million (the Advance Payment ). The Advance Payment was deferred as it remained subject to a true-up calculation that was directly dependent on the fair market value in March 2008 of the Astra product rights retained by the Company. The calculated True-Up Amount of \$243.7 million was returned to AZLP in March 2008 and Merck recognized a pretax gain of \$723.7 million related to the residual Advance Payment balance.

In 1998, Astra purchased an option (the Asset Option ) to buy Merck's interest in the KBI Inc. ( KBI ) products, excluding the gastrointestinal medicines *Nexium* and *Prilosec* (the Non-PPI Products ), for a payment of \$443.0 million, which was deferred. The Asset Option is exercisable in the first half of 2010 at an exercise price equal

to the net present value as of March 31, 2008 of projected future pretax revenue to be received by the Company from the Non-PPI Products (the Appraised Value ). Merck also had the right to require Astra to purchase such interest in 2008 at the Appraised Value. In February 2008, the Company advised AZLP that it would not exercise the Asset Option, thus the \$443.0 million remains deferred.

The sum of the Limited Partner Share of Agreed Value, the Appraised Value and the True-Up Amount was guaranteed to be a minimum of \$4.7 billion. Distribution of the Limited Partner Share of Agreed Value less payment of the True-Up

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Amount resulted in cash receipts to Merck of \$4.0 billion and an aggregate pretax gain of \$2.2 billion which is included in Other (income) expense, net. AstraZeneca's purchase of Merck's interest in the Non-PPI Products is contingent upon the exercise of the Asset Option by AstraZeneca in 2010 and, therefore, payment of the Appraised Value may or may not occur. Also, in March 2008, the outstanding loan from Astra in the amount of \$1.38 billion plus interest through the redemption date was settled. As a result of these transactions, the Company received net proceeds from AZLP of \$2.6 billion in the first quarter of 2008.

**Sanofi Pasteur MSD**

Total vaccine sales reported by SPMSD were \$566.8 million and \$439.3 million in the third quarter of 2008 and 2007, respectively, and were \$1.41 billion and \$898.9 million for the first nine months of 2008 and 2007, respectively. The increase in both periods was driven by higher sales of *Gardasil*. SPMSD sales of *Gardasil* were \$220.1 million and \$137.0 million for the third quarter of 2008 and 2007, respectively, and were \$694.1 million and \$245.0 million for the first nine months of 2008 and 2007, respectively.

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

**Liquidity and Capital Resources**

(\$ in millions)	September 30, 2008	December 31, 2007
Cash and investments	\$ 13,053.0	\$ 15,390.0
Working capital	\$ 4,990.3	\$ 2,787.2
Total debt to total liabilities and equity	14.3%	11.9%

The increase in working capital was primarily attributable to net cash receipts from AZLP as discussed above in Selected Joint Venture and Affiliate Information.

During the first nine months of 2008, cash provided by operating activities of \$5.6 billion reflects \$2.1 billion received in connection with a partial redemption of the Company's partnership interest in AZLP discussed above, representing a distribution of the Company's accumulated earnings on its investment in AZLP since inception. Cash provided by operating activities in the first nine months of 2008 was also impacted by a \$675 million payment made in connection with the previously disclosed resolution of investigations of civil claims by federal and state authorities relating to certain past marketing and selling activities and a \$500 million payment into a *Vioxx* settlement fund. Cash provided by operating activities of \$4.7 billion for the same period of 2007 reflects the payment made under a previously disclosed settlement with the Internal Revenue Service. On an ongoing basis, cash provided by operations will continue to be the Company's primary source of funds to finance operating needs and capital expenditures. Cash used by investing activities in the first nine months of 2008 was \$1.4 billion compared with \$2.0 billion in the first nine months of 2007. The lower use of cash by investing activities primarily reflects a distribution from AZLP in 2008 representing a return of the Company's investment in AZLP and a \$1.1 billion payment in 2007 in connection with the December 2006 acquisition of Sirna Therapeutics, Inc., partially offset by higher purchases of securities and other investments and an increase in restricted assets. Cash used in financing activities was \$3.8 billion for the first nine months of 2008 compared with \$3.5 billion in the first nine months of 2007 reflecting higher purchases of treasury stock and lower proceeds from the exercise stock options, partially offset by a net increase in short-term borrowings. In August 2008, the Company executed a \$4.1 billion letter of credit agreement with a financial institution, which satisfied certain conditions set forth in the U.S. *Vioxx* Settlement Agreement (see Note 8 to the consolidated financial statements). The Company pledged collateral to the financial institution of approximately \$5.1 billion pursuant to the terms of the letter of credit agreement. Although the amount of assets pledged as collateral is set by the letter of credit agreement and such assets are held in custody by a third party, the assets are managed by the Company. The Company considers the assets pledged under the letter of credit agreement to be restricted. As a result, \$2.1 billion and \$1.4 billion of cash and investments, respectively, were classified as restricted current assets and \$1.6 billion of investments were classified as restricted non-current assets. The letter of credit amount and required collateral



balances will decline as payments (after the first \$750 million) under the Settlement Agreement are made. As of September 30, 2008, \$3.7 billion was recorded within Deferred income taxes and other current assets and \$1.4 billion was classified as Other assets.

In addition, in August 2008, the Company deposited \$500 million into a *Vioxx* settlement fund. In October 2008, the Company made an additional payment into the settlement fund of \$250 million pursuant to the Settlement Agreement. The Company will not make any additional payments into the settlement fund in 2008.

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As previously disclosed, Merck's Canadian tax returns for the years 1998 through 2004 are being examined by the Canada Revenue Agency (CRA). In October 2006, the CRA issued the Company a notice of reassessment containing adjustments related to certain intercompany pricing matters, which result in additional Canadian and provincial tax due of approximately \$1.5 billion (U.S. dollars) plus interest of approximately \$1.0 billion (U.S. dollars). In addition, in July 2007, the CRA proposed additional adjustments for 1999 relating to another intercompany pricing matter. The adjustments would increase Canadian tax due by approximately \$21 million (U.S. dollars) plus \$22 million (U.S. dollars) of interest. It is possible that the CRA will propose similar adjustments for later years. The Company disagrees with the positions taken by the CRA and believes they are without merit. The Company intends to contest the assessments through the CRA appeals process and the courts if necessary. In connection with the appeals process, during 2007, the Company pledged collateral to two financial institutions, one of which provided a guarantee to the CRA and the other to the Quebec Ministry of Revenue representing a portion of the tax and interest assessed. The collateral is included in Other Assets in the Consolidated Balance Sheet and totaled approximately \$1.3 billion at September 30, 2008. During the first nine months of 2008, approximately \$400 million of cash and cash equivalents in the collateral account was transferred out and a corresponding amount of investments was transferred in. The Company has previously established reserves for these matters. While the resolution of these matters may result in liabilities higher or lower than the reserves, management believes that resolution of these matters will not have a material effect on the Company's financial position or liquidity. However, an unfavorable resolution could have a material adverse effect on the Company's results of operations or cash flows in the quarter in which an adjustment is recorded or tax is due.

