

SCHERING PLOUGH CORP

Form 10-Q

October 29, 2009

**Table of Contents**

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**Form 10-Q**

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934**  
**For the quarterly period ended September 30, 2009**

**Commission file number 1-6571**

**SCHERING-PLOUGH CORPORATION**  
*(Exact name of registrant as specified in its charter)*

**New Jersey**  
*State or other jurisdiction of  
incorporation or organization*  
**2000 Galloping Hill Road, Kenilworth, NJ**  
*(Address of principal executive offices)*

**22-1918501**  
*(I.R.S. Employer  
identification No.)*  
**07033**  
*Zip Code*

**Registrant's telephone number, including area code:**  
**(908) 298-4000**

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

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

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

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐  
(Do not check if a smaller reporting company)

Indicate whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

Common Shares Outstanding as of September 30, 2009: 1,639,151,392

**PART I. FINANCIAL INFORMATION**

**TABLE OF CONTENTS**

**PART I. FINANCIAL INFORMATION**

Item 1. Financial Statements

STATEMENTS OF CONDENSED CONSOLIDATED OPERATIONS

STATEMENTS OF CONDENSED CONSOLIDATED CASH FLOWS

CONDENSED CONSOLIDATED BALANCE SHEETS

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Item 4. Controls and Procedures

**PART II. OTHER INFORMATION**

**SIGNATURES**

EX-12

EX-15

EX-31.1

EX-31.2

EX-32.1

EX-32.2

EX-101 INSTANCE DOCUMENT

EX-101 SCHEMA DOCUMENT

EX-101 CALCULATION LINKBASE DOCUMENT

EX-101 LABELS LINKBASE DOCUMENT

EX-101 PRESENTATION LINKBASE DOCUMENT

EX-101 DEFINITION LINKBASE DOCUMENT

---

Table of Contents**Item 1. Financial Statements**

**SCHERING-PLOUGH CORPORATION AND SUBSIDIARIES**  
**STATEMENTS OF CONDENSED CONSOLIDATED OPERATIONS**

(Unaudited)  
(Amounts in millions, except per share figures)

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
Net sales	\$ 4,499	\$ 4,576	\$ 13,539	\$ 14,154
Cost of sales	1,719	1,737	4,738	5,782
Selling, general and administrative	1,511	1,660	4,629	5,208
Research and development	913	893	2,580	2,679
Other expense/(income), net	102	(39)	297	189
Special, merger and acquisition-related charges	29	101	133	218
Equity income	(387)	(434)	(1,157)	(1,444)
Income before income taxes	612	658	2,319	1,522
Income tax expense	97	44	328	133
Net income	515	614	1,991	1,389
Preferred stock dividends	38	38	113	113
Net income available to common shareholders	\$ 477	\$ 576	\$ 1,878	\$ 1,276
Diluted earnings per common share	\$ 0.29	\$ 0.35	\$ 1.13	\$ 0.78
Basic earnings per common share	\$ 0.29	\$ 0.35	\$ 1.14	\$ 0.78
Dividends per common share	\$ 0.065	\$ 0.065	\$ 0.195	\$ 0.195

The accompanying notes are an integral part of these Condensed Consolidated Financial Statements.

Table of Contents

**SCHERING-PLOUGH CORPORATION AND SUBSIDIARIES**  
**STATEMENTS OF CONDENSED CONSOLIDATED CASH FLOWS**

(Unaudited)  
(Amounts in millions)

	<b>Nine Months  Ended  September 30,  2009                      2008</b>	
<b>Operating Activities:</b>		
Net income	\$ 1,991	\$ 1,389
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	929	1,813
Accrued share-based compensation	135	170
Special, merger and acquisition-related charges and payments	(54)	115
Gain on sale of divested products		(160)
Changes in assets and liabilities:		
Accounts receivable	(179)	(132)
Inventories	(129)	(135)
Prepaid expenses and other assets	120	(22)
Accounts payable	28	16
Other liabilities	(217)	(479)
Net cash provided by operating activities	2,624	2,575
<b>Investing Activities:</b>		
Capital expenditures	(522)	(542)
Dispositions of property and equipment	48	33
Contributions to benefit-related trusts	(367)	
Proceeds from divested products, net	23	241
Purchases of short-term investments	(2,035)	
Maturities of short-term investments	1,554	27
Other, net	(10)	(3)
Net cash used for investing activities	(1,309)	(244)
<b>Financing Activities:</b>		
Payments of long-term debt	(71)	(791)
Cash dividends paid to common shareholders	(318)	(317)
Cash dividends paid to preferred shareholders	(113)	(113)
Net change in short-term borrowings	(122)	(207)
Stock option exercises	167	15
Other, net		(3)
Net cash used for financing activities	(457)	(1,416)

Effect of exchange rates on cash and cash equivalents	81	(35)
<b>Net increase in cash and cash equivalents</b>	<b>939</b>	<b>880</b>
<b>Cash and cash equivalents, beginning of period</b>	<b>3,373</b>	<b>2,279</b>
<b>Cash and cash equivalents, end of period</b>	<b>\$ 4,312</b>	<b>\$ 3,159</b>

The accompanying notes are an integral part of these Condensed Consolidated Financial Statements.

Table of Contents**SCHERING-PLOUGH CORPORATION AND SUBSIDIARIES****CONDENSED CONSOLIDATED BALANCE SHEETS****(Unaudited)****(Amounts in millions, except per share figures)**

	<b>September 30, 2009</b>	<b>December 31, 2008</b>
<b>ASSETS</b>		
<b>Current Assets:</b>		
Cash and cash equivalents	\$ 4,312	\$ 3,373
Short-term investments	487	5
Accounts receivable, net	3,127	2,816
Inventories	3,459	3,114
Deferred income taxes	578	435
Prepaid expenses and other current assets	1,203	1,228
 Total current assets	 13,166	 10,971
Property, plant and equipment	11,012	10,440
Less accumulated depreciation	4,088	3,607
 Property, net	 6,924	 6,833
Goodwill	2,879	2,778
Other intangible assets, net	5,981	6,154
Other assets	1,597	1,381
 <b>Total assets</b>	 <b>\$ 30,547</b>	 <b>\$ 28,117</b>

**LIABILITIES AND SHAREHOLDERS EQUITY**

<b>Current Liabilities:</b>		
Accounts payable	\$ 1,709	\$ 1,677
Short-term borrowings and current portion of long-term debt	185	245
Income taxes	232	183
Accrued compensation	967	1,010
Other accrued liabilities	1,996	2,078
 Total current liabilities	 5,089	 5,193
<b>Long-term Liabilities:</b>		
Long-term debt, net of current portion	8,033	7,931
Deferred income taxes	1,523	1,551
Other long-term liabilities	3,002	2,913
 Total long-term liabilities	 12,558	 12,395
Commitments and contingent liabilities (Note 17)		

**Shareholders Equity:**



Edgar Filing: SCHERING PLOUGH CORP - Form 10-Q

2007 Mandatory convertible preferred shares \$1 par value; \$250 per share face value; issued: 10 at September 30, 2009 and December 31, 2008	2,500	2,500
Common shares authorized: 2,400, \$.50 par value; issued: 2,132 at September 30, 2009 and 2,118 at December 31, 2008	1,066	1,059
Paid-in capital	5,340	5,045
Retained earnings	10,737	9,181
Accumulated other comprehensive loss	(1,360)	(1,913)
Total	18,283	15,872
Less treasury shares: 493 at September 30, 2009 and 492 at December 31, 2008; at cost	5,383	5,343
Total shareholders equity	12,900	10,529
<b>Total liabilities and shareholders equity</b>	<b>\$ 30,547</b>	<b>\$ 28,117</b>

The accompanying notes are an integral part of these Condensed Consolidated Financial Statements.

**Table of Contents**

**SCHERING-PLOUGH CORPORATION AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(Unaudited)**

**1. BASIS OF PRESENTATION**

These unaudited Condensed Consolidated Financial Statements of Schering-Plough Corporation and subsidiaries (Schering-Plough), have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (SEC) for reporting on Form 10-Q. Certain information and disclosures normally included in financial statements prepared in accordance with U.S. Generally Accepted Accounting Principles have been condensed or omitted pursuant to such SEC rules and regulations. These statements should be read in conjunction with the accounting policies and notes to the consolidated financial statements included in Schering-Plough's 2008 10-K.

In the opinion of Schering-Plough's management, these financial statements reflect all adjustments necessary, including normal recurring accruals, for a fair presentation of the statements of operations, cash flows and financial position for the interim periods presented.

Third quarter and nine months ended September 30, 2008, income tax expense has been revised from the prior year 10-Q which reflected an overstatement of income tax expense relating to the accounting for the purchase of Organon BioSciences N.V. (OBS). This change resulted in a reduction of income tax expense and a corresponding increase in net income and net income available to common shareholders of \$25 million for the third quarter of 2008 and \$74 million for the nine months ended September 30, 2008, along with an associated increase in per share amounts.

In November 2007, Schering-Plough acquired OBS, a company that discovers, develops and manufactures human prescription and animal health products.

Schering-Plough has evaluated all subsequent events through October 29, 2009, the date of filing of this 10-Q.

***Impact of Recently Issued Accounting Standards***

In June 2009, the Financial Accounting Standards Board (FASB) issued guidance which is included in the Codification in FASB Accounting Standards Codification (ASC) 105, Generally Accepted Accounting Principles. This guidance modifies the Generally Accepted Accounting Principles (GAAP) hierarchy by establishing only two levels of GAAP, authoritative and nonauthoritative accounting literature. Effective July 2009, the FASB ASC, also known collectively as the Codification, is considered the single source of authoritative U.S. accounting and reporting standards, except for additional authoritative rules and interpretive releases issued by the SEC. This guidance is effective for financial statements issued for reporting periods that end after September 15, 2009. Where possible, FASB references have been replaced with ASC references.

As of January 1, 2009, Schering-Plough implemented the transition guidance related to FASB Staff Position (FSP) Emerging Issues Task Force (EITF) 03-6-1, Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities, which is included in the codification in ASC 260-10, Earnings Per Share (ASC 260-10). ASC 260-10 requires Schering-Plough to treat unvested deferred stock units as participating securities in accordance with the two-class method in the calculation of both basic and diluted earnings per share. ASC 260-10 must be applied retrospectively. The effect of the retrospective application of ASC 260-10 was not material to Schering-Plough's earnings per share in 2008, 2007 or 2006.

As of June 30, 2009, Schering-Plough implemented FASB ASC 825-10-65-1, Financial Instruments (ASC 825-10-65-1). ASC 825-10-65-1 provides disclosure about fair value of financial instruments in interim as well as in annual financial statements. This guidance is effective for periods ending after June 15, 2009. In the second quarter of 2009, Schering-Plough implemented this guidance. See Note 13, Financial Instruments.

Effective January 1, 2008, the Company adopted FASB ASC 820-10, Fair Value Measurements and Disclosures (ASC 820-10) with respect to its financial assets and liabilities. In February 2008, the FASB issued updated guidance related to fair value measurements, which is included in the Codification in ASC 820-10, Fair Value Measurements and Disclosures (see Note 14, Fair Value Measurements). The updated guidance provided a one year deferral of the effective date of ASC 820-10 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually.

**Table of Contents**

**SCHERING-PLOUGH CORPORATION AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The implementation of the non-financial items measured on a non-recurring basis did not have a material impact on Schering-Plough's condensed consolidated financial statements.

In December 2007, the FASB issued guidance which is included in the Codification in ASC 808, Collaborative Arrangements (ASC 808), which is effective for calendar-year companies beginning January 1, 2009. ASC 808 clarified the manner in which costs, revenues and sharing payments made to, or received by, a partner in a collaborative arrangement should be presented in the income statement and set forth certain disclosures that should be required in the partners' financial statements. The implementation of this standard did not have a material impact on Schering-Plough's condensed consolidated financial statements. Schering-Plough has a number of collaborative arrangements. For collaborative arrangements, sales are generally included in Net sales and payments to collaboration partners are classified in the statement of condensed consolidated operations based on their nature in Cost of sales or Research and development, as appropriate.

In December 2007, the FASB issued guidance which is included in the Codification in ASC 805, Business Combination (ASC 805). For calendar-year companies, the standard is applicable to new business combinations occurring on or after January 1, 2009. ASC 805 requires an acquiring entity to recognize all the assets acquired and liabilities assumed in a transaction at the acquisition-date fair value with limited exceptions. Most significantly, ASC 805 requires that acquisition costs generally be expensed as incurred, certain acquired contingent liabilities be recorded at fair value, and acquired in-process research and development be recorded at fair value as an indefinite-lived intangible asset at the acquisition date. The implementation of this standard did not have a material impact on Schering-Plough's condensed consolidated financial statements.

In December 2007, the FASB issued guidance which is included in the Codification in ASC 810-10-65-1, Consolidation (ASC 810-10-65-1), which is effective for calendar-year companies beginning January 1, 2009. This standard revised the accounting treatment for noncontrolling minority interests of partially-owned subsidiaries. The standard establishes new accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. The implementation of this standard did not have a material impact on Schering-Plough's condensed consolidated financial statements.

In March 2008, the FASB issued guidance which is included in the Codification in ASC 815-10, Derivatives and Hedging. This guidance is effective for calendar-year companies beginning January 1, 2009. The guidance enhances required disclosures regarding derivatives and hedging activities. The implementation of this standard did not have a material impact on Schering-Plough's condensed consolidated financial statements.

In April 2008, the FASB issued ASC 350, Intangibles-Goodwill and Other (ASC 350). ASC 350 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset. ASC 350 is effective for calendar-year companies beginning January 1, 2009. The requirement for determining useful lives must be applied prospectively to intangible assets acquired after the effective date and the disclosure requirements must be applied prospectively to all intangible assets recognized as of, and subsequent to, the effective date. The implementation of this standard did not have a material impact on Schering-Plough's condensed consolidated financial statements.

In April 2009, the FASB issued updated guidance related to business combinations, which is included in the Codification in ASC 805-20, Business Combinations Identifiable Assets, Liabilities and Any Noncontrolling Interest

(ASC 805-20). ASC 805-20 amends the provisions in ASC 805 for the initial recognition and measurement, subsequent measurement and accounting, and disclosures for assets and liabilities arising from contingencies in business combinations. ASC 805-20 is effective for contingent assets or contingent liabilities acquired in business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. The implementation of this standard did not have a material impact on Schering-Plough's condensed consolidated financial statements.

In May 2009, the FASB issued guidance which is included in the Codification in ASC 855, Subsequent Events (ASC 855). This guidance establishes the accounting and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. It requires the disclosure of the date through which an entity has evaluated subsequent events and the basis for that date. This guidance is effective for interim or annual financial periods ending after June 15, 2009, and as such, became effective for the

**Table of Contents**

**SCHERING-PLOUGH CORPORATION AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Company on June 30, 2009. The implementation of this standard did not have a material impact on Schering-Plough's condensed consolidated financial statements.

In June 2009, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 166, Accounting for Transfers of Financial Assets, an amendment of SFAS No. 140 (SFAS 166), which has not yet been codified in the ASC. SFAS 166 amends SFAS No. 140 to improve the relevance, representational faithfulness, and comparability of the information that a reporting entity provides in its financial reports about a transfer of financial assets; the effects of a transfer on its financial position, financial performance, and cash flows; and a transferor's continuing involvement in transferred financial assets. This Statement is effective as of the beginning of each reporting entity's first annual reporting period that begins after November 15, 2009, for interim periods within that first annual reporting period, and for interim and annual reporting periods thereafter. Earlier application is prohibited. The recognition and measurement provisions of this Statement shall be applied to transfers that occur on or after the effective date. Schering-Plough is currently assessing the impact of the adoption of SFAS 166.

In June 2009, the FASB issued SFAS No. 167, Amendments to FASB Interpretation No. 46(R) (SFAS 167), which has not yet been codified in the ASC. SFAS 167 amends certain requirements of FASB Interpretation No. 46 (revised December 2003), Consolidation of Variable Interest Entities, to improve financial reporting by enterprises involved with variable interest entities and to provide more relevant and reliable information to users of financial statements. This Statement is effective as of the beginning of each reporting entity's first annual reporting period that begins after November 15, 2009, for interim periods within that first annual reporting period, and for interim and annual reporting periods thereafter. Earlier application is prohibited. Schering-Plough is currently assessing the impact of the adoption of SFAS 167.

In August 2009, the FASB issued Accounting Standards Update (ASU) No. 2009-05, Fair Value Measurements and Disclosures (Topic 820) (ASU 2009-05). ASU 2009-05 provided amendments to ASC 820-10, Fair Value Measurements and Disclosures Overall, for the fair value measurement of liabilities. ASU 2009-05 provides clarification that in circumstances in which a quoted price in an active market for the identical liability is not available, a reporting entity is required to measure fair value using certain techniques. ASU 2009-05 also clarifies that when estimating the fair value of a liability, a reporting entity is not required to include a separate input or adjustment to other inputs relating to the existence of a restriction that prevents the transfer of a liability. ASU 2009-05 also clarifies that both a quoted price in an active market for the identical liability at the measurement date and the quoted price for the identical liability when traded as an asset in an active market when no adjustments to the quoted price of the asset are required are Level 1 fair value measurements. The new guidance is effective for interim and annual periods beginning after August 27, 2009, and applies to all fair-value measurements of liabilities required by GAAP. Schering-Plough is currently assessing the impact of the adoption of ASU 2009-05.

In October 2009, the FASB issued ASU 2009-13, Multiple-Deliverable Revenue Arrangements, (amendments to FASB ASC Topic 605, Revenue Recognition) (ASU 2009-13). ASU 2009-13 requires entities to allocate revenue in an arrangement using estimated selling prices of the delivered goods and services based on a selling price hierarchy. The amendments eliminate the residual method of revenue allocation and require revenue to be allocated using the relative selling price method. ASU 2009-13 should be applied on a prospective basis for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, with early adoption permitted. Schering-Plough is currently assessing the impact of the adoption of ASU 2009-13.



Table of Contents**SCHERING-PLOUGH CORPORATION AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2. PRODUCTIVITY TRANSFORMATION PROGRAM**

Schering-Plough's Productivity Transformation Program (PTP) is designed to reduce and avoid costs and increase productivity.

The following table summarizes activities reflected in the condensed consolidated financial statements related to the Productivity Transformation Program, for the nine months ended September 30, 2009:

	<b>Charges Included in</b>						
	<b>Special, Merger and Acquisition-</b>					<b>Non-cash</b>	
	<b>Research and</b>	<b>Related</b>	<b>Total</b>	<b>Cash</b>	<b>Charges</b>	<b>Accrued</b>	
	<b>Cost of Sales</b>	<b>Development</b>	<b>Charges</b>	<b>Payments</b>	<b>/(Credits)</b>	<b>Liability</b>	
	<b>(Dollars in millions)</b>						
Accrued liability at January 1, 2009							\$ 155
Employee termination costs	\$	\$	\$ 98	\$ 98	\$ (156)	\$	(58)
Asset write-offs	5			5		5	
Inventory write-offs	38			38		38	
Accelerated depreciation	12	2		14		14	
Foreign exchange and other						(4)	(4)
Total	\$ 55	\$ 2	\$ 98	\$ 155	\$ (156)	\$ 53	
Accrued liability at September 30, 2009							\$ 93

For the three months ended September 30, 2009, special, merger and acquisition-related costs totaled \$29 million, of which \$24 million related to employee termination costs and \$5 million related to the planned merger with Merck & Co., Inc (Merck). Planned merger costs are not included in the table above. For the nine months ended September 30, 2009, special, merger and acquisition-related costs totaled \$133 million, of which \$98 million related to employee termination costs and \$35 million related to the planned merger with Merck.

The following table summarizes activities reflected in the condensed consolidated financial statements related to the Productivity Transformation Program, for the nine months ended September 30, 2008:



	<b>Special, and Acquisition- Related Charges</b>	<b>Total Charges</b>	<b>Cash Payments</b>	<b>Non-cash Charges</b>	<b>Accrued Liability</b>
			<b>(Dollars in millions)</b>		
Accrued liability at January 1, 2008					\$ 174
Employee termination costs	\$ 177	\$ 177	\$ (197)	\$ 32	12
Accrued liability at September 30, 2008					\$ 186

For the three months ended September 30, 2008, special and acquisition-related charges totaled \$101 million (\$93 million of employee termination costs and \$8 million related to OBS integration activities). For the nine months ended September 30, 2008, special and acquisition-related charges totaled \$218 million (\$177 million of employee termination costs and \$41 million to OBS integration activities).

### 3. EQUITY INCOME

In May 2000, Schering-Plough and Merck entered into two separate sets of agreements to jointly develop and market certain products in the U.S. including (1) two cholesterol-lowering drugs and (2) an allergy/asthma drug. In December 2001, the cholesterol agreements were expanded to include all countries of the world except Japan. In general, the companies agreed that the collaborative activities under these agreements would operate in a virtual joint venture to the maximum degree possible by relying on the respective infrastructures of the two

**Table of Contents**

**SCHERING-PLOUGH CORPORATION AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

companies. These agreements generally provide for equal sharing of development costs and for co-promotion of approved products by each company.

The cholesterol agreements provide for Schering-Plough and Merck to jointly develop and commercialize ezetimibe in the cholesterol management field:

- i. as a once-daily monotherapy (managed as ZETIA in the U.S. and Asia and EZETROL in Europe);
- ii. in co-administration with various approved statin drugs; and
- iii. as a fixed-combination tablet of ezetimibe and simvastatin (Zocor), Merck's cholesterol-modifying medicine. This combination medication (ezetimibe/simvastatin) is managed as VYTORIN in the U.S. and as INEGY in many international countries.

ZETIA/EZETROL (ezetimibe) and VYTORIN/INEGY (the combination of ezetimibe/simvastatin) are approved for use in the U.S. and have been launched in many international markets.

Schering-Plough utilizes the equity method of accounting in recording its share of activity from the Merck/Schering-Plough cholesterol joint venture. As such, Schering-Plough's net sales do not include the sales of the joint venture. The cholesterol joint venture agreements provide for the sharing of operating income generated by the joint venture based upon percentages that vary by product, sales level and country. In the U.S. market, Schering-Plough receives a greater share of profits on the first \$300 million of annual ZETIA sales. Above \$300 million of annual ZETIA sales, Merck and Schering-Plough generally share profits equally. Schering-Plough's allocation of the joint venture income is increased by milestones recognized. Further, either company's share of the joint venture's income from operations is subject to a reduction if that company fails to perform a specified minimum number of physician details in a particular country. The companies agree annually to the minimum number of physician details by country.

The companies bear the costs of their own general sales forces and commercial overhead in marketing joint venture products around the world. In the U.S., Canada and Puerto Rico, the cholesterol agreements provide for a reimbursement to each company for physician details that are set on an annual basis, and in Italy, a contractual amount is included in the profit sharing calculation that is not reimbursed. In the U.S., Canada and Puerto Rico this amount is equal to each company's agreed physician details multiplied by a contractual fixed fee. Schering-Plough reports these amounts as part of equity income from the cholesterol joint venture. These amounts do not represent a reimbursement of specific, incremental and identifiable costs for Schering-Plough's detailing of the cholesterol products in these markets. In addition, these amounts are not reflective of Schering-Plough's sales effort related to the joint venture as Schering-Plough's sales force and related costs associated with the joint venture are generally estimated to be higher.

Costs of the joint venture that the companies contractually share are 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 market support, market research, market expansion, a specialty sales force and physician education programs.

Certain specified research and development expenses are generally shared equally by Schering-Plough and Merck.

The unaudited financial information below presents summarized combined financial information for the Merck/Schering-Plough cholesterol joint venture for the three and nine months ended September 30, 2009 and 2008:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
	<b>(Dollars in millions)</b>			
Net sales	\$ 1,029	\$ 1,102	\$ 3,007	\$ 3,487
Cost of sales	43	41	128	145
Income from operations	746	777	2,116	2,413

Table of Contents**SCHERING-PLOUGH CORPORATION AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Amounts related to physician details, among other expenses, that are invoiced by Schering-Plough and Merck in the U.S., Canada and Puerto Rico are deducted from income from operations of the cholesterol joint venture.

Schering-Plough's share of the cholesterol joint venture's income from operations for the three and nine months ended September 30, 2009 was \$357 million and \$1.1 billion, respectively. For the three and nine months ended September 30, 2008, Schering-Plough's share of the cholesterol joint venture's income from operations were \$393 million and \$1.3 billion, respectively. Included in Schering-Plough's share of income from operations is income of \$19 million and \$83 million, for the three and nine months ended September 30, 2008, respectively, related to the termination of a respiratory joint venture with Merck. In the U.S. market, Schering-Plough receives a greater share of income from operations on the first \$300 million of annual ZETIA sales. As a result, Schering-Plough's share of the cholesterol joint venture's income from operations is generally higher in the first quarter than in subsequent quarters.

The following information provides a summary of the components of Schering-Plough's equity income from the cholesterol joint venture for the three and nine months ended September 30, 2009 and 2008:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
	<b>(Dollars in millions)</b>			
Schering-Plough's share of income from operations	\$ 357	\$ 393	\$ 1,064	\$ 1,288
Contractual amounts for physician details	35	49	108	172
Elimination of intercompany profit and other, net	(5)	(8)	(15)	(16)
Total equity income from cholesterol joint venture	\$ 387	\$ 434	\$ 1,157	\$ 1,444

At September 30, 2009 and December 31, 2008, Schering-Plough had net receivables (including undistributed income) from the Merck/Schering-Plough Joint Venture of \$75 million and \$130 million, respectively.

Equity income from the joint venture excludes any profit arising from transactions between Schering-Plough and the joint venture until such time as there is an underlying profit realized by the joint venture in a transaction with a party other than Schering-Plough or Merck.

Due to the virtual nature of the cholesterol joint venture, Schering-Plough incurs substantial costs, such as selling, general and administrative costs, that are not reflected in Equity income and are borne by the overall cost structure of Schering-Plough. These costs are reported on their respective line items in the statements of condensed consolidated operations and are not separately identifiable. The cholesterol agreements do not provide for any jointly owned facilities and, as such, products resulting from the joint venture are manufactured in facilities owned by either Schering-Plough or Merck.

Schering-Plough and Merck are developing a single-tablet combination of ezetimibe and atorvastatin as a treatment for elevated cholesterol levels.

In April 2008, the Merck/Schering-Plough joint venture received a not-approvable letter from the U.S. Food and Drug Administration (FDA) for the proposed fixed combination of loratadine/montelukast. During the second quarter of 2008 the respiratory joint venture was terminated in accordance with the agreements. This action has no impact on the cholesterol joint venture.

See Note 17, Legal, Environmental and Regulatory Matters,      Litigation and Investigations relating to the Merck/Schering-Plough Cholesterol Joint Venture,    for additional information.