In July 2007, the CRA notified the Company that it is in the process of proposing a penalty of \$160 million (U.S. dollars) in connection with the 2006 notice. The penalty is for failing to provide information on a timely basis. The Company vigorously disagrees with the penalty and feels it is inapplicable and that appropriate information was provided on a timely basis. The Company is pursuing all appropriate remedies to avoid having the penalty assessed and was notified in early August 2007 that the CRA is holding the imposition of a penalty in abeyance pending a review of the Company's submissions as to the inapplicability of a penalty.

Capital expenditures totaled \$914.3 million and \$726.3 million for the first nine months of 2008 and 2007, respectively. Capital expenditures for full year 2008 are estimated to be \$1.4 billion.

Dividends paid to stockholders were \$2.5 billion for the first nine months of both 2008 and 2007. In May and July 2008, 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 2008.

The Company purchased \$2.5 billion of its common stock (62.3 million shares) for its Treasury during the first nine months of 2008. The Company has approximately \$2.6 billion remaining under the July 2002 treasury stock purchase authorization.

In April 2008, the Company extended the maturity date of its \$1.5 billion, 5-year revolving credit facility from April 2012 to April 2013. The facility provides backup liquidity for the Company's commercial paper borrowing facility and is to be used for general corporate purposes. The Company has not drawn funding from this facility.

**Financial Instruments and Market Risk Disclosure**

To manage foreign currency risks of future cash flows derived from foreign currency denominated sales, the Company has an established revenue hedging risk management program in which the Company primarily uses purchased local currency put options to layer in hedges over time to partially hedge anticipated third-party sales. During 2008, on a limited basis, the Company also utilized collars and forward exchange contracts in its revenue hedge risk management program.

**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 of the Annual Report on Form 10-K for the year ended December 31, 2007. 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 in the Company's 2007 Annual Report on Form 10-K because of the potential for a significant impact on the financial statements due to the inherent uncertainty in such estimates. Other than the adoption of FAS 157, as discussed below (see also Note 4 to the consolidated

financial statements), there have been no significant changes in the Company's critical accounting policies since December 31, 2007.

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**Table of Contents***Fair Value Measurements*

On January 1, 2008, the Company adopted FAS 157, which clarifies the definition of fair value, establishes a framework for measuring fair value, and expands the disclosures on fair value measurements. FAS 157 establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. FAS 157 describes three levels of inputs that may be used to measure fair value (see Note 4 to the consolidated financial statements). The Company's Level 3 assets primarily include mortgage-backed and asset-backed securities, as well as certain corporate notes and bonds for which there was a decrease in the observability of market pricing for these investments. On January 1, 2008, the Company had \$1,273.1 million invested in a short-term fixed income fund (the Fund). Due to market liquidity conditions, cash redemptions from the Fund were restricted. As a result of this restriction on cash redemptions, the Company did not consider the Fund to be traded in an active market with observable pricing on January 1, 2008 and these amounts were categorized as Level 3. On January 7, 2008, the Company elected to be redeemed-in-kind from the Fund and received its share of the underlying securities of the Fund. As a result, \$1,099.7 million of the underlying securities were transferred out of Level 3 as it was determined these securities had observable markets. As of September 30, 2008, \$183.7 million of the investment securities associated with the redemption-in-kind remained classified in Level 3 (approximately 1.7% of the Company's investment securities) as the securities contained at least one significant input which was unobservable (all of which were pledged under certain collateral arrangements (see Note 12 to the consolidated financial statements)). These securities 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 at September 30, 2008.

**Recently Issued Accounting Standards**

In October 2008, the Financial Accounting Standards Board (FASB) issued Staff Position 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active* (FSP 157-3), which clarifies the application of FAS 157 in a market that is not active. FSP 157-3 was effective for the Company at September 30, 2008, and the effect of adoption on the Company's financial position and results of operations was not material.

In June 2008, the FASB issued Staff Position EITF 03-6-1, *Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities* (FSP EITF 03-6-1), which is effective January 1, 2009. FSP EITF 03-6-1 clarifies that share-based payment awards that entitle holders to receive nonforfeitable dividends before they vest will be considered participating securities and included in the basic earnings per share calculation. The Company is assessing the impact of adoption of FSP EITF 03-6-1 on its results of operations.

In May 2008, the FASB issued Statement No. 162, *The Hierarchy of Generally Accepted Accounting Principles* (FAS 162), which is effective in the fourth quarter of 2008. FAS 162 identifies the sources of accounting principles and the framework for selecting the principles used (order of authority) in the preparation of financial statements that are presented in conformity with generally accepted accounting standards in the United States. The Company does not expect the adoption of FAS 162 to have a material impact on its financial statements.

In March 2008, the FASB issued Statement No. 161, *Disclosures about Derivative Instruments and Hedging Activities* (FAS 161), which is effective January 1, 2009. FAS 161 requires enhanced disclosures about derivative instruments and hedging activities to allow for a better understanding of their effects on an entity's financial position, financial performance, and cash flows. Among other things, FAS 161 requires disclosure of the fair values of derivative instruments and associated gains and losses in a tabular format. Since FAS 161 requires only additional disclosures about the Company's derivatives and hedging activities, the adoption of FAS 161 will not affect the Company's financial position or results of operations.

In December 2007, the FASB ratified the consensus reached by the Emerging Issues Task Force (EITF) on Issue No. 07-1 (EITF 07-1), *Accounting for Collaborative Arrangements*. EITF 07-1 is effective for the Company beginning January 1, 2009 and will be applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date. EITF 07-1 defines collaborative arrangements and establishes reporting requirements for



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transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. The Company is assessing the impact of adoption of EITF 07-1 on its financial position and results of operations.