Table of Contents**SCHERING-PLOUGH CORPORATION AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****4. SHARE-BASED COMPENSATION**

A summary of the options, deferred stock units and performance-based deferred stock units granted during the three and nine months ended September 30, 2009 and 2008 is as follows:

Number of Underlying Shares  in Thousands	Three Months Ended September 30,				Nine Months Ended September 30,			
	2009		2008		2009		2008	
	Weighted-Average		Weighted-Average		Weighted-Average		Weighted-Average	
	Underlying	Grant-Date	Underlying	Grant-Date	Underlying	Grant-Date	Underlying	Grant-Date
	Shares	Fair Value	Shares	Fair Value	Shares	Fair Value	Shares	Fair Value
Stock options	9	\$ 8.53	13	\$ 6.58	7,829	\$ 7.67	13,597	\$ 5.35
Deferred stock units	9	25.55	64	19.79	4,618	22.89	4,772	18.93
Performance-based deferred stock units					1,043	27.93	1,064	19.35
Total Awards	18		77		13,490		19,433	

Options generally become exercisable in equal annual installments over a three-year period. The deferred stock units generally vest at the end of a three-year period from the date they were granted. The performance-based deferred stock units vest at the end of a three-year performance period if specific pre-established levels of performance, market conditions and service are met.

The weighted-average assumptions used in the Black-Scholes option pricing model for the three and nine months ended September 30, 2009 and 2008, were as follows:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2009	2008	2009	2008
Dividend yield	1.1%	1.1%	1.1%	1.1%
Volatility	40.6%	37.0%	41.5%	31.4%
Risk-free interest rate	2.4%	3.2%	1.9%	2.8%
Expected term of options (in years)	4.5	4.5	4.5	4.5

Total compensation expense related to stock options, deferred stock units and performance-based deferred stock units for the three and nine months ended September 30, 2009 was \$53 million and \$135 million, respectively. Total compensation expense related to stock options, deferred stock units and performance-based deferred stock units for

the three and nine months ended September 30, 2008 was \$52 million and \$171 million, respectively.

At September 30, 2009, the total remaining unrecognized compensation cost related to the performance-based deferred stock units granted in 2009 amounted to \$23 million, which will be amortized over the weighted-average remaining requisite service period of 2.25 years. The remaining unrecognized compensation cost for the performance-based deferred stock units may vary each reporting period based on changes in the expected achievement of performance measures.

Table of Contents**SCHERING-PLOUGH CORPORATION AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****5. OTHER EXPENSE/(INCOME), NET**

The components of other expense/(income), net are as follows:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
	<b>(Dollars in millions)</b>			
Interest cost incurred	\$ 119	\$ 140	\$ 348	\$ 428
Less: amount capitalized on construction	(6)	(4)	(16)	(14)
Interest expense	113	136	332	414
Interest income	(6)	(19)	(17)	(58)
Foreign exchange (gains)/losses	(5)	4	(18)	10
Gain on sales of assets		(160)		(177)
Total other expense/(income), net	\$ 102	\$ (39)	\$ 297	\$ 189

In September 2008, Schering-Plough completed its previously announced divestitures of certain Animal Health products as required by regulatory agencies in the U.S. and Europe in connection with the acquisition of OBS. As a result of these divestitures, Schering-Plough recognized a gain of \$160 million (\$149 million after tax). In addition, during the nine months ended September 30, 2008, Schering-Plough recognized a gain of \$17 million (\$12 million after tax) on the sale of a manufacturing site. These gains were included in Gain on sales of assets. Net cash proceeds from the divested animal health products were \$210 million.

During 2008, Schering-Plough participated in health care refinancing programs adopted by local government fiscal authorities in a major European market. During the three and nine months ended September 30, 2008, Schering-Plough transferred \$47 million of its trade accounts receivables owned by a foreign subsidiary to third-party financial institutions without recourse. The transfer of trade accounts receivable qualified as sales of accounts receivable under SFAS No. 140, Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities. For the three and nine months ended September 30, 2008, the transfer of these trade accounts receivable did not have a material impact on Schering-Plough's Statements of Condensed Consolidated Operations. Cash flows from these transactions are included in the change in accounts receivable in operating activities.

**6. INCOME TAXES**

Schering-Plough reported a U.S. Net Operating Loss (NOL) carryforward of approximately \$1.3 billion on its 2008 tax return, which will be available to offset future U.S. taxable income, in varying amounts, through 2028.



This U.S. NOL carryforward could be materially reduced after examination of Schering-Plough's income tax returns by the Internal Revenue Service (IRS). Schering-Plough continues to maintain a valuation allowance against its U.S. deferred tax assets, as management cannot conclude that it is more likely than not the benefit of the U.S. net deferred tax assets can be realized.

Table of Contents**SCHERING-PLOUGH CORPORATION AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****7. RETIREMENT PLANS AND OTHER POST-RETIREMENT BENEFITS**

Schering-Plough has defined benefit pension plans covering eligible employees in the U.S. and certain foreign countries. In addition, Schering-Plough provides post-retirement medical and life insurance benefits primarily to its eligible U.S. retirees and their dependents through its post-retirement benefit plans.

The components of net pension expense were as follows:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
	<b>(Dollars in millions)</b>			
Service cost	\$ 54	\$ 54	\$ 157	\$ 162
Interest cost	61	58	177	176
Expected return on plan assets	(59)	(59)	(172)	(178)
Amortization, net	11	7	32	20
Settlement	1		1	
Net pension expense	\$ 68	\$ 60	\$ 195	\$ 180

The components of other post-retirement benefits expense were as follows:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
	<b>(Dollars in millions)</b>			
Service cost	\$ 6	\$ 7	\$ 18	\$ 21
Interest cost	9	10	27	29
Expected return on plan assets	(2)	(3)	(8)	(9)
Amortization, net	(1)	1	(3)	3
Net other post-retirement benefits expense	\$ 12	\$ 15	\$ 34	\$ 44

For the three and nine months ended September 30, 2009, Schering-Plough made regular contributions of \$30 million and \$216 million, respectively, to its retirement plans. For the three and nine months ended September 30, 2008,

Schering-Plough contributed \$57 million and \$153 million, respectively, to its retirement plans. Schering-Plough expects to make regular contributions of approximately \$40 million to its retirement plans during the remainder of 2009.

In addition, in 2009 Schering-Plough contributed an aggregate of \$367 million of cash equivalents to non-qualified trusts designated to fund certain pension and other employee benefit payments related to the planned combination with Merck. These amounts are included in Other assets in the Condensed Consolidated Balance Sheets. Further, Schering-Plough expects to fund certain deferred compensation plan requirements in the approximate amount of \$170 million during the remainder of 2009.

## **8. EARNINGS PER COMMON SHARE**

As of January 1, 2009, Schering-Plough began to treat unvested deferred stock units as participating securities in accordance with the two-class method in the calculation of both basic and diluted earnings per share. This was also applied retrospectively. The effect of the retrospective application of this method was not material to Schering-Plough's earnings per share in 2008.

Table of Contents**SCHERING-PLOUGH CORPORATION AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following tables summarize the components of basic and diluted earnings per common share computations.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
	(Dollars in millions)			
<u>Reconciliation of undistributed earnings:</u>				
Net income available to common shareholders	\$ 477	\$ 576	\$ 1,878	\$ 1,276
Less: Dividends on common stock	106	106	318	317
Less: Dividends on unvested participating securities	1	1	4	3
Undistributed earnings(1)	\$ 370	\$ 469	\$ 1,556	\$ 956

	Three Months Ended September 30, 20092008		Nine Months Ended September 30, 20092008	
	(Dollars and shares in millions)			
<u>Basic earnings per common share computation:</u>				
Net income available to common shareholders	\$ 477	\$ 576	\$ 1,878	\$ 1,276
Less: Dividend equivalents on unvested participating securities	1	1	4	3
Less: Undistributed earnings allocated to unvested participating securities(1)	4	5	17	11
Undistributed earnings allocated to common shareholders	\$ 472	\$ 570	\$ 1,857	\$ 1,262
EPS denominator:				
Weighted-average shares outstanding for basic earnings per common share	1,637	1,626	1,632	1,623
Basic earnings per common share	\$ 0.29	\$ 0.35	\$ 1.14	\$ 0.78

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
	<b>(Dollars and shares in millions)</b>			

Diluted earnings per common share computation:

Net income available to common shareholders	\$ 477	\$ 576	\$ 1,878	\$ 1,276
Add: Preferred stock dividends(3)				
Less: Dividend equivalents on unvested participating securities	1	1	4	3
Less: Undistributed earnings allocated to unvested participating securities(1)	4	5	17	11
	\$ 472	\$ 570	\$ 1,857	\$ 1,262

## EPS denominator calculation:

Weighted-average shares outstanding for basic earnings per common share	1,637	1,626	1,632	1,623
Dilutive effect of options(2)	12	2	7	3
Dilutive effect of preferred shares(3)				

Weighted-average shares outstanding for diluted earnings per common share	1,649	1,628	1,639	1,626
Diluted earnings per common share	\$ 0.29	\$ 0.35	\$ 1.13	\$ 0.78

Table of Contents**SCHERING-PLOUGH CORPORATION AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

- . For the three and nine months ended September 30, 2009, 17 million of unvested outstanding deferred stock units (1) and performance-based deferred stock units are considered participating securities. For the three and nine months ended September 30, 2008, 18 million of unvested outstanding deferred stock units and performance-based deferred stock units are considered participating securities. The undistributed earnings are allocated to both common shares and unvested participating securities in computing the earnings per share under the two-class method.
- (2) For the three and nine months ended September 30, 2009, 34 million and 38 million, respectively, of equivalent common shares issuable under Schering-Plough's stock incentive plans were excluded from the computation of diluted EPS because their effect would have been antidilutive. For the three and nine months ended September 30, 2008, 54 million and 53 million, respectively, of equivalent common shares issuable under Schering-Plough's stock incentive plans were excluded from the computation of diluted EPS because their effect would have been antidilutive.
- (3) For the three and nine months ended September 30, 2009, approximately 88 million and 89 million of common shares, obtainable upon conversion of Schering-Plough's 2007 mandatory convertible preferred stock were excluded from the computation of diluted earnings per share because their effect would have been antidilutive. For the three months and nine months ended September 30, 2008 approximately 91 million common shares, obtainable upon conversion of the 2007 mandatory convertible preferred stock were excluded from the computation of diluted earnings per share because their effect would have been antidilutive.

**9. COMPREHENSIVE INCOME**

Comprehensive income is comprised of the following:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
	<b>(Dollars in millions)</b>			
Net income	\$ 515	\$ 614	\$ 1,991	\$ 1,389
Foreign currency translation adjustment	341	(732)	535	(282)
Unrealized gain (loss) on investments available for sale	8	(10)	18	(15)
Total comprehensive income/(loss)	\$ 864	\$ (128)	\$ 2,544	\$ 1,092

**10. INVENTORIES**

Inventories consisted of the following:

	<b>September 30, 2009</b>	<b>December 31, 2008</b>
	<b>(Dollars in millions)</b>	
Finished products	\$ 1,126	\$ 1,212
Goods in process	1,948	1,428
Raw materials and supplies	622	679
Total inventories and inventory classified in other non-current assets	\$ 3,696	\$ 3,319

For the nine months ended September 30, 2008, \$840 million of amortization of the fair value step-up recorded as part of the OBS acquisition are included in Depreciation and amortization in the condensed consolidated statements of cash flows.

Included in Other assets (non-current) at September 30, 2009 and December 31, 2008 was \$237 million and \$205 million, respectively, of inventory not expected to be sold within one year.

## **11. GOODWILL AND OTHER INTANGIBLE ASSETS**

Goodwill was \$2,879 million at September 30, 2009 as compared to \$2,778 million at December 31, 2008. The increase was due to foreign currency translation.

Table of Contents**SCHERING-PLOUGH CORPORATION AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The components of other intangible assets, net are as follows:

	<b>September 30, 2009</b>			<b>December 31, 2008</b>		
	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Net</b>	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Net</b>
	<b>(Dollars in millions)</b>					
Patents	\$ 3,983	\$ 725	\$ 3,258	\$ 3,803	\$ 418	\$ 3,385
Trademarks and other	2,854	294	2,560	2,756	180	2,576
Licenses and other	806	643	163	796	603	193
Total other intangible assets	\$ 7,643	\$ 1,662	\$ 5,981	\$ 7,355	\$ 1,201	\$ 6,154

These intangible assets are amortized on the straight-line method over their respective useful lives. The residual value of intangible assets is estimated to be zero. Amortization expense for the three months ended September 30, 2009 and 2008 was \$139 million and \$148 million, respectively and \$401 million and \$439 million for the nine months ended September 30, 2009 and 2008, respectively. Annual amortization expenses related to these intangible assets for the years 2009 to 2013 is expected to be approximately \$535 million.

**12. BORROWINGS**

Schering-Plough's outstanding borrowings at September 30, 2009 and December 31, 2008 were as follows:

	<b>September 30, 2009</b>	<b>December 31, 2008</b>
	<b>(Dollars in millions)</b>	
<i>Short-term</i>		
Short-term borrowings and current portion of long-term debt	\$ 184	\$ 244
Current portion of capital leases	1	1
Total short-term borrowings and current portion of long-term debt	\$ 185	\$ 245
<i>Long-term</i>		
5.00% senior unsecured Euro-denominated notes due 2010	\$ 732	\$ 698
Floating rate Euro-denominated term loan due 2012	659	698
5.30% senior unsecured notes due 2013	1,248	1,247
5.375% senior unsecured Euro-denominated notes due 2014	2,194	2,090
6.00% senior unsecured notes due 2017	996	995
6.50% senior unsecured notes due 2033	1,143	1,143



6.55% senior unsecured notes due 2037	994	994
Capital leases	21	19
Other long-term borrowings	46	47
Total long-term borrowings, net of current portion	\$ 8,033	\$ 7,931

The decrease in the Floating rate Euro-denominated term loan due 2012 was due to an early principal repayment of Euro 50 million in the first quarter of 2009. No prepayment penalty was incurred relating to this principal repayment. The other changes in outstanding Euro-denominated borrowings at September 30, 2009 were due to foreign currency translation on Euro-denominated debt balances.

### 13. FINANCIAL INSTRUMENTS

The table below presents the carrying values and estimated fair values for certain of Schering-Plough's financial instruments at September 30, 2009 and December 31, 2008. Estimated fair values were determined based on market prices, where available, or dealer quotes. The carrying values of all other financial instruments, including cash and cash equivalents, approximated their estimated fair values at September 30, 2009 and December 31, 2008.

Table of Contents**SCHERING-PLOUGH CORPORATION AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

	<b>September 30, 2009</b>		<b>December 31, 2008</b>	
	<b>Carrying Value</b>	<b>Estimated Fair Value</b>	<b>Carrying Value</b>	<b>Estimated Fair Value</b>
	<b>(Dollars in millions)</b>			
<b>ASSETS:</b>				
Short-term investments	\$ 487	\$ 487	\$ 5	\$ 5
Long-term investments(1)	557	557	157	157
<b>LIABILITIES:</b>				
Short-term borrowings and current portion of long-term debt	\$ 185	\$ 185	\$ 245	\$ 245
Long-term debt	8,033	8,926	7,931	7,891

- . Long-term investments, which are included in other non-current assets, primarily consist of cash, debt and equity securities held in non-qualified trusts to fund employee benefit obligations. The related employee benefit obligations are included as liabilities in the condensed consolidated balance sheets. These assets can only be used to fund the related employee benefit obligations.

**14. FAIR VALUE MEASUREMENTS**

Schering-Plough's condensed consolidated balance sheet at September 30, 2009 includes the following assets that are measured at fair value on a recurring basis:

	<b>Total Fair Value at September 30, 2009</b>	<b>Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1) (Dollars in millions)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
<b>Assets</b>				
Securities held for employee compensation	\$ 115	\$ 115	\$	\$
Other	10	7	3	
Total assets	\$ 125	\$ 122	\$ 3	\$

At September 30, 2009 there were no liabilities that were subject to fair value measurement.

The majority of Schering-Plough's assets measured at fair value on a recurring basis are measured using unadjusted quoted prices in active markets for identical items (Level 1) as inputs, multiplied by the number of units held at the balance sheet date. As of September 30, 2009, assets with fair values measured using significant other observable inputs (Level 2) include measurements using quoted prices for identical items in markets that are not active and measurements using inputs that are derived principally from or corroborated by observable market data.

## **15. SEGMENT DATA**

Schering-Plough has three reportable segments: Prescription Pharmaceuticals, Animal Health and Consumer Health Care. The segment sales and profit data that follow are consistent with Schering-Plough's current management reporting structure. The Prescription Pharmaceuticals segment discovers, develops, manufactures and markets human pharmaceutical products. The Animal Health segment discovers, develops, manufactures and markets animal health products. The Consumer Health Care segment develops, manufactures and markets over-the-counter, foot care and sun care products, primarily in the U.S.

Table of Contents**SCHERING-PLOUGH CORPORATION AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)***Net sales by segment:*

	Three Months Ended September 30, 20092008		Nine Months Ended September 30, 20092008	
	(Dollars in millions)			
Prescription Pharmaceuticals	\$ 3,548	\$ 3,539	\$ 10,515	\$ 10,798
Animal Health	669	759	1,976	2,299
Consumer Health Care	282	278	1,048	1,057
Consolidated net sales	\$ 4,499	\$ 4,576	\$ 13,539	\$ 14,154

*Profit by segment:*

	Three Months Ended September 30, 20092008		Nine Months Ended September 30, 20092008	
	(Dollars in millions)			
Prescription Pharmaceuticals(1)	\$ 705	\$ 653	\$ 2,471	\$ 1,916
Animal Health(1)/(2)	76	222	320	141
Consumer Health Care	58	75	235	243
Corporate and other(3)	(227)	(292)	(707)	(778)
Income before income taxes	\$ 612	\$ 658	\$ 2,319	\$ 1,522

- (1) For the three months ended September 30, 2009, the Prescription Pharmaceuticals and the Animal Health segments' profits include expense of \$108 million and \$35 million, respectively, primarily related to the amortization of fair values of intangible assets acquired as part of the OBS transaction. For the nine months ended September 30, 2009, the Prescription Pharmaceuticals and the Animal Health segment's profits include expense of \$307 million and \$99 million, respectively, related to the amortization of fair values of intangible assets acquired as part of the OBS transaction. For the three months ended September 30, 2008, the Prescription Pharmaceuticals and the Animal Health segments' profits include expense of \$112 million and \$113 million, respectively, related to purchase accounting items from the OBS transaction. For the nine months ended September 30, 2008, the Prescription Pharmaceuticals segment's profit and the Animal Health segment's profits include expense of \$715 million and \$559 million, respectively, related to purchase accounting items from the OBS transaction.

- (2) For the three and nine months ended September 30, 2008, the profits of the Animal Health segment includes the gain on sale of previously announced divestitures of certain Animal Health products of \$160 million. See Note 5, Other Expense/(Income), net, for additional information.
- (3) For the three and nine months ended September 30, 2009, Corporate and other included special, merger and acquisition related charges of \$29 million and \$133 million, respectively. For the three and nine months ended September 30, 2008, Corporate and other included special and acquisition related charges of \$101 million and \$218 million, respectively.

Schering-Plough's consolidated net sales do not include sales of VYTORIN and ZETIA, which are managed in the cholesterol joint venture with Merck, as Schering-Plough accounts for this joint venture under the equity method of accounting (see Note 3, Equity Income, for additional information). The Prescription Pharmaceuticals segment includes equity income from the Merck/Schering-Plough joint venture.

Corporate and other includes interest income and expense, foreign exchange gains and losses, headquarters expenses, special, merger and acquisition-related charges and other miscellaneous items. The accounting policies used for segment reporting are the same as those described in Note 1, Summary of Significant Accounting Policies, in Schering-Plough's 2008 10-K.

Table of Contents**SCHERING-PLOUGH CORPORATION AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Sales of products comprising 10 percent or more of Schering-Plough's U.S. or international sales for the three and nine months ended September 30, 2009, were as follows:

	<b>Three Months Ended September 30, 2009</b>		<b>Nine Months Ended September 30, 2009</b>	
	<b>Amount (Dollars in millions)</b>	<b>Percentage of Applicable Sales (%)</b>	<b>Amount (Dollars in millions)</b>	<b>Percentage of Applicable Sales (%)</b>
<b>U.S.</b>				
NASONEX	\$ 151	11%	\$ 491	12%
<b>International</b>				
REMICADE	608	19%	1,691	18%

For the three and nine months ended September 30, 2009, net sales outside the U.S. totaled \$3.2 billion and \$9.3 billion, respectively. Net sales outside the U.S. approximated 70 percent and 69 percent of consolidated net sales for the three and nine months ended September 30, 2009, respectively.

Schering-Plough does not disaggregate assets on a segment basis for internal management reporting and, therefore, such information is not presented.

**16. PRODUCT LICENSES**

In December 2007, Schering-Plough and Centocor revised their distribution agreement regarding the development, commercialization and distribution of both REMICADE and SIMPONI (golimumab), extending Schering-Plough's rights to exclusively market REMICADE to match the duration of Schering-Plough's exclusive marketing rights for SIMPONI. On October 6, 2009 the European Commission approved SIMPONI as a treatment for rheumatoid arthritis and other immune system disorders in two presentations—a novel auto-injector and pre-filled syringe. As a result, Schering-Plough's marketing rights for both products extend for 15 years from the first commercial sale of SIMPONI in the EU following the receipt of pricing and reimbursement approval within the EU. After operating expenses and subject to certain adjustments, Schering-Plough currently is entitled to receive an approximately 60 percent share of profits on Schering-Plough's distribution in the Schering-Plough marketing territory. Beginning in 2010, share of profits will change over time to a 50 percent share of profits by 2014 for both products and the share of profits will remain fixed thereafter for the remainder of the term. Schering-Plough may independently develop and market SIMPONI for a Crohn's disease indication in its territories, with an option for Centocor to participate. In addition, Schering-Plough and Centocor agreed to share certain development costs relating to SIMPONI's auto-injector delivery system.

**17. LEGAL, ENVIRONMENTAL AND REGULATORY MATTERS**

Schering-Plough is involved in various claims, investigations and legal proceedings.

Schering-Plough records a liability for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. Schering-Plough adjusts its liabilities for contingencies to reflect the current best estimate of probable loss or minimum liability, as the case may be. Where no best estimate is determinable, Schering-Plough records the minimum amount within the most probable range of its liability. Expected insurance recoveries have not been considered in determining the amounts of recorded liabilities for environmental related matters.

If Schering-Plough believes that a loss contingency is reasonably possible, rather than probable, or the amount of loss cannot be estimated, no liability is recorded. However, where a liability is reasonably possible, disclosure of the loss contingency is made.

Schering-Plough reviews the status of all claims, investigations and legal proceedings on an ongoing basis, including related insurance coverages. From time to time, Schering-Plough may settle or otherwise resolve these matters on terms and conditions management believes are in the best interests of Schering-Plough. Resolution of any or all claims, investigations and legal proceedings, individually or in the aggregate, could have a material adverse effect on Schering-Plough's condensed consolidated results of operations, cash flows or financial condition.

**Table of Contents**

**SCHERING-PLOUGH CORPORATION AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Except for the matters discussed in the remainder of this Note, the recorded liabilities for contingencies at September 30, 2009, and the related expenses incurred during the three and nine months ended September 30, 2009, were not material. In the opinion of management, based on the advice of legal counsel, the ultimate outcome of these matters, except matters discussed in the remainder of this Note, is not expected to have a material impact on Schering-Plough's consolidated results of operations, cash flows or financial condition.

***AWP Litigation and Investigations***

Schering-Plough continues to respond to existing and new litigation by certain states and private payors and investigations by the Department of Health and Human Services, the Department of Justice and several states into industry and Schering-Plough practices regarding average wholesale price (AWP). Schering-Plough is cooperating with these investigations.

These litigations and investigations relate to whether the AWP used by pharmaceutical companies for certain drugs improperly exceeds the average prices paid by providers and, as a consequence, results in unlawful inflation of certain reimbursements for drugs by state programs and private payors that are based on AWP. The complaints allege violations of federal and state law, including fraud, Medicaid fraud and consumer protection violations, among other claims. In the majority of cases, the plaintiffs are seeking class certifications. In some cases, classes have been certified. The outcome of these litigations and investigations could include substantial damages, the imposition of substantial fines, penalties and injunctive or administrative remedies.

***Securities and Class Action Litigation***

***Federal Securities Litigation***

Following Schering-Plough's announcement that the FDA had been conducting inspections of Schering-Plough's manufacturing facilities in New Jersey and Puerto Rico and had issued reports citing deficiencies concerning compliance with current Good Manufacturing Practices, several lawsuits were filed against Schering-Plough and certain named officers. These lawsuits allege that the defendants violated the federal securities law by allegedly failing to disclose material information and making material misstatements. Specifically, they allege that Schering-Plough failed to disclose an alleged serious risk that a new drug application for CLARINEX would be delayed as a result of these manufacturing issues, and they allege that Schering-Plough failed to disclose the alleged depth and severity of its manufacturing issues. These complaints were consolidated into one action in the U.S. District Court for the District of New Jersey, and a consolidated amended complaint was filed on October 11, 2001, purporting to represent a class of shareholders who purchased shares of Schering-Plough stock from May 9, 2000 through February 15, 2001. The complaint seeks compensatory damages on behalf of the class. The Court certified the shareholder class on October 10, 2003. Notice of pendency of the class action was sent to members of that class in July 2007. On February 18, 2009 the Court signed an order preliminarily approving a settlement agreement. The proposed settlement agreement was presented to the Court on June 1, 2009. The Court took the settlement agreement under advisement.

***ERISA Litigation***

On March 31, 2003, Schering-Plough was served with a putative class action complaint filed in the U.S. District Court in New Jersey alleging that Schering-Plough, Schering-Plough's Employee Savings Plan (Plan) administrator, several



current and former directors, and certain former corporate officers breached their fiduciary obligations to certain participants in the Plan. The complaint seeks damages in the amount of losses allegedly suffered by the Plan. The complaint was dismissed on June 29, 2004. The plaintiffs appealed. On August 19, 2005 the U.S. Court of Appeals for the Third Circuit reversed the dismissal by the District Court and the matter has been remanded back to the District Court for further proceedings. On September 30, 2008, the District Court entered an order granting in part, and denying in part, the named putative class representative's motion for class certification. Schering-Plough thereafter petitioned the United States District Court of Appeals for the Third Circuit for leave to appeal the class certification decision. Schering-Plough's petition was granted on December 10, 2008 and the appeal is currently pending before the Third Circuit.

**Table of Contents**

**SCHERING-PLOUGH CORPORATION AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*K-DUR Antitrust Litigation*

Schering-Plough had settled patent litigation with Upsher-Smith, Inc. (Upsher-Smith) and ESI Lederle, Inc. (Lederle) relating to generic versions of K-DUR, Schering-Plough's long-acting potassium chloride product supplement used by cardiac patients, for which Lederle and Upsher Smith had filed Abbreviated New Drug Applications. Following the commencement of an FTC administrative proceeding alleging anti-competitive effects from those settlements (which has been resolved in Schering-Plough's favor), alleged class action suits were filed in federal and state courts on behalf of direct and indirect purchasers of K-DUR against Schering-Plough, Upsher-Smith and Lederle. These suits claim violations of federal and state antitrust laws, as well as other state statutory and common law causes of action. These suits seek unspecified damages. In February 2009, a special master recommended that the U.S. District Court for the District of New Jersey dismiss the class action lawsuits on summary judgment. The U.S. District Court judge has not yet ruled on the recommendation.