In December 2007, the FASB issued Statement No. 141R, *Business Combinations* ( FAS 141R ), and Statement No. 160, *Noncontrolling Interests in Consolidated Financial Statements an amendment of ARB No. 51* ( FAS 160 ). FAS 141R expands the scope of acquisition accounting to all transactions under which control of a business is obtained. Among other things, FAS 141R requires that contingent consideration as well as contingent assets and liabilities be recorded at fair value on the acquisition date, that acquired in-process research and development be capitalized and recorded as intangible assets at the acquisition date, and also requires transaction costs and costs to restructure the acquired company be expensed. FAS 160 provides guidance for the accounting, reporting and disclosure of noncontrolling interests and requires, among other things, that noncontrolling interests be recorded as equity in the consolidated financial statements. FAS 141R and FAS 160 are both effective January 1, 2009. The Company is assessing the impacts of these standards on its financial position and results of operations.

**Legal Proceedings**

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. The following discussion is limited to recent developments concerning legal proceedings and should be read in conjunction with the consolidated financial statements contained in (i) this report, (ii) the Company's Reports on Form 10-Q for the quarters ended March 31, 2008 and June 30, 2008 and (iii) the Company's Annual Report on Form 10-K for the year ended December 31, 2007.

**Vioxx Litigation***Product Liability Lawsuits*

As previously disclosed, individual and putative class actions have been filed against the Company in state and federal courts alleging personal injury and/or economic loss with respect to the purchase or use of *Vioxx*. All such actions filed in federal court are coordinated in a multidistrict litigation in the U.S. District Court for the Eastern District of Louisiana (the MDL ) before District Judge Eldon E. Fallon. A number of such actions filed in state court are coordinated in separate coordinated proceedings in state courts in New Jersey, California and Texas, and the counties of Philadelphia, Pennsylvania and Washoe and Clark Counties, Nevada. As of September 30, 2008, the Company had been served or was aware that it had been named as a defendant in approximately 11,575 lawsuits, which include approximately 29,200 plaintiff groups, alleging personal injuries resulting from the use of *Vioxx*, and in approximately 246 putative class actions alleging personal injuries and/or economic loss. (All of the actions discussed in this paragraph are collectively referred to as the *Vioxx* Product Liability Lawsuits .) Of these lawsuits, approximately 9,000 lawsuits representing approximately 23,400 plaintiff groups are or are slated to be in the federal MDL and approximately 725 lawsuits representing approximately 725 plaintiff groups are included in a coordinated proceeding in New Jersey Superior Court before Judge Carol E. Higbee.

In addition to the *Vioxx* Product Liability Lawsuits discussed above, the claims of over 25,100 plaintiffs had been dismissed as of September 30, 2008. Of these, there have been over 3,650 plaintiffs whose claims were dismissed with prejudice (i.e., they cannot be brought again) either by plaintiffs themselves or by the courts. Over 21,450 additional plaintiffs have had their claims dismissed without prejudice (i.e., subject to the applicable statute of limitations, they can be brought again). Of these, approximately 13,575 plaintiff groups represent plaintiffs who had lawsuits pending in the New Jersey Superior Court at the time of the Settlement Agreement described below and who have expressed an intent to enter the program established by the Settlement Agreement; Judge Higbee has dismissed these cases without prejudice for administrative reasons.

On November 9, 2007, Merck announced that it had entered into an agreement (the Settlement Agreement ) with the law firms that comprise the executive committee of the Plaintiffs Steering Committee ( PSC ) of the federal *Vioxx* MDL as well as representatives of plaintiffs counsel in the Texas, New Jersey and California state coordinated proceedings to resolve state and federal myocardial infarction ( MI ) and ischemic stroke ( IS ) claims filed as of that date in the United States. The Settlement Agreement, which also applies to tolled claims, was signed by the parties after several

meetings with three of the four judges overseeing the coordination of more than 95% of the U.S. *Vioxx* Product Liability Lawsuits. The Settlement Agreement applies only to U.S. legal residents and those who allege that their MI or IS occurred in the United States.

The entire Settlement Agreement, including accompanying exhibits, may be found at [www.merck.com](http://www.merck.com). The Company has included this website address only as an inactive textual reference and does not intend it to be an active link to its website nor does it incorporate by reference the information contained therein. Merck will pay a fixed aggregate amount of \$4.85 billion into two funds (\$4.0 billion for MI claims and \$850 million for IS claims) for qualifying claims that enter into the

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resolution process (the Settlement Program). Individual claimants will be examined by administrators of the Settlement Program to determine qualification based on objective, documented facts provided by claimants, including records sufficient for a scientific evaluation of independent risk factors. The conditions in the Settlement Agreement require claimants to pass three gates: an injury gate requiring objective, medical proof of an MI or IS (each as defined in the Settlement Agreement), a duration gate based on documented receipt of at least 30 *Vioxx* pills, and a proximity gate requiring receipt of pills in sufficient number and proximity to the event to support a presumption of ingestion of *Vioxx* within 14 days before the claimed injury.

The Settlement Agreement provides that Merck does not admit causation or fault. The Settlement Agreement provided that Merck's payment obligations would be triggered only if, among other conditions, (1) law firms on the federal and state PSCs and firms that have tried cases in the coordinated proceedings elect to recommend enrollment in the program to 100% of their clients who allege either MI or IS and (2) by June 30, 2008, plaintiffs enroll in the Settlement Program at least 85% of each of all currently pending and tolled (i) MI claims, (ii) IS claims, (iii) eligible MI and IS claims together which involve death, and (iv) eligible MI and IS claims together which allege more than 12 months of use. Under the terms of the Settlement Agreement, Merck could exercise a right to walk away from the Settlement Agreement if the thresholds and other requirements were not met. The Company waived that right as of August 4, 2008. The waiver of that right triggered Merck's obligation to pay a fixed total of \$4.85 billion. Payments will be made in installments into the settlement fund. The first payment of \$500 million was made in August 2008 and an additional payment of \$250 million was made in October 2008. Additional payments will be made on a periodic basis going forward, when and as needed to fund payments of claims and administrative expenses.

Merck's total payment for both funds of \$4.85 billion is a fixed amount to be allocated among qualifying claimants based on their individual evaluation. While at this time the exact number of claimants covered by the Settlement Agreement is unknown, the total dollar amount is fixed. The distribution of interim payments to qualified claimants began in August 2008 and will continue on a rolling basis until all claimants who qualify for an interim payment are paid. Final payments will be made after the examination of all of the eligible claims has been completed.

After the Settlement Agreement was announced on November 9, 2007, judges in the Federal MDL, California, Texas and New Jersey State coordinated proceedings entered a series of orders. The orders: (1) temporarily stayed their respective litigations; (2) required plaintiffs to register their claims by January 15, 2008; (3) required plaintiffs with cases pending as of November 9, 2007 to preserve and produce records and serve expert reports; and (4) required plaintiffs who file thereafter to make similar productions on an accelerated schedule. The Clark County, Nevada and Washoe County, Nevada coordinated proceedings were also generally stayed.

As of October 30, 2008, the last day for enrollment in the Settlement Program, more than 48,100 of the approximately 48,325 individuals who were eligible for the Settlement Program and whose claims are not 1) dismissed, 2) expected to be dismissed in the near future, or 3) tolled claims that appear to have been abandoned have submitted some or all of the materials required for enrollment in the Settlement Program to resolve state and federal MI and IS claims filed against the Company in the United States. If all of these eligible submissions are completed in accordance with the Settlement Agreement, this would represent more than 99% of the eligible MI and IS claims previously registered with the Settlement Program.

On April 14, 2008 and June 3, 2008, two groups of various private insurance companies and health plans filed suit against BrownGreer, the claims administrator for the Settlement Program (the Claims Administrator), and U.S. Bancorp, escrow agent for the Settlement Program (the AvMed and Greater New York Benefit Fund suits). The private insurance companies and health plans claim to have paid healthcare costs on behalf of some of the enrolling claimants and seek to enjoin the Claims Administrator from paying enrolled claimants until their claims for reimbursement from the enrolled claimants are resolved. Each group sought temporary restraining orders and preliminary injunctions. Judge Fallon denied these requests. In AvMed, the defendants moved to sever the claims of the named plaintiffs and, in Greater New York Benefit Fund, to strike the class allegations. Judge Fallon granted these motions. AvMed has appealed both of these decisions. The Fifth Circuit will hear argument on AvMed's appeal on November 4, 2008. Greater New York Benefit Fund has served a notice of appeal.

The Company maintains a list of *Vioxx* Product Liability Lawsuits scheduled for trial at its website at [www.merck.com](http://www.merck.com) which it will periodically update as appropriate. The Company has included its website address only as an inactive



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reference and does not intend it to be an active link to its website nor does it incorporate by reference the information contained therein.

The Company has previously disclosed the outcomes of several *Vioxx* Product Liability Lawsuits that were tried prior to January 1, 2008.

The following sets forth certain significant rulings that occurred in or after the third quarter of 2008 with respect to the *Vioxx* Product Liability Lawsuits.

On April 19, 2007, Judge Randy Wilson, who presides over the Texas *Vioxx* coordinated proceeding, dismissed the failure to warn claim of plaintiff Ruby Ledbetter, whose case was scheduled to be tried on May 14, 2007. Judge Wilson relied on a Texas statute enacted in 2003 that provides that there can be no failure to warn regarding a prescription medicine if the medicine is distributed with FDA approved labeling. There is an exception in the statute if required, material, and relevant information was withheld from the FDA that would have led to a different decision regarding the approved labeling, but Judge Wilson found that the exception is preempted by federal law unless the FDA finds that such information was withheld. Judge Wilson is currently presiding over approximately 1,000 *Vioxx* suits in Texas in which a principal allegation is failure to warn. Judge Wilson certified the decision for an expedited appeal to the Texas Court of Civil Appeals. Plaintiffs appealed the decision. On March 20, 2008, plaintiffs moved to dismiss their appeal, seeking instead to vacate the trial court's decision. Merck filed an opposition to plaintiffs' motion. On May 15, 2008, the Court of Appeals issued an order granting plaintiffs' motion to dismiss the appeal, but denying plaintiffs' motion to vacate the order dismissing the claim. On July 25, 2008, the appeal was dismissed by agreement of the parties.

In April 2006, in a trial involving two plaintiffs, Thomas Cona and John McDarby, in Superior Court of New Jersey, Law Division, Atlantic County, the jury returned a split verdict. The jury determined that *Vioxx* did not substantially contribute to the heart attack of Mr. Cona, but did substantially contribute to the heart attack of Mr. McDarby. The jury also concluded that, in each case, Merck violated New Jersey's consumer fraud statute, which allows plaintiffs to receive their expenses for purchasing the drug, trebled, as well as reasonable attorneys' fees. The jury awarded \$4.5 million in compensatory damages to Mr. McDarby and his wife, who also was a plaintiff in that case, as well as punitive damages of \$9 million. On June 8, 2007, Judge Higbee denied Merck's motion for a new trial. On June 15, 2007, Judge Higbee awarded approximately \$4 million in the aggregate in attorneys' fees and costs. The Company appealed the judgments in both cases and the Appellate Division held oral argument on both cases on January 16, 2008. On May 29, 2008, the New Jersey Appellate Division vacated the consumer fraud awards in both cases on the grounds that the Product Liability Act provides the sole remedy for personal injury claims. The Appellate Division also vacated the McDarby punitive damage award on the grounds that it is preempted and vacated the attorney's fees and costs awarded under the Consumer Fraud Act in both cases. The Court upheld the McDarby compensatory award. The Company has filed with the Supreme Court of New Jersey a petition to appeal those parts of the trial court's rulings that the Appellate Division affirmed. Plaintiffs filed a cross-petition to appeal those parts of the trial court's rulings that the Appellate Division reversed. Those petitions are currently pending. On October 8, 2008, the Supreme Court of New Jersey granted Merck's petition for certification of appeal, limited solely to the issue of whether the Federal Food, Drug and Cosmetic Act preempts state law tort claims predicated on the alleged inadequacy of warnings contained in *Vioxx* labeling that was approved by the FDA. The court denied the plaintiff's cross-petition. As previously reported, in September 2006, Merck filed a notice of appeal of the August 2005 jury verdict in favor of the plaintiff in the Texas state court case, *Ernst v. Merck*. On May 29, 2008, the Texas Court of Appeals reversed the trial court's judgment and issued a judgment in favor of Merck. The Court of Appeals found the evidence to be legally insufficient on the issue of causation. Plaintiffs have filed a motion for rehearing *en banc* in the Court of Appeals. Merck filed a response in October 2008.

As previously reported, in April 2006, in *Garza v. Merck*, a jury in state court in Rio Grande City, Texas returned a verdict in favor of the family of decedent Leonel Garza. The jury awarded a total of \$7 million in compensatory damages to Mr. Garza's widow and three sons. The jury also purported to award \$25 million in punitive damages even though under Texas law, in this case, potential punitive damages were capped at \$750,000. On May 14, 2008, the San Antonio Court of Appeals reversed the judgment and rendered a judgment in favor of Merck. On May 29, 2008, plaintiffs filed a motion for rehearing, which is currently pending.