*Third-party Payor Actions*

Several purported class action litigations have been filed following the announcement of the settlement of the Massachusetts Investigation. Plaintiffs in these actions seek damages on behalf of third-party payors resulting from the allegations of off-label promotion and improper payments to physicians that were at issue in the Massachusetts Investigation.

*Litigation and Investigations relating to the Merck/Schering-Plough Cholesterol Joint Venture*

*Background.* In January 2008, the Merck/Schering-Plough Cholesterol Joint Venture announced the results of the ENHANCE clinical trial (Effect of Combination Ezetimibe and High-Dose Simvastatin vs. Simvastatin Alone on the Atherosclerotic Process in Patients with Heterozygous Familial Hypercholesterolemia). In July 2008 the Merck/Schering-Plough Cholesterol Joint Venture announced the results of the SEAS clinical trial (Simvastatin and Ezetimibe in Aortic Stenosis). Litigation and investigations with respect to matters relating to these clinical trials have been disclosed in prior filings.

Schering-Plough is cooperating fully with the various investigations and responding to the requests for information, and Schering-Plough intends to vigorously defend the lawsuits that have been filed relating to the ENHANCE study.

*Investigations and Inquiries.* Through the date of filing this 10-Q, Schering-Plough, the Cholesterol Joint Venture and/or its joint venture partner, Merck, received a number of governmental inquiries and have been the subject of a number of investigations and inquiries relating to the ENHANCE clinical trial. These include several letters from Congress, including the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, 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 Merck/Schering-Plough Cholesterol Joint Venture's ENHANCE clinical trial. These also include several subpoenas from state officials, including State Attorneys General, and requests for information from U.S. Attorneys and the Department of Justice seeking similar information and documents. In addition, Schering-Plough received letters from the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce seeking certain information and documents related to the SEAS clinical trial, and other matters. Schering-Plough, Merck and the Joint Venture are cooperating with these investigations and responding to the inquiries.

In January 2008, after the initial release of ENHANCE data, the FDA stated that it would review the results of the ENHANCE trial. On January 8, 2009 the FDA announced the results of its review. The FDA stated that following two years of treatment,

Carotid artery thickness increased by 0.011 mm in the VYTORIN group and by 0.006 mm in the simvastatin group. The difference in the changes in carotid artery thickness between the two groups was **not** statistically significant.

The levels of LDL cholesterol decreased by 56% in the VYTORIN group and decreased by 39% in the simvastatin group. The difference in the reductions in LDL cholesterol between the two groups **was** statistically significant.

**Table of Contents**

**SCHERING-PLOUGH CORPORATION AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The FDA also stated that the results from ENHANCE do not change its position that an elevated LDL cholesterol is a risk factor for cardiovascular disease and that lowering LDL cholesterol reduces the risk for cardiovascular disease. The FDA also stated that pending the results of the IMPROVE-IT clinical trial, patients should not stop taking VYTORIN or other cholesterol lowering medications and should talk to their doctors if they have any questions.

*Litigation.* Schering-Plough continues to respond to existing and new litigation, including civil class action lawsuits alleging common law and state consumer fraud claims in connection with Schering-Plough's sale and promotion of the Merck/Schering-Plough joint venture products VYTORIN and ZETIA; several putative shareholder securities class action lawsuits (where several officers are also named defendants) alleging false and misleading statements and omissions by Schering-Plough and its representatives related to the timing of disclosures concerning the ENHANCE results, allegedly in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934; a putative shareholder securities class action lawsuit (where several officers and directors are also named), alleging material misstatements and omissions related to the ENHANCE results in the offering documents in connection with Schering-Plough's 2007 securities offerings, allegedly in violation of the Securities Act of 1933, including Section 11; several putative class action suits alleging that Schering-Plough and certain officers and directors breached their fiduciary duties under ERISA and seeking damages in the amount of losses allegedly suffered by the Plans; a Shareholder Derivative Action alleging that the Board of Directors breached its fiduciary obligations relating to the timing of the release of the ENHANCE results; and a letter on behalf of a single shareholder requesting that the Board of Directors investigate the allegations in the litigation described above and, if warranted, bring any appropriate legal action on behalf of Schering-Plough.

On July 15, 2009, Schering-Plough and Merck announced a settlement with a multistate group of 36 Attorneys General that was investigating whether the companies violated state consumer protection laws in connection with the ENHANCE clinical trial or the promotion and marketing of VYTORIN. As part of the civil resolution of these investigations, the companies agreed to reimburse the 35 states and the District of Columbia for their collective investigative costs, which totaled \$5.4 million. The payments under this settlement were made by the Merck/Schering-Plough Pharmaceuticals cholesterol joint venture. The settlement agreement does not require any further payment.

With respect to VYTORIN and ZETIA, the agreement also includes voluntary assurances of compliance by the companies, including assurances that the companies will continue to comply with various laws and regulations, such as the U.S. Food and Drug Administration (FDA) Amendments Act, the Food, Drug and Cosmetic Act, and various laws requiring truthful and non-misleading marketing of products. The agreement is not an admission by the companies of any misconduct or liability.

On August 5, 2009, Schering-Plough, Merck and the cholesterol joint venture entered into settlement agreements resolving for a total fixed amount of \$41.5 million, civil class action litigation relating to the purchase or use of VYTORIN and ZETIA. The cholesterol joint venture recorded these charges in the second quarter 2009.

The settlements resolve all but one of the class action lawsuits (including claims for attorneys' fees, costs and nongovernmental liens) that seek economic damages related to the purchase of VYTORIN and ZETIA. The settlements were reached with plaintiffs seeking to represent proposed classes of consumers, insurers and other entities and with a separate group of independently represented health plans that purchased, used or paid money

towards the purchase of VYTORIN or ZETIA from the time of the products' introduction to the market. The agreement with the proposed classes is subject to court approval and certain conditions related to participation. The agreement with the independently represented health plans is not a class settlement and does not require court approval.

*Legal Proceedings Related to the Merck Combination*

*Class Action Suits.* Since the announcement of the proposed combination, several putative class action lawsuits seeking to enjoin the merger, among other things, have been filed on behalf of shareholders of Schering-Plough in federal and state court.

**Table of Contents**

**SCHERING-PLOUGH CORPORATION AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

On April 30, 2009, the federal actions were consolidated. On July 23, 2009, Schering-Plough entered into an agreement regarding a settlement of the consolidated federal class action for certain disclosures relating to the proposed merger. See Schering-Plough's Form 8-K filed July 24, 2009. The agreement to make the additional disclosures does not constitute an acknowledgment that the additional disclosures are required under any applicable state or federal law, statute, rule or regulation. The parties also agreed that plaintiffs' counsel may apply to the Court for an award of attorneys' fees and costs.

Two additional putative class action complaints have been filed on behalf of public shareholders of Merck. On June 4, 2009, plaintiffs filed a consolidated class action complaint seeking, among other things, class action status, an order preliminarily and permanently enjoining the proposed combination, rescission of the combination if it is consummated, and attorneys' fees and expenses. On July 23, 2009, Schering-Plough and Merck entered into an agreement regarding a settlement of these consolidated actions for certain disclosures relating to the proposed merger which had previously been made. The agreement to make the additional disclosures does not constitute an acknowledgment that the additional disclosures are required under any applicable state or federal law, statute, rule or regulation. The parties also agreed that plaintiffs' counsel may apply to the court for an award of attorneys' fees and costs.

*Centocor Distribution Agreement.* On May 27, 2009, Centocor, a wholly owned subsidiary of Johnson & Johnson, delivered to Schering-Plough a notice initiating an arbitration proceeding to resolve whether, as a result of the proposed merger between Schering-Plough and Merck, Centocor is permitted to terminate Schering-Plough's rights to distribute and commercialize REMICADE and golimumab (SIMPONI) in certain territories. The arbitration process involves a number of steps, including the selection of an independent arbitrator, information exchanges and hearings, before a final decision will be reached. The arbitration process is expected to continue in 2010.

***Tax Matters***

In October 2001, IRS auditors asserted that two interest rate swaps that Schering-Plough entered into with an unrelated party should be recharacterized as loans from affiliated companies, resulting in additional tax liability for the 1991 and 1992 tax years. In September 2004, Schering-Plough made payments to the IRS in the amount of \$194 million for income tax and \$279 million for interest. Schering-Plough filed refund claims for the tax and interest with the IRS in December 2004. Following the IRS's denial of Schering-Plough's claims for a refund, Schering-Plough filed suit in May 2005 in the U.S. District Court for the District of New Jersey for refund of the full amount of the tax and interest. On August 28, 2009, the District Court ruled in the Government's favor. Schering-Plough is considering its options, including appealing the decision. Schering-Plough's tax reserves were adequate to cover the above-mentioned payments.

***Pending Administrative Obligations***

In connection with the settlement of an investigation with the U.S. Department of Justice and the U.S. Attorney's Office for the Eastern District of Pennsylvania, Schering-Plough entered into a five-year corporate integrity agreement (CIA). The CIA was amended in August 2006 in connection with the settlement of the Massachusetts Investigation, commencing a new five-year term. Failure to comply with the obligations under the CIA could result in financial penalties. To date, Schering-Plough believes it has complied with its obligations.

***Other Matters***

***Products Liability***

Beginning in May 2007, a number of complaints were filed in various jurisdictions asserting claims against Organon USA, Inc., Organon Pharmaceuticals USA, Inc., Organon International (Organon), and Schering-Plough Corporation arising from Organon's marketing and sale of NUVARING, a combined hormonal contraceptive vaginal ring. The plaintiffs contend that Organon and Schering-Plough failed to adequately warn of the alleged increased risk of venous thromboembolism (VTE) posed by NUVARING, and/or downplayed the risk of VTE. The plaintiffs seek damages for injuries allegedly sustained from their product use, including some alleged

**Table of Contents**

**SCHERING-PLOUGH CORPORATION AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

deaths, heart attacks and strokes. The majority of the cases are currently pending in a federal Multidistrict litigation venued in Missouri and in New Jersey state court. Other cases are pending in other states.

*French Matter*

Based on a complaint to the French competition authority from a competitor in France and pursuant to a court order, the French competition authority has obtained documents from a French subsidiary of Schering-Plough relating to SUBUTEX, one of the products that the subsidiary markets and sells. Any resolution of this matter adverse to the French subsidiary could result in the imposition of civil fines and injunctive or administrative remedies. On July 17, 2007, the Juge des Libertés et de la Détention ordered the annulment of the search and seizure on procedural grounds. On July 19, 2007, the French authority appealed the order to the French Supreme Court. On May 20, 2009, the French Supreme Court overturned that annulment and remanded the case to the Paris Court of Appeal on the basis that the Juge des Libertés et de la Détention had not examined each document to assess whether it should have been seized and whether it had been lawfully seized. The case is now pending before the Paris Court of Appeal.

In April 2007, the competitor also requested interim relief, a portion of which was granted by the French competition authority in December 2007. The interim relief required Schering-Plough's French subsidiary to publish in two specialized newspapers information including that the generic has the same quantitative and qualitative composition and the same pharmaceutical form as, and is substitutable for, SUBUTEX. In February 2008, the Paris Court of Appeal confirmed the decision of the French competition authority. In January 2009, the French Supreme Court confirmed the decision of the French competition authority.

*Environmental*

Schering-Plough has responsibilities for environmental cleanup under various state, local and federal laws, including the Comprehensive Environmental Response, Compensation and Liability Act, commonly known as Superfund. At several Superfund sites (or equivalent sites under state law), Schering-Plough is alleged to be a potentially responsible party (PRP). Schering-Plough believes that it is remote at this time that there is any material liability in relation to such sites. Schering-Plough estimates its obligations for cleanup costs for Superfund sites based on information obtained from the federal Environmental Protection Agency (EPA), an equivalent state agency and/or studies prepared by independent engineers, and on the probable costs to be paid by other PRPs. Schering-Plough records a liability for environmental assessments and/or cleanup when it is probable a loss has been incurred and the amount can be reasonably estimated.

**18. MERGER AGREEMENT WITH MERCK & CO., INC.**

On March 9, 2009 Merck & Co., Inc. (Merck) and Schering-Plough announced that their Boards of Directors had unanimously approved a definitive merger agreement under which Merck and Schering-Plough will combine, under the name Merck, in a stock and cash transaction. The merger agreement was filed as an exhibit to Schering-Plough's Form 8-K dated March 11, 2009. The merger was approved by shareholders of Schering-Plough and Merck on August 7, 2009.

Under the terms of the agreement, Schering-Plough shareholders will receive 0.5767 shares and \$10.50 in cash for each share of Schering-Plough. Each Merck share will automatically become a share of the combined company.



The transaction is subject to the satisfaction of customary closing conditions and regulatory approvals, including expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, as well as clearance by certain other foreign jurisdictions. On October 22, 2009 Merck and Schering-Plough received clearance for the transaction from the European Commission under the EC Merger Regulation. Merck and Schering-Plough expect to complete the transaction in the fourth quarter of 2009.

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Shareholders of Schering-Plough Corporation

We have reviewed the accompanying condensed consolidated balance sheet of Schering-Plough Corporation and subsidiaries (the Company) as of September 30, 2009, and the related statements of condensed consolidated operations for the three and nine-month periods ended September 30, 2009 and 2008, and the statements of condensed consolidated cash flows for the nine-month periods ended September 30, 2009 and 2008. These interim financial statements are the responsibility of the Company's management.

We conducted our reviews in accordance with the standards of the Public Company Accounting Oversight Board (United States). A review of interim financial information consists principally of applying analytical procedures and making inquiries of persons responsible for financial and accounting matters. It is substantially less in scope than an audit conducted in accordance with the standards of the Public Company Accounting Oversight Board (United States), the objective of which is the expression of an opinion regarding the financial statements taken as a whole. Accordingly, we do not express such an opinion.

Based on our reviews, we are not aware of any material modifications that should be made to such condensed consolidated interim financial statements for them to be in conformity with accounting principles generally accepted in the United States of America.

We have previously audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of the Company as of December 31, 2008, and the related statements of consolidated operations, shareholders' equity, and cash flows for the year then ended (not presented herein); and in our report dated February 27, 2009, we expressed an unqualified opinion on those consolidated financial statements and included an explanatory paragraph regarding the Company's adoption of Statement of Financial Accounting Standards (SFAS) No. 158, *Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans* and Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*. In our opinion, the information set forth in the accompanying condensed consolidated balance sheet as of December 31, 2008 is fairly stated, in all material respects, in relation to the consolidated balance sheet from which it has been derived.

/s/ Deloitte & Touche LLP

Parsippany, New Jersey  
October 29, 2009

**Table of Contents**

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

**EXECUTIVE OVERVIEW**

***Overview of Schering-Plough***

Schering-Plough is an innovation-driven science-centered global health care company. Schering-Plough discovers, develops and manufactures pharmaceuticals for three customer markets – prescription, animal health, and consumer. While most of the research and development activity is directed toward prescription products, there are important applications of this central research and development platform into the animal health products and the consumer health care products. Schering-Plough also accesses external innovation via partnering, in-licensing and acquisition for all three customer markets.

***Strategy Focused on Science***

In 2003, soon after Fred Hassan was elected as Chairman of the Board and Chief Executive Officer of Schering-Plough Corporation, he initiated a six-to-eight year strategic plan, called the Action Agenda. A key component of the Action Agenda is applying science to meet unmet medical needs. A core strategy of Schering-Plough is to invest substantial funds in scientific research with the goal of creating therapies and treatments that address important unmet medical needs and also have commercial value. Consistent with this core strategy, Schering-Plough has increased its investment in research and development. Schering-Plough has been successful in advancing the pipeline and has several late-stage projects that will require sizable resources to complete. Schering-Plough continues to develop the later-phase pipeline compounds (e.g., sugammadex in the U.S., thrombin receptor antagonist, vicriviroc and boceprevir), and its progressing early pipeline includes drug candidates across a wide range of therapeutic areas.

Another key component of the Action Agenda is the focus on building long-term value for shareholders and for the patients who rely upon Schering-Plough's drugs. This longer-term focus includes concurrent emphasis on growing sales, disciplined cost controls and investing in research and development for the future. Schering-Plough's geographic diversity adds to growth and makes performance less sensitive to any one geographic area.

Early on, Hassan, and the new management team that he recruited, applied the Action Agenda to stabilizing, repairing and turning around Schering-Plough after Schering-Plough encountered challenges earlier this decade under a prior management team. Currently, Schering-Plough continues work in the fourth of five phases of the Action Agenda. During the fourth, or Build the Base phase, Schering-Plough continues to focus on its strategy of value creation across a broad front.

As part of the Action Agenda, Schering-Plough continues to work to enhance infrastructure, upgrade processes and systems and strengthen talent. While these efforts are being implemented on a companywide basis, Schering-Plough is focusing especially on research and development to support Schering-Plough's science-based business.

In April 2008, Schering-Plough announced the Productivity Transformation Program (PTP). The goal of this program is to create a leaner, stronger company to support Schering-Plough's goal of building long-term high performance despite the current challenging pharmaceutical industry environment and the particular challenges facing Schering-Plough. This program targets savings of \$1.5 billion on an annualized basis by 2012 and is designed to reduce and avoid costs, while increasing productivity. Of the total targeted savings, approximately \$1.25 billion are anticipated to be accomplished by the end of 2010. The balance of the cost savings are anticipated to be achieved by 2012. Schering-Plough believes it is on track to achieve targeted savings. During 2009, actions have begun to create

greater efficiency in the global supply chain. Beyond this program, Schering-Plough anticipates investing in new high-priority clinical trials, the pursuit of strategic opportunities, including product launches and anticipates natural cost growth.

The pharmaceutical industry is under increasing political and regulatory pressure, particularly in the United States. The strength Schering-Plough built during the earlier phases of the Action Agenda, including the diversified group of products, customer segments, and geographic areas, as well as its highly experienced executive team, will be helpful in weathering current and future challenges.

On March 9, 2009, Schering-Plough and Merck announced that their Board of Directors unanimously approved a definitive merger agreement under which Merck and Schering-Plough will combine, under the name Merck, in a stock and cash transaction. The terms of the proposed combination and other information about both

## **Table of Contents**

companies are included in the Form S-4 (Registration No. 333-159371) declared effective June 24, 2009. The merger was approved by shareholders of Schering-Plough and Merck on August 7, 2009. Among the anticipated strengths of the combined company discussed in the S-4 is the focus of both companies' cultures on scientific innovation. Unless stated otherwise, all forward-looking information contained in this Management's Discussion and Analysis of Financial Condition and Results of Operations does not take into account or give any effect to the impact of Schering-Plough's planned combination with Merck. See Note 18 to Schering-Plough's condensed consolidated financial statements, Merger Agreement with Merck & Co., Inc. in this 10-Q.

### ***Results and Highlights for the three and nine months ended September 30, 2009:***

Schering-Plough's net sales for the three months ended September 30, 2009 totaled \$4.5 billion, down 2 percent as compared to the third quarter of 2008, reflecting 4 percent operational growth and an unfavorable impact from foreign exchange of 6 percent. For the nine months ended September 30, 2009, net sales were \$13.5 billion, a 4 percent decrease compared to the nine months ended September 30, 2008, including an estimated unfavorable impact of 8 percent from foreign exchange.

For the three and nine months ended September 30, 2009, net sales outside the U.S. totaled \$3.2 billion and \$9.3 billion, respectively. This approximated 70 percent and 69 percent of consolidated net sales for the three and nine months ended September 30, 2009, respectively.

Net income available to common shareholders for the three and nine months ended September 30, 2009 was \$477 million and \$1.9 billion, respectively.

Global sales of Schering-Plough's cholesterol franchise products, VYTORIN and ZETIA, declined 5 percent in the third quarter of 2009 to \$1.1 billion, reflecting a 2 percent operational decrease and a 3 percent unfavorable impact from foreign exchange. Sales declined 10 percent in the U.S. In international markets, sales increased 3 percent, reflecting operational growth of 10 percent and a 7 percent unfavorable impact from foreign exchange. Global sales of Schering-Plough's cholesterol franchise products, VYTORIN and ZETIA, declined 12 percent in the first nine months of 2009 to \$3.1 billion, reflecting a 7 percent operational decrease and a 5 percent unfavorable impact from foreign exchange. Sales declined 18 percent in the U.S. In international markets, sales declined 1 percent, reflecting operational growth of 11 percent and a 12 percent unfavorable impact from foreign exchange. ZETIA in Japan, sold under a co-marketing agreement with Bayer, contributed \$47 million and \$119 million for the three and nine months ended September 30, 2009, respectively, as compared to \$24 million and \$47 million for the three and nine months ended September 30, 2008, respectively.

Equity income was \$387 million for the three months ended September 30, 2009 as compared to \$434 million for the same period in 2008. For the nine months ended September 30, 2009, equity income totaled \$1.2 billion, as compared to \$1.4 billion for the same period in 2008.

## **Strategic Alliances**

As is typical in the pharmaceutical industry, Schering-Plough licenses manufacturing, marketing and/or distribution rights to certain products to others, and also manufactures, markets and/or distributes products owned by others pursuant to licensing and joint venture arrangements. Any time that third parties are involved, there are additional factors relating to the third party and outside the control of Schering-Plough that may create positive or negative impacts on Schering-Plough. VYTORIN, ZETIA and REMICADE are subject to such arrangements and are key to Schering-Plough's current business and financial performance.

In addition, any potential strategic alternatives may be impacted by the change of control provisions in those arrangements, which could result in VYTORIN and ZETIA being acquired by Merck or REMICADE and golimumab (SIMPONI) reverting back to Centocor. The change in control provision relating to VYTORIN and ZETIA is included in the contract with Merck, filed as Exhibit 10(r) in Schering-Plough's 2008 10-K, and the change of control provision relating to REMICADE and golimumab (SIMPONI) is contained in the contract with Centocor, filed as Exhibit 10(v) in Schering-Plough's 2008 10-K. Schering-Plough believes the proposed combination with Merck will not provide for the rights to market REMICADE and golimumab (SIMPONI) reverting to Centocor, and Centocor has initiated arbitration based on Centocor's belief that the opposite is true. Refer to "Legal Proceedings Related to the Merck combination," in Part II, Item 1, "Legal Proceedings" of this 10-Q.

## **Table of Contents**

In addition, the VYTORIN and ZETIA agreements provide for the right to terminate due to bankruptcy of the other party or material breach by the other party of its obligations. The REMICADE agreement provides for the right to terminate the agreement due to insolvency or bankruptcy of the other party or material breach by the other party of its obligations.

### **Cholesterol Franchise**

Schering-Plough's cholesterol franchise products, VYTORIN and ZETIA, are managed through a joint venture between Schering-Plough and Merck for the treatment of elevated cholesterol levels in all markets outside Japan. ZETIA is Schering-Plough's novel cholesterol absorption inhibitor. VYTORIN is the combination of ZETIA and Zocor (simvastatin), a statin medication developed by Merck. The financial commitment to compete in the cholesterol-reduction market is shared with Merck, and profits from the sales of VYTORIN and ZETIA are also shared with Merck. The operating results of the joint venture with Merck are recorded using the equity method of accounting.

The cholesterol-reduction market is the single largest pharmaceutical category in the world. VYTORIN and ZETIA are competing in this market. Global total combined franchise sales of VYTORIN and ZETIA, declined 5 percent in the third quarter of 2009 to \$1.1 billion, reflecting a 2 percent operational decrease and a 3 percent unfavorable impact from foreign exchange. Sales declined 10 percent in the U.S. In international markets, sales increased 3 percent, reflecting operational growth of 10 percent and a 7 percent unfavorable impact from foreign exchange. Global sales of Schering-Plough's cholesterol franchise products, VYTORIN and ZETIA, declined 12 percent in the first nine months of 2009 to \$3.1 billion, reflecting a 7 percent operational decrease and a 5 percent unfavorable impact from foreign exchange. Sales declined 18 percent in the U.S. In international markets, sales declined 1 percent, reflecting operational growth of 11 percent and a 12 percent unfavorable impact from foreign exchange. As of September 2009, total combined prescription share for VYTORIN and ZETIA in the U.S. was down versus December 2008 from 10.1 percent to 8.3 percent. In the past, Schering-Plough's profitability has been largely dependent upon the performance of the cholesterol franchise; while performance of the cholesterol franchise is still material to Schering-Plough, as the product diversity has become stronger (through the OBS acquisition as well as development of other Schering-Plough products) the dependence on the cholesterol franchise is lessening.

Japan is not included in the joint venture with Merck. In the Japanese market, Bayer Healthcare is co-marketing Schering-Plough's cholesterol-absorption inhibitor, ZETIA, as a monotherapy and co-administered with a statin for use in patients with hypercholesterolemia, familial hypercholesterolemia or homozygous sitosterolemia. ZETIA was launched in Japan during June 2007. Schering-Plough's sales of ZETIA in Japan under the co-marketing agreement with Bayer Healthcare are recognized in net sales and included in Other Pharmaceuticals. ZETIA sales in Japan totaled \$47 million and \$119 million for the three and nine months ended September 30, 2009, respectively.

### **License Arrangements with Centocor**

REMICADE is prescribed for the treatment of inflammatory diseases such as rheumatoid arthritis, early rheumatoid arthritis, psoriatic arthritis, Crohn's disease, ankylosing spondylitis, plaque psoriasis and ulcerative colitis. REMICADE is Schering-Plough's second largest marketed pharmaceutical product line (after the cholesterol franchise). REMICADE is licensed from and manufactured by Centocor, Inc., a Johnson & Johnson company. During 2005, Schering-Plough exercised an option under its contract with Centocor for license rights to develop and commercialize golimumab (SIMPONI), a fully human monoclonal antibody. Schering-Plough has exclusive marketing rights to both products outside the U.S., Japan and certain Asian markets. In December 2007, Schering-Plough and Centocor revised their distribution agreement regarding the development, commercialization and distribution of both REMICADE and SIMPONI, extending Schering-Plough's rights to exclusively market REMICADE to match the duration of Schering-Plough's exclusive marketing rights for SIMPONI. On October 6, 2009

the European Commission approved SIMPONI as a treatment for rheumatoid arthritis and other immune system disorders in two presentations – a novel auto-injector and pre-filled syringe. As a result, Schering-Plough's marketing rights for both products extend for 15 years from the first commercial sale of SIMPONI in the EU following the receipt of pricing and reimbursement approval within the EU. After operating expenses and subject to certain adjustments, Schering-Plough currently is entitled to receive an approximately 60 percent share of profits on Schering-Plough's distribution in the Schering-Plough marketing territory. Beginning in 2010, share of profits will change over time to a 50 percent share of profits by 2014 for both products and the share of profits will remain fixed thereafter for the remainder of the term. . Schering-Plough



## **Table of Contents**

may independently develop and market SIMPONI for a Crohn's disease indication in its territories, with an option for Centocor to participate. In addition, Schering-Plough and Centocor agreed to share certain development costs relating to SIMPONI's auto-injector delivery system.