*Other Lawsuits*

As previously disclosed, on July 29, 2005, a New Jersey state trial court certified a nationwide class of third-party payors (such as unions and health insurance plans) that paid in whole or in part for the *Vioxx* used by their plan members or insureds. The named plaintiff in that case sought recovery of certain *Vioxx* purchase costs (plus penalties) based on allegations that the purported class members paid more for *Vioxx* than they would have had they known of the product's alleged risks. On March 31, 2006, the New Jersey Superior Court, Appellate Division, affirmed the class certification

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order. On September 6, 2007, the New Jersey Supreme Court reversed the certification of a nationwide class action of third-party payors, finding that the suit does not meet the requirements for a class action. Claims of certain individual third-party payors remain pending in the New Jersey court, and counsel representing various third-party payors have filed additional such actions. Judge Higbee lifted the stay on these cases and the parties are currently discussing discovery issues.

At the parties' request, Judge Higbee has extended the briefing schedule in *Martin-Kleinman v. Merck*, which is a putative consumer class action pending in New Jersey Superior Court. The Court will set a new schedule after resolving certain discovery issues.

There are also pending in various U.S. courts putative class actions purportedly brought on behalf of individual purchasers or users of *Vioxx* claiming either reimbursement of alleged economic loss or an entitlement to medical monitoring. The majority of these cases are at early procedural stages. On June 12, 2008, a Missouri state court certified a class of Missouri plaintiffs seeking reimbursement for out-of-pocket costs relating to *Vioxx*. The plaintiffs do not allege any personal injuries from taking *Vioxx*. The Company filed a petition for interlocutory review on June 23, 2008, which was granted on July 30, 2008. During the pendency of the appeal, discovery is proceeding in the lower court.

Plaintiffs also have filed a class action in California state court seeking class certification of California third-party payors and end-users. The parties are engaged in class certification discovery and briefing.

As previously reported, the Company has also been named as a defendant in separate lawsuits brought by the Attorneys General of nine states, and the City of New York. A Colorado taxpayer has also filed a derivative suit, on behalf of the State of Colorado, naming the Company. These actions allege that the Company misrepresented the safety of *Vioxx* and seek (i) recovery of the cost of *Vioxx* purchased or reimbursed by the state and its agencies; (ii) reimbursement of all sums paid by the state and its agencies for medical services for the treatment of persons injured by *Vioxx*; (iii) damages under various common law theories; and/or (iv) remedies under various state statutory theories, including state consumer fraud and/or fair business practices or Medicaid fraud statutes, including civil penalties.

In addition, the Company has been named in six other lawsuits containing similar allegations filed by (or on behalf of) governmental entities seeking the reimbursement of alleged Medicaid expenditures for *Vioxx* or statutory penalties tied to such expenditures. Those lawsuits are (1) a class action filed by Santa Clara County, California on behalf of all similarly situated California counties, (2) separate actions filed by Erie County, Chautauqua County, and Orange County, New York, (3) a *qui tam* action brought by a resident of the District of Columbia, and (4) a *qui tam* action brought by a resident of Florida. With the exception of a case filed by the Texas Attorney General (which remains in Texas state court and is currently scheduled for trial in September 2009), a case recently filed by the Michigan Attorney General (which has been removed to federal court and will likely be transferred to the federal MDL shortly) and the recently-filed Orange County and Florida cases (which will be removed to federal court and will likely be transferred to the federal MDL), the rest of the actions described in this paragraph have been transferred to the federal MDL and are in the discovery phase.

***Shareholder Lawsuits***

As previously disclosed, in addition to the *Vioxx* Product Liability Lawsuits, the Company and various current and former officers and directors are defendants in various putative class actions and individual lawsuits under the federal securities laws and state securities laws (the *Vioxx* Securities Lawsuits). All of the *Vioxx* Securities Lawsuits pending in federal court have been transferred by the Judicial Panel on Multidistrict Litigation (the JPML) to the United States District Court for the District of New Jersey before District Judge Stanley R. Chesler for inclusion in a nationwide MDL (the Shareholder MDL). Judge Chesler has consolidated the *Vioxx* Securities Lawsuits for all purposes. The putative class action, which requested damages on behalf of purchasers of Company stock between May 21, 1999 and October 29, 2004, alleged that the defendants made false and misleading statements regarding *Vioxx* in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, and sought unspecified compensatory damages and the costs of suit, including attorneys' fees. The complaint also asserted claims under Section 20A of the Securities and Exchange Act against certain defendants relating to their sales of Merck stock and under Sections 11, 12 and 15 of the Securities Act of 1933 against certain defendants based on statements in a registration statement and certain

prospectuses filed in connection with the Merck Stock Investment Plan, a dividend reinvestment plan. On April 12, 2007, Judge Chesler granted defendants' motion to dismiss the complaint with prejudice. Plaintiffs appealed Judge Chesler's decision to the United States Court of Appeals for the Third Circuit. On September 9, 2008, the Third Circuit issued an opinion reversing Judge Chesler's order and remanding the case to the district court. On September 23, 2008, Merck filed a petition seeking rehearing *en banc* which was denied.

In October 2005, a Dutch pension fund filed a complaint in the District of New Jersey alleging violations of federal securities laws as well as violations of state law against the Company and certain officers. Pursuant to the Case

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Management Order governing the Shareholder MDL, the case, which is based on the same allegations as the *Vioxx* Securities Lawsuits, was consolidated with the *Vioxx* Securities Lawsuits. Defendants' motion to dismiss the pension fund's complaint was filed on August 3, 2007. In September 2007, the Dutch pension fund filed an amended complaint rather than responding to defendants' motion to dismiss. In addition in 2007, six new complaints were filed in the District of New Jersey on behalf of various foreign institutional investors also alleging violations of federal securities laws as well as violations of state law against the Company and certain officers.

As previously disclosed, various shareholder derivative actions filed in federal court were transferred to the Shareholder MDL and consolidated for all purposes by Judge Chesler (the *Vioxx* Derivative Lawsuits). On May 5, 2006, Judge Chesler granted defendants' motion to dismiss and denied plaintiffs' request for leave to amend their complaint. Plaintiffs appealed, arguing that Judge Chesler erred in denying plaintiffs' leave to amend their complaint with materials acquired during discovery. On July 18, 2007, the United States Court of Appeals for the Third Circuit reversed the District Court's decision on the grounds that Judge Chesler should have allowed plaintiffs to make use of the discovery material to try to establish demand futility, and remanded the case for the District Court's consideration of whether, even with the additional materials, plaintiffs' request to amend their complaint would still be futile. Plaintiffs filed their brief in support of their request for leave to amend their complaint in November 2007. The Court denied the motion in June 2008 and closed the case. Plaintiffs have appealed Judge Chesler's decision to the United States Court of Appeals for the Third Circuit.