## **Manufacturing, Sales and Marketing**

Schering-Plough supports commercialized products with manufacturing, sales and marketing efforts. Schering-Plough is also moving forward with additional investments to enhance its infrastructure and business, including capital expenditures for the drug development process (where products are moved from the drug discovery pipeline to markets), information technology systems, and post-marketing studies and monitoring.

Schering-Plough continually reviews the business, including manufacturing operations, to identify actions that will enhance long-term competitiveness. However, Schering-Plough's manufacturing cost base is relatively fixed, and actions to significantly reduce Schering-Plough's manufacturing infrastructure, including specific reviews of Schering-Plough's manufacturing operations that will be made as part of the Productivity Transformation Program involve complex issues. As a result, shifting products between manufacturing plants can take many years due to construction and regulatory requirements, including revalidation and registration requirements. As part of the Productivity Transformation Program, during 2009, actions have begun to create greater efficiency in the global supply chain. Future events and decisions may lead to asset impairments or related costs.

## **Regulatory and Competitive Environment**

Schering-Plough is subject to the jurisdiction of various national, state and local regulatory agencies. Regulatory compliance is complex and costly, impacting the timing needed to bring new drugs to market and to market drugs for new indications.

Schering-Plough engages in clinical trial research in many countries around the world. Research activities must comply with stringent regulatory standards and are subject to inspection by the U.S., the EU, and local country regulatory authorities. Schering-Plough is subject to pharmacovigilance reporting requirements in many countries and other jurisdictions, including the U.S., the EU, and the EU member states. Clinical trials and post-marketing surveillance of certain marketed drugs of competitors within the industry have raised safety concerns that have led to recalls, withdrawals or adverse labeling of marketed products.

A number of intermediaries are involved between drug manufacturers, such as Schering-Plough, and patients who use the drugs. These intermediaries impact the patient's ability, and their prescribers' ability, to choose and pay for a particular drug. These intermediaries include health care providers, such as hospitals and clinics; payors and their representatives, such as employers, insurers, managed care organizations and governments; and others in the supply chain, such as pharmacists and wholesalers. Further, in the U.S., many of Schering-Plough's pharmaceutical products are subject to increasingly competitive pricing as certain of the intermediaries (including managed care groups, institutions and government agencies) seek price discounts. In most international markets, Schering-Plough operates in an environment of government-mandated cost-containment programs. Also, the pricing, sales and marketing programs and arrangements, and related business practices of Schering-Plough and other participants in the health care industry are under continued scrutiny from federal and state regulatory, investigative, prosecutorial and administrative entities.

The market for pharmaceutical products is competitive. Schering-Plough's operations may be affected by technological advances of competitors, industry consolidation, patents granted to competitors, loss of patent protection due to challenges by competitors, competitive combination products, new products of competitors, new information from clinical trials of marketed products or post-marketing surveillance and generic competition as Schering-Plough's

products mature.

## **DISCUSSION OF OPERATING RESULTS**

### ***Net Sales***

A significant portion of net sales is made to major pharmaceutical and health care product distributors and major retail chains in the U.S. Consequently, net sales and quarterly growth comparisons may be affected by fluctuations in the buying patterns of major distributors, retail chains and other trade buyers. These fluctuations may result from seasonality; pricing; wholesaler, retail and trade buying decisions; changes in overall demand factors or other factors. In addition to these fluctuations, sales of many pharmaceutical products in the U.S. are subject to increased pricing pressure from managed care groups, institutions, government agencies, and other

**Table of Contents**

groups seeking discounts. Schering-Plough and other pharmaceutical manufacturers in the U.S. market are also required to provide statutorily defined rebates to various government agencies in order to participate in the Medicaid program, veterans health care programs and other government-funded programs. The Medicare Prescription Drug Improvement and Modernization Act of 2003 contains a prescription drug benefit for individuals who are eligible for Medicare and has resulted in increased use of generics and increased purchasing power of those negotiating on behalf of Medicare recipients. In most international markets, Schering-Plough operates in an environment where governments have mandated cost-containment programs, placed restrictions on physician prescription levels and patient reimbursements, emphasized greater use of generic drugs and enacted across-the-board price cuts as methods to control costs.

Consolidated Net sales for the three months ended September 30, 2009 totaled \$4.5 billion, a decrease of \$77 million or 2 percent compared with the same period in 2008, including an estimated unfavorable impact of 6 percent from foreign exchange. For the nine months ended September 30, 2009, consolidated net sales totaled \$13.5 billion, a decrease of \$615 million or 4 percent as compared to the same period in 2008, including an estimated unfavorable impact of 8 percent from foreign exchange. For the three months and nine months ended September 30, 2009, net sales outside the U.S. totaled \$3.2 billion and \$9.3 billion, respectively. Net sales outside the U.S. approximated 70 percent and 69 percent of consolidated net sales, for the three and nine month periods ended September 30, 2009, respectively.

Net sales for the three and nine months ended September 30, 2009 and 2008 were as follows:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2009	2008	Increase (Decrease) (%)	2009	2008	Increase (Decrease) (%)
	(Dollars in millions)			(Dollars in millions)		
<b>PRESCRIPTION PHARMACEUTICALS</b>	<b>\$ 3,548</b>	<b>\$ 3,539</b>		<b>\$ 10,515</b>	<b>\$ 10,798</b>	<b>(3%)</b>
REMICADE	608	564	8%	1,691	1,627	4%
NASONEX	266	258	3%	893	876	2%
TEMODAR	278	273	2%	781	760	3%
PEGINTRON	198	235	(16%)	629	689	(9%)
CLARINEX/AERIUS	164	176	(7%)	564	630	(10%)
FOLLISTIM/PUREGON	122	142	(14%)	397	450	(12%)
NUVARING	131	118	11%	375	330	14%
CLARITIN Rx	95	87	9%	323	326	(1%)
AVELOX	70	65	7%	250	274	(9%)
INTEGRILIN	74	84	(12%)	223	236	(5%)
REBETOL	64	63	1%	197	193	2%
CAELYX	67	80	(16%)	195	232	(16%)
REMERON	74	61	21%	174	190	(8%)
ZEMURON	30	72	(59%)	95	202	(53%)
Other Pharmaceutical	1,307	1,261	4%	3,728	3,783	(1%)
<b>ANIMAL HEALTH</b>	<b>669</b>	<b>759</b>	<b>(12%)</b>	<b>1,976</b>	<b>2,299</b>	<b>(14%)</b>
<b>CONSUMER HEALTH CARE</b>	<b>282</b>	<b>278</b>	<b>2%</b>	<b>1,048</b>	<b>1,057</b>	<b>(1%)</b>
OTC	173	160	8%	590	550	7%
OTC CLARITIN	85	92	(7%)	342	350	(2%)
MIRALAX	41	31	33%	114	85	35%

Edgar Filing: SCHERING PLOUGH CORP - Form 10-Q

Other OTC	47	37	26%	134	115	16%
Foot Care	92	96	(5%)	266	286	(7%)
Sun Care	17	22	(19%)	192	221	(13%)
<b>CONSOLIDATED NET SALES</b>	<b>\$ 4,499</b>	<b>\$ 4,576</b>	<b>(2%)</b>	<b>\$ 13,539</b>	<b>\$ 14,154</b>	<b>(4%)</b>

Sales of Prescription Pharmaceuticals in the third quarter of 2009 totaled \$3.5 billion, roughly flat as compared to the third quarter of 2008. The unfavorable impact of foreign exchange on sales of Prescription Pharmaceuticals was 6 percent. Sales of Prescription Pharmaceuticals for the nine months ended September 30,

## **Table of Contents**

2009 totaled \$10.5 billion, a \$283 million or 3 percent decrease as compared to the nine months ended September 30, 2008, including an unfavorable impact of foreign exchange of 9 percent.

International net sales of REMICADE, a drug for the treatment of immune-mediated inflammatory disorders such as rheumatoid arthritis, early rheumatoid arthritis, psoriatic arthritis, Crohn's disease, ankylosing spondylitis, plaque psoriasis, and ulcerative colitis, were up \$44 million or 8 percent to \$608 million in the third quarter of 2009 and \$64 million or 4 percent to \$1.7 billion for the nine months of 2009, driven primarily by continued market growth, offset by an unfavorable impact from foreign exchange. Competitive products for the indications referred to above were introduced during 2007, 2008 and 2009. In addition, SIMPONI (golimumab), a once-monthly, subcutaneous treatment for certain inflammatory diseases, has been launched in Canada and Germany; launches in other international markets are ongoing or planned.

Global net sales of NASONEX Nasal Spray, a once-daily corticosteroid nasal spray for allergies rose \$8 million or 3 percent to \$266 million in the third quarter of 2009. Operational sales (sales excluding the impact of foreign exchange) were higher in both the U.S. and internationally as compared to the 2008 period. For the nine months ended September 30, 2009 sales increased \$17 million or 2 percent to \$893 million due to higher sales in the U.S. and international market, offset by an unfavorable impact from foreign exchange. Competitive products were introduced in 2007 and 2008.

Global net sales of TEMODAR Capsules, a treatment for certain types of brain tumors, increased \$5 million or 2 percent to \$278 million in the third quarter of 2009 and \$21 million or 3 percent to \$781 million for the nine months ended September 30, 2009 due to higher sales in both the U.S. and Japan, offset by an overall unfavorable impact from foreign exchange. TEMODAR lost exclusivity in the European Union (EU) in 2009.

Global net sales of PEGINTRON Powder for Injection, a pegylated interferon product for treating hepatitis C, decreased 16 percent to \$198 million in the third quarter of 2009. For the nine months ended September 30, 2009, PEGINTRON decreased 9 percent to \$629 million, primarily due to an unfavorable impact from foreign exchange and lower sales in the U.S.

Global net sales of CLARINEX (marketed as AERIUS in many countries outside the U.S.), for the treatment of seasonal outdoor allergies and year-round indoor allergies, decreased 7 percent to \$164 million in the third quarter of 2009 and decreased 10 percent to \$564 million in the nine months ended September 30, 2009, primarily due to an unfavorable impact from foreign exchange and lower sales in the U.S.

Global net sales of FOLLISTIM/PUREGON, a recombinant follicle-stimulating hormone for treating infertility, were \$122 million in the third quarter of 2009, a decrease of 14 percent from the prior year period. For the nine months ended September 30, 2009, global net sales decreased by 12 percent to \$397 million, compared to 2008, primarily reflecting lower demand for fertility treatments. FOLLISTIM/PUREGON lost patent exclusivity in the EU in 2009.

Global net sales of NUVARING, a contraception product, were \$131 million, in the third quarter of 2009, a 11 percent increase compared to the third quarter of 2008 and \$375 million for the nine months ended September 30, 2009, a 14 percent increase compared to 2008. This increase was primarily due to growth in the U.S.

International net sales of CLARITIN in the prescription business increased 9 percent to \$95 million in the third quarter of 2009 as compared to 2008, primarily due to higher sales in Japan. For the nine months ended September 30, 2009 net sales decreased 1 percent to \$323 million, as compared to 2008, primarily due to an unfavorable impact of foreign exchange.

Net sales of AVELOX, a fluoroquinolone antibiotic for the treatment of certain respiratory and skin infections, sold primarily in the U.S. by Schering-Plough as a result of its license agreement with Bayer, increased by \$5 million or 7 percent to \$70 million in the third quarter of 2009. For the nine months ended September 30, 2009, net sales decreased by 9 percent to \$250 million, primarily due to a weak respiratory tract infection season.

Global net sales of INTEGRILIN Injection, a glycoprotein platelet aggregation inhibitor for the treatment of patients with acute coronary syndrome, which is sold primarily in the U.S. by Schering-Plough, decreased 12 percent to \$74 million in the third quarter of 2009. For the nine months ended September 30, 2009, sales were \$223 million, a decrease of 5 percent compared to 2008.

**Table of Contents**

International net sales of CAELYX, for the treatment of ovarian cancer, metastatic breast cancer and Kaposi's sarcoma, decreased 16 percent to \$67 million and \$195 million in the three and nine months ended September 30, 2009, respectively, compared to 2008, primarily due to unfavorable foreign exchange.

Other pharmaceutical net sales include a large number of lower sales volume human prescription pharmaceutical products in the third quarter of 2009. Several of these products are sold in limited markets outside the U.S., and many are multiple-source products no longer protected by patents. These products include treatments for respiratory, cardiovascular, dermatological, infectious, oncological and other diseases.

Animal Health global net sales totaled \$669 million in the 2009 third quarter, a 12 percent decrease as compared to \$759 million in the third quarter of 2008. Excluding the unfavorable impact of foreign exchange of 7 percent, Animal Health sales would have been down by 5 percent as compared to the third quarter of 2008. The sales decline was primarily due to the overall economic environment, difficult comparisons against the 2008 launch of bluetongue vaccine as well as back orders on certain products due primarily to the ongoing integration of Animal Health manufacturing practices and quality standards. For the nine months ended September 30, 2009, Animal Health sales decreased by 14 percent from \$2.3 billion to \$2.0 billion. The Animal Health segment's sales growth rate is impacted by intense competition and the frequent introduction of generic products.

Global net sales of Consumer Health Care products, which include OTC, foot care and sun care products, for the three and nine months ended September 30, 2009 were roughly in line with the 2008 periods. Higher sales of MIRALAX and other OTC products were offset by lower sales of OTC CLARITIN, sun care and foot care products. Competition to MIRALAX was introduced in 2009. Future sales in the Consumer Health Care segment are difficult to predict because the consumer health care market is highly competitive, with heavy advertising to consumers and frequent competitive product introductions.