In addition, as previously disclosed, various putative class actions filed in federal court under the Employee Retirement Income Security Act (ERISA) against the Company and certain current and former officers and directors (the *Vioxx* ERISA Lawsuits) and, together with the *Vioxx* Securities Lawsuits and the *Vioxx* Derivative Lawsuits, the *Vioxx* Shareholder Lawsuits) have been transferred to the Shareholder MDL and consolidated for all purposes. The consolidated complaint asserts claims on behalf of certain of the Company's current and former employees who are participants in certain of the Company's retirement plans for breach of fiduciary duty. The lawsuits make similar allegations to the allegations contained in the *Vioxx* Securities Lawsuits. On July 11, 2006, Judge Chesler granted in part and denied in part defendants' motion to dismiss the ERISA complaint. In October 2007, plaintiffs moved for certification of a class of individuals who were participants in and beneficiaries of the Company's retirement savings plans at any time between October 1, 1998 and September 30, 2004 and whose plan accounts included investments in the Merck Common Stock Fund and/or Merck common stock. That motion is pending. On October 6, 2008 defendants filed a motion for judgment on the pleadings seeking dismissal of the complaint.

As previously disclosed, on October 29, 2004, two individual shareholders made a demand on the Company's Board to take legal action against Mr. Raymond Gilmartin, former Chairman, President and Chief Executive Officer and other individuals for allegedly causing damage to the Company with respect to the allegedly improper marketing of *Vioxx*. In December 2004, the Special Committee of the Board of Directors retained the Honorable John S. Martin, Jr. of Debevoise & Plimpton LLP to conduct an independent investigation of, among other things, the allegations set forth in the demand. Judge Martin's report was made public in September 2006. Based on the Special Committee's recommendation made after careful consideration of the Martin report and the impact that derivative litigation would have on the Company, the Board rejected the demand. On October 11, 2007, the shareholders filed a lawsuit in state court in Atlantic County, NJ against current and former executives and directors of the Company alleging that the Board's rejection of their demand was unreasonable and improper, and that the defendants breached various duties to the Company in allowing *Vioxx* to be marketed. The current and former executive and director defendants filed motions to dismiss the complaint in June 2008. Those motions are pending.

***International Lawsuits***

As previously disclosed, in addition to the lawsuits discussed above, the Company has been named as a defendant in litigation relating to *Vioxx* in various countries (collectively, the *Vioxx* Foreign Lawsuits) in Europe, as well as Canada, Brazil, Argentina, Australia, The Philippines, Turkey, and Israel.

On May 30, 2008, the provincial court of Queen's Bench in Saskatchewan, Canada entered an order certifying a class of *Vioxx* users in Canada, except those in Quebec. The class includes individual purchasers who allege inducement to purchase by unfair marketing practices; individuals who allege *Vioxx* was not of acceptable quality, defective or not fit for the purpose of managing pain associated with approved indications; or ingestors who claim *Vioxx* caused or

exacerbated a cardiovascular or gastrointestinal condition. On June 17, 2008, the Court of Appeal for Saskatchewan granted the Company leave to appeal the certification order and the appeal is pending before that court. On July 28, 2008, the Superior court in Ontario decided to certify an overlapping class of *Vioxx* users in Canada, except those in Quebec and Saskatchewan, who allege negligence and an entitlement to elect to waive the tort. The Company's motion for leave to

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appeal that decision is pending before the Ontario Divisional Court. Earlier, in November 2006, the Superior court in Quebec authorized the institution of a class action on behalf of all individuals who, in Québec, consumed *Vioxx* and suffered damages arising out of its ingestion. As of September 30, 2008, the plaintiffs have not instituted an action based upon that authorization.

*Additional Lawsuits*

Based on media reports and other sources, the Company anticipates that additional *Vioxx* Product Liability Lawsuits, *Vioxx* Shareholder Lawsuits and *Vioxx* Foreign Lawsuits (collectively, the *Vioxx* Lawsuits ) will be filed against it and/or certain of its current and former officers and directors in the future.

*Insurance*

As previously disclosed, the Company has product liability insurance for claims brought in the *Vioxx* Product Liability Lawsuits with stated upper limits of approximately \$630 million after deductibles and co-insurance. This insurance provides coverage for legal defense costs and potential damage amounts in connection with the *Vioxx* Product Liability Lawsuits. Through an arbitration proceeding and negotiated settlements, the Company received an aggregate of approximately \$590 million in product liability insurance proceeds relating to the *Vioxx* Product Liability Lawsuits, plus approximately \$45 million in fees and interest payments. The Company has no additional insurance for the *Vioxx* Product Liability Lawsuits. The Company's insurance coverage with respect to the *Vioxx* Lawsuits will not be adequate to cover its defense costs and losses.

The Company also has Directors and Officers insurance coverage applicable to the *Vioxx* Securities Lawsuits and *Vioxx* Derivative Lawsuits with stated upper limits of approximately \$190 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 arbitration proceeding referenced above, 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, in November 2004, the Company was advised by the staff of the Securities and Exchange Commission ( SEC ) that it was commencing an informal inquiry concerning *Vioxx*. On January 28, 2005, the Company announced that it received notice that the SEC issued a formal notice of investigation. Also, the Company has received subpoenas from the U.S. Department of Justice (the DOJ ) requesting information related to the Company's research, marketing and selling activities with respect to *Vioxx* in a federal health care investigation under criminal statutes. In addition, as previously disclosed, investigations are being conducted by local authorities in certain cities in Europe in order to determine whether any criminal charges should be brought concerning *Vioxx*. The Company is cooperating with these governmental entities in their respective investigations (the *Vioxx* Investigations ). The Company cannot predict the outcome of these inquiries; however, they could result in potential civil and/or criminal dispositions.

As previously disclosed, on May 20, 2008, the Company reached civil settlements with Attorneys General from 29 states and the District of Columbia to fully resolve previously disclosed investigations under state consumer protection laws related to past activities for *Vioxx*. As part of the civil resolution of these investigations, Merck paid a total of \$58 million to be divided among the 29 states and the District of Columbia. In April 2008, Merck announced it had taken a pretax charge in the first quarter of \$55 million in anticipation of this settlement. The agreement also includes compliance measures that supplement policies and procedures previously established by the Company.

In addition, the Company received a subpoena in September 2006 from the State of California Attorney General seeking documents and information related to the placement of *Vioxx* on California's Medi-Cal formulary. The Company is cooperating with the Attorney General in responding to the subpoena.

*Reserves*

As discussed above, on November 9, 2007, Merck entered into the Settlement Agreement with the law firms that comprise the executive committee of the PSC of the federal *Vioxx* MDL as well as representatives of plaintiffs' counsel in the Texas, New Jersey and California state coordinated proceedings to resolve state and federal MI and IS claims



filed as of that date in the United States. The Settlement Agreement, which also applies to tolled claims, was signed by the parties after several meetings with three of the four judges overseeing the coordination of more than 95% of the U.S. *Vioxx* Product Liability Lawsuits. The Settlement Agreement applies only to U.S. legal residents and those who allege that their MI or IS occurred in the United States. As a result of entering into the Settlement Agreement, the Company

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recorded a pretax charge of \$4.85 billion in 2007 which represents the fixed aggregate amount to be paid to plaintiffs qualifying for payment under the Settlement Program.

The Company currently anticipates that *Vioxx* Product Liability Lawsuits will be tried in the future. The Company believes that it has meritorious defenses to 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. The Company has not established any reserves for any potential liability relating to the *Vioxx* Lawsuits not included in the Settlement Program or the *Vioxx* Investigations (other than as set forth above), including for those cases in which verdicts or judgments have been entered against the Company, and are now in post-verdict proceedings or on appeal. In each of those cases the Company believes it has strong points to raise on appeal and therefore that unfavorable outcomes in such cases are not probable. Unfavorable outcomes in the *Vioxx* Litigation (as defined below) 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, 2007, the Company had a reserve of \$5.372 billion which represented the aggregate amount to be paid under the Settlement Agreement and its future legal defense costs related to (i) the *Vioxx* Product Liability Lawsuits, (ii) the *Vioxx* Shareholder Lawsuits, (iii) the *Vioxx* Foreign Lawsuits, and (iv) the *Vioxx* Investigations (collectively, the *Vioxx* Litigation). During the first half of 2008, the Company spent approximately \$156 million in the aggregate in legal defense costs related to the *Vioxx* Litigation. In the third quarter of 2008, the Company spent approximately \$66 million in the aggregate in legal defense costs related to the *Vioxx* Litigation. In addition, in the third quarter the Company paid \$500 million into the settlement fund in connection with the Settlement Agreement referred to above. Thus, as of September 30, 2008, the Company had a reserve of approximately \$4.649 billion related to the *Vioxx* Litigation.

Some of the significant factors considered in the review of the 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, but that certain lawsuits will continue to be pending; 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* Product Liability Lawsuits. Events such as trials, which may occur in 2009, and the inherent inability to predict the ultimate outcomes of such trials and the disposition of *Vioxx* Product Liability Lawsuits not participating in or not eligible for the Settlement Program, limit the Company's ability to reasonably estimate its legal costs beyond 2009. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase its reserves for legal defense costs at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

**Other Product Liability Litigation**

As previously disclosed, the Company is a defendant in product liability lawsuits in the United States involving *Fosamax* (the *Fosamax* Litigation). As of September 30, 2008, approximately 700 cases, which include approximately 1,143 plaintiff groups had been filed and were pending against Merck in either federal or state court, including two cases which seek class action certification, as well as damages and medical monitoring. In these actions, plaintiffs allege, among other things, that they have suffered osteonecrosis of the jaw, generally subsequent to invasive dental procedures such as tooth extraction or dental implants, and/or delayed healing, in association with the use of *Fosamax*. On August 16, 2006, the JPML ordered that the *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 United States District Court for the Southern District of New York. As a result of the JPML order, approximately 583 of the cases are before Judge Keenan. Judge Keenan issued a Case Management Order (and various amendments thereto) setting forth a schedule governing the proceedings which focuses 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. Briefing and argument on plaintiffs

motions for certification of medical monitoring classes were completed in 2007 and Judge Keenan issued an order denying the motions on January 3, 2008. On January 28, 2008, Judge Keenan issued a further order dismissing with prejudice all class claims asserted in the first four class action lawsuits filed against Merck that sought personal injury damages and/or medical monitoring relief on a class wide basis. In October 2008, Judge Keenan issued an order requiring that *Daubert* motions be filed in May 2009 and scheduling trials in the first three cases in the MDL for August 2009, October 2009, and January 2010, respectively.

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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. On October 6, 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 osteonecrosis of the jaw, but not solely seeking medical monitoring, be designated as a mass tort for centralized management purposes before Judge Carol Higbee in Atlantic County Superior Court. Judge Higbee has scheduled an initial case management conference in the New Jersey matters for November 14, 2008.

Discovery is ongoing in both the *Fosamax* MDL litigation as well as in various state court cases. The Company intends to defend against these lawsuits.

As of December 31, 2007, the Company had a remaining reserve of approximately \$27 million solely for its future legal defense costs for the *Fosamax* Litigation. During the first half of 2008, the Company spent approximately \$17 million and added \$40 million to its reserve. In the third quarter, the Company spent approximately \$8 million. Consequently, as of September 30, 2008, the Company had a reserve of approximately \$42 million. Some of the significant factors considered in the establishment and ongoing assessment of the reserve for the *Fosamax* Litigation legal defense costs were as follows: the actual costs incurred by the Company thus far; the development of the Company's legal defense strategy and structure in light of the creation of the *Fosamax* MDL; the number of cases being brought against the Company; and the anticipated timing, progression, and related costs of pre-trial activities in the *Fosamax* Litigation. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves. Due to the uncertain nature of litigation, the Company is unable to estimate its costs beyond the completion of the first three federal trials discussed above. The Company has not established any reserves for any potential liability relating to the *Fosamax* Litigation. Unfavorable outcomes in the *Fosamax* Litigation could have a material adverse effect on the Company's financial position, liquidity and results of operations.

**Vytorin/Zetia Litigation**

As previously disclosed, since December 2007, the Company and its joint venture partner, Schering-Plough, have received several letters addressed to both companies from the House Committee on Energy and Commerce, its Subcommittee on Oversight and Investigations ( O&I ), and the Ranking Minority Member of the Senate Finance Committee, collectively seeking a combination of witness interviews, documents and information on a variety of issues related to the ENHANCE clinical trial, the sale and promotion of *Vytorin*, as well as sales of stock by corporate officers. In addition, on August 21 and September 2, 2008, respectively, the companies received additional letters from O&I seeking certain information and documents related to the SEAS clinical trial. As previously disclosed, the companies have each received subpoenas from the New York and New Jersey State Attorneys General Offices and a letter from the Connecticut Attorney General seeking similar information and documents. In addition, the Company has received five Civil Investigative Demands ( CIDs ) from a multistate group of 35 State Attorneys General who are jointly investigating whether the companies violated state consumer protection laws when marketing *Vytorin*. Finally, on September 10, 2008, the Company received a letter from the Civil Division of the U.S. Department of Justice informing it that the DOJ is investigating whether the companies' conduct relating to the promotion of *Vytorin* caused false claims to be submitted to federal health care programs. The Company is cooperating with these investigations and working with Schering-Plough to respond to the inquiries. In addition, since mid-January 2008, the Company has become aware of or been served with approximately 140 civil class action lawsuits alleging common law and state consumer fraud claims in connection with the MSP Partnership's sale and promotion of *Vytorin* and *Zetia*. Certain of those lawsuits allege personal injuries and/or seek medical monitoring.

Also, as previously disclosed, on April 3, 2008, a Merck shareholder filed a putative class action lawsuit in federal court in the Eastern District of Pennsylvania alleging that Merck and its Chairman, President and Chief Executive Officer, Richard T. Clark, 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 on October 6, 2008 and names as defendants Merck; Merck/Schering-Plough Pharmaceuticals, LLC; and certain of the Company's officers and directors. Specifically, the complaint alleges that Merck delayed releasing unfavorable results of a clinical study

regarding the efficacy of *Vytorin* and that 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 Merck's earnings would suffer. On April 22, 2008, a member of a Merck ERISA plan filed a putative class action lawsuit against the Company and certain of its officers and directors alleging they breached their fiduciary duties under ERISA. Since that time, there have been other similar ERISA lawsuits filed against the Company 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*.

Plaintiffs in these suits allege that the ERISA plan's investment in Company stock was imprudent because the Company'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. The Company intends to defend the lawsuits referred to in this section vigorously. Unfavorable outcomes resulting from the government investigations or the civil litigation could have a material adverse effect on the Company's financial position, liquidity and results of operations.

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**Table of Contents****Patent Litigation**

From time to time, generic manufacturers of pharmaceutical products file Abbreviated New Drug Applications ( ANDA s ) with the FDA seeking to market generic forms of the Company s products prior to the expiration of relevant patents owned by the Company. Generic pharmaceutical manufacturers have submitted ANDA s to the FDA seeking to market in the United States a generic form of *Propecia*, *Prilosec*, *Nexium*, *Singulair* and *Primaxin* prior to the expiration of the Company s (and AstraZeneca s in the case of *Prilosec* and *Nexium*) patents concerning these products. In addition, an ANDA has been submitted to the FDA seeking to market in the United States a generic form of *Zetia* prior to the expiration of Schering-Plough s patent concerning that product. The generic companies ANDA s generally include allegations of non-infringement, invalidity and unenforceability of the patents. Generic manufacturers have received FDA approval to market a generic form of *Prilosec*. The Company has filed patent infringement suits in federal court against companies filing ANDA s for generic finasteride (*Propecia*), montelukast (*Singulair*), imipenem/cilastatin (*Primaxin*) and AstraZeneca and the Company have filed patent infringement suits in federal court against companies filing ANDA s for generic omeprazole (*Prilosec*) and esomeprazole (*Nexium*). Also, the Company and Schering-Plough have filed a patent infringement suit in federal court against companies filing ANDA s for generic ezetimibe (*Zetia*). Similar patent challenges exist in certain foreign jurisdictions. 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 dates 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. As previously disclosed, in February 2007, the Company received a notice from Teva Pharmaceuticals ( Teva ), a generic company, indicating that it had filed an ANDA for montelukast and that it is challenging the U.S. patent that is listed for *Singulair*. On April 2, 2007, the Company filed a patent infringement action against Teva. The lawsuit automatically stays FDA approval of Teva s ANDA for 30 months or until an adverse court decision, if any, whichever may occur earlier. A trial in this matter has been scheduled to begin on February 23, 2009.

**Other Litigation**

There are various other legal proceedings, principally product liability and intellectual property suits involving the Company, which are pending. While it is not feasible to predict the outcome of such proceedings or the proceedings discussed in this Item, in the opinion of the Company, all such proceedings are either adequately covered by insurance or, if not so covered, should not ultimately result in any liability that would have a material adverse effect on the financial position, liquidity or results of operations of the Company, other than proceedings for which a separate assessment is provided in this Item.

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**Item 4. Controls and Procedures**

Management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures. Based on their evaluation, as of the end of the period covered by this Form 10-Q, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) are effective. There have been no changes in internal control over financial reporting, for the period covered by this report, that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting. As the Company has previously disclosed, it is proceeding with a multi-year implementation of an enterprise wide resource planning system. During October 2008, the Company implemented this system at certain North American sites which included modifications to the design, operation and documentation of its internal controls over financial reporting. The Company also continues to transition certain financial functions into regionalized shared service environments, at certain of the Company's locations.

**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 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, 2007, as filed on February 28, 2008, the Company discusses in more detail various important 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**

Information with respect to certain legal proceedings is incorporated by reference from Management's Discussion and Analysis of Financial Condition and Results of Operations contained in Part I of this report.

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

Issuer purchases of equity securities for the three months ended September 30, 2008 were as follows:

**ISSUER PURCHASES OF EQUITY SECURITIES**

Period	Total Number of Shares Purchased <sup>(1)</sup>	Average Price Paid Per Share	(\$ in millions) Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs <sup>(1)</sup>
July 1 - July 31, 2008	8,647,445	\$ 33.07	\$ 3,260.6
August 1 - August 31, 2008	10,743,405	\$ 35.03	\$ 2,884.2
September 1 - September 30, 2008	9,241,000	\$ 32.67	\$ 2,582.3
Total	28,631,850	\$ 33.68	\$ 2,582.3

<sup>(1)</sup> All shares purchased during the period were made as part of a plan announced in July 2002 to purchase \$10 billion in Merck shares.

**Item 6. Exhibits**

Number	Description
3.1	Restated Certificate of Incorporation of Merck & Co., Inc. (May 17, 2007) Incorporated by reference to Current Report on Form 8-K dated May 17, 2007
3.2	By-Laws of Merck & Co., Inc. (as amended effective May 31, 2007) Incorporated by reference to Current Report on Form 8-K dated May 31, 2007
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  
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**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 3, 2008

/s/ Bruce N. Kuhlik

BRUCE N. KUHLIK  
Executive Vice President and General Counsel

Date: November 3, 2008

/s/ John Canan

JOHN CANAN  
Senior Vice President and Controller

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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

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