***Costs, Expenses and Equity Income***

A summary of costs, expenses and equity income for the three and nine months ended September 30, 2009 and 2008 is as follows:

	<b>Three Months Ended September 30,</b>			<b>Nine Months Ended September 30,</b>		
	<b>2009</b>	<b>2008</b>	<b>Increase</b>	<b>2009</b>	<b>2008</b>	<b>Increase</b>
	<b>(Dollars in millions)</b>		<b>(Decrease)</b>	<b>(Dollars in millions)</b>		<b>(Decrease)</b>
			<b>%</b>			<b>%</b>
Gross margin	61.8%	62.0%	(0.2%)	65.0%	59.1%	5.9%
Selling, general and administrative (SG&A)	\$ 1,511	\$ 1,660	(9%)	\$ 4,629	\$ 5,208	(11%)
Research and development (R&D)	913	893	2%	2,580	2,679	(4%)
Other expense/(income), net	102	(39)	N/M	297	189	57%
Special and acquisition related charges	29	101	(71%)	133	218	(39%)
Equity income from cholesterol joint venture	(387)	(434)	(11%)	(1,157)	(1,444)	(20%)

N/M Not a meaningful percentage

Substantially all the sales of cholesterol products are not included in Schering-Plough's net sales. The results of these sales are reflected in equity income from cholesterol joint venture. In addition, due to the virtual nature of the joint venture, Schering-Plough incurs substantial selling, general and administrative expenses that are not captured in Equity income but are included in Schering-Plough's statements of condensed consolidated operations. As a result, Schering-Plough's gross margin, and ratios of SG&A expenses and R&D expenses as a percentage of net sales do not reflect the benefit of the impact of the joint venture's operating results.

*Gross margin*

Gross margin decreased to 61.8 percent in the third quarter of 2009 as compared to 62 percent for the third quarter of 2008. Gross margin increased to 65.0 percent for the nine months ended September 30, 2009, as compared to 59.1 percent for the nine months ended September 30, 2008. Gross margin for the three and nine months ended September 30, 2009 was unfavorably impacted by \$186 million and \$449 million, respectively, of amortization of fair values of intangible assets and special charges in 2009. Gross margin for the three and nine months ended September 30, 2008 was unfavorably impacted by \$221 million and \$1.3 billion of purchase accounting items included in cost of sales.



**Table of Contents**

*Selling, general and administrative*

Selling, general and administrative expenses (SG&A) were \$1.5 billion in the third quarter of 2009 and \$4.6 billion in the nine months ended September 30, down 9 percent compared to the third quarter of 2008 and lower 11 percent versus the nine months ended September 30, 2008, primarily due to the impact of foreign exchange and Productivity Transformation Program actions.

*Research and development*

Research and development (R&D) spending increased 2 percent to \$913 million in the third quarter of 2009 related to higher spending for clinical trials and related activities, partially offset by the impact of foreign exchange. For the nine months ended September 30, 2009, R&D spending decreased 4 percent to \$2.6 billion as compared to 2008 due to the impact of foreign exchange, Productivity Transformation Program actions and the timing of clinical trials and related activities. Changes in R&D spending also reflect the timing of Schering-Plough's funding of both internal research efforts and research collaborations with various partners to discover and develop a steady flow of innovative products.

*Other expense/(income), net*

Schering-Plough had \$102 million of other expense/(income), net for the three months ended September 30, 2009 as compared to \$39 million of other income, net in 2008. For the nine months ended September 30, 2009 and 2008 other expense/(income), net were \$297 million and \$189 million, respectively. For the three and nine months ended September 30, 2008, Other expense/(income), net includes \$160 million of gain on sale of certain divested animal health products associated with the OBS acquisition.

*Special, merger and acquisition-related charges*

Special, merger and acquisition-related charges relate to Productivity Transformation Program activities as well as planned merger related costs. For the three and nine months ended September 30, 2009, special, merger and acquisition-related charges were \$29 million and \$133 million, respectively. The costs for the three and nine months ended September 30, 2009 included \$24 million and \$98 million, respectively, of employee termination costs. For the three and nine months ended September 30, 2008, special and acquisition-related charges were \$101 million and \$218 million, respectively.

The following table summarizes activities reflected in the condensed consolidated financial statements related to the Productivity Transformation Program, for the nine months ended September 30, 2009:

Charges Included in						
			Special, Merger and Acquisition-	Non-cash		
		Research and	Related	Total	Cash	Accrued
Cost of	Development	Charges	Charges	Payments	/(Credits)	Liability
Sales						
(Dollars in millions)						

Edgar Filing: SCHERING PLOUGH CORP - Form 10-Q

Accrued liability at January 1, 2009												\$	155
Employee termination costs	\$		\$		\$	98	\$	98	\$	(156)	\$		(58)
Asset write-offs		5						5				5	
Inventory write-offs		38						38				38	
Accelerated depreciation		12		2				14				14	
Foreign exchange and other												(4)	(4)
Total	\$	55	\$	2	\$	98	\$	155	\$	(156)	\$	53	
Accrued liability at September 30, 2009													\$ 93

**Table of Contents**

The following table summarizes activities reflected in the condensed consolidated financial statements related to the Productivity Transformation Program, for the nine months ended September 30, 2008:

	<b>Special, and Acquisition- Related Charges</b>	<b>Total Charges</b>	<b>Cash Payments (Dollars in millions)</b>	<b>Non-cash Charges</b>	<b>Accrued Liability</b>
Accrued liability at January 1, 2008					\$ 174
Employee termination costs	\$ 177	\$ 177	\$ (197)	\$ 32	12
Accrued liability at September 30, 2008					\$ 186

For the three months ended September 30, 2008, special and acquisition-related charges totaled \$101 million (\$93 million of employee termination costs and \$8 million related to OBS integration activities). For the nine months ended September 30, 2008, special and acquisition-related charges totaled \$218 million (\$177 million of employee termination costs and \$41 million related to OBS integration activities).

*Equity income*

Sales of the Merck/Schering-Plough cholesterol joint venture for the three and nine months ended September 30, 2009 totaled \$1.0 billion and \$3.0 billion, respectively, as compared to \$1.1 billion and \$3.5 billion for the three and nine months ended September 30, 2008.

Equity income from the Merck/Schering-Plough cholesterol joint venture totaled \$387 million and \$1.2 billion for the three and nine months ended September 30, 2009 as compared to \$434 million and \$1.4 billion for the three and nine months ended September 30, 2008 due primarily to decreased sales of cholesterol products.

It should be noted that Schering-Plough incurs substantial selling, general and administrative and other costs, which are not reflected in equity income from the cholesterol joint venture and instead are included in the overall cost structure of Schering-Plough.

The companies bear the costs of their own general sales forces and commercial overhead in marketing joint venture products around the world. In the U.S., Canada and Puerto Rico, the cholesterol agreements provide for a reimbursement to each company for physician details that are set on an annual basis, and in Italy, a contractual amount is included in the profit sharing calculation that is not reimbursed. In the U.S., Canada and Puerto Rico, this amount is equal to each company's agreed physician details multiplied by a contractual fixed fee. Schering-Plough reports these amounts as part of equity income from the cholesterol joint venture. These amounts do not represent a reimbursement of specific, incremental and identifiable costs for Schering-Plough's detailing of the cholesterol products in these markets. In addition, these amounts are not reflective of Schering-Plough's sales effort related to the joint venture, as Schering-Plough's sales force and related costs associated with the joint venture are generally estimated to be higher.

In the U.S. market, Schering-Plough receives a greater share of profits on the first \$300 million of annual ZETIA sales. Above \$300 million of annual ZETIA sales, Merck and Schering-Plough generally share profits equally.

Costs of the joint venture that the companies contractually share are 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 market support, market research, market expansion, a specialty sales force and physician education programs.

Certain specified research and development expenses are generally shared equally by Schering-Plough and Merck.

*Provision for Income Taxes*

Tax expense was \$97 million and \$328 million for the three and nine months ended September 30, 2009. Tax expense was \$44 million and \$133 million for the three and nine months ended September 30, 2008. The tax provision for the three and nine months ended September 30, 2009 included tax benefits of \$27 million and \$99 million, respectively, primarily related to the amortization of fair values of certain assets acquired as part of the OBS acquisition. The tax provision for the three and nine months ended September 30, 2008 included tax benefits of \$95 million and \$291 million, respectively, primarily related to the amortization of fair values of

**Table of Contents**

certain assets acquired as part of the OBS acquisition. The income tax expense primarily relates to foreign taxes and does not include any benefit related to U.S. operating losses.

Schering-Plough reported a U.S. Net Operating Loss (NOL) carryforward of approximately \$1.3 billion on its 2008 tax return, which will be available to offset future U.S. taxable income, in varying amounts, through 2028. This U.S. NOL carryforward could be materially reduced after examination of Schering-Plough's income tax returns by the Internal Revenue Service (IRS). Schering-Plough continues to maintain a valuation allowance against its U.S. deferred tax assets, as management cannot conclude that it is more likely than not the benefit of the U.S. net deferred tax assets can be realized.

**LIQUIDITY AND FINANCIAL RESOURCES*****Discussion of Cash Flow***

	<b>Nine Months Ended September 30, 2009                      2008 (Dollars in millions)</b>	
Cash flow provided by operating activities	\$ 2,624	\$ 2,575
Cash flow used for investing activities	(1,309)	(244)
Cash flow used for financing activities	(457)	(1,416)

***Operating Activities***

In the nine months ended September 30, 2009, operating activities provided \$2.6 billion of cash, consistent with net cash provided by operations of \$2.6 billion for the nine months ended September 30, 2008.

***Investing Activities***

Net cash used for investing activities during the nine months ended September 30, 2009 was \$1.3 billion and primarily relates to purchases of short-term investments of \$2.0 billion, capital expenditures of \$522 million, payments of \$367 million to non-qualified trusts designated to fund employee benefit payments related to the planned combination with Merck, partially offset by maturities of short-term investments of \$1.6 billion. Net cash used for investing activities for the nine months ended September 30, 2008 was \$244 million and included \$542 million of capital expenditures partially offset by net proceeds from the divested products of \$241 million and the disposition of property and equipment of \$33 million.

***Financing Activities***

Net cash used for financing activities was \$457 million for the nine months ended September 30, 2009, compared to \$1.4 billion of cash used for financing activities for the same period in 2008. Uses of cash for financing activities for the nine months ended September 30, 2009 and 2008 included the payment of dividends on common and preferred shares of \$431 million for both periods. Schering-Plough also paid down \$70 million of long-term debt during the nine months ended September 30, 2009.

***Other Discussion of Cash Flows***

At September 30, 2009, Schering-Plough had net debt (total debt less cash, cash equivalents and short-term investments) of approximately \$3.4 billion. Cash generated from operations and available cash and short-term investments are expected to provide Schering-Plough with the ability to fund cash needs for the intermediate term. Schering-Plough expects to fund certain deferred compensation plan requirements in the approximate amount of \$170 million during the remainder of 2009.

***Borrowings and Credit Facilities***

At September 30, 2009 and December 31, 2008, short-term borrowings and current portion of long-term debt totaled \$185 million and \$245 million, respectively.

Total debt at September 30, 2009 was \$8.2 billion, in line with the total debt balance at December 31, 2008. Total debt includes Euro-denominated notes and a Euro-denominated term loan. The total debt balance was affected by a pay down in the Euro-denominated term loan offset by the impact of foreign currency translation.

**Table of Contents**

The pay down of long-term debt included an early principal repayment of Euro 50 million (\$70 million) in the first quarter of 2009 which resulted in a decrease in the Floating rate Euro-denominated term loan due 2012. There was no prepayment penalty associated with this principal payment. The reported U.S. dollar amounts of outstanding debt balances and interest expense on the Euro-denominated term loan will fluctuate due to the impact of foreign currency translation.

Schering-Plough has a \$2.0 billion credit facility with a syndicate of banks available for general corporate purposes. This facility has a floating interest rate, matures in August 2012 and is used primarily to support Schering-Plough's commercial paper borrowings. As of September 30, 2009, no borrowings were outstanding under this facility.

Schering-Plough's current unsecured senior credit ratings and outlook are as follows:

<b>Senior Unsecured Credit Ratings</b>	<b>Long-Term</b>	<b>Short-Term</b>	<b>Long-Term Review Status</b>
Moody's Investors Service	Baa1	P-2	Stable
Standard and Poor's	A-	A-2	Stable
Fitch Ratings	BBB+	F-2	Positive

In February 2009, Moody's Investors Service changed its Long Term Review Status on Schering-Plough's credit ratings from negative outlook to stable. In March 2009, following the announcement of the proposed merger between Merck and Schering-Plough, Fitch Ratings changed its Long Term Review Status from stable outlook to positive.

From a cash perspective, Schering-Plough remains invested in highly-liquid and highly-rated securities. Schering-Plough remains focused on the credit markets and continues to closely monitor the broader financial and economic situation. Schering-Plough believes the ability of commercial paper issuers, such as Schering-Plough, with one or more short-term credit ratings of P-2 from Moody's, A-2 from S&P and/or F-2 from Fitch to issue or rollover outstanding commercial paper can, at times, be less than that of companies with higher short-term credit ratings. Further, the total amount of commercial paper capacity available to these issuers, such as Schering-Plough, is typically less than that of higher-rated companies. In addition, Schering-Plough's ability to issue commercial paper in the future is dependent on capital market conditions at that time. Schering-Plough's sizable lines of credit with commercial banks as well as cash and short-term investments held by U.S. and international subsidiaries serve as alternative sources of liquidity.

Schering-Plough's credit ratings could decline below their current levels. The impact of such decline could reduce the availability of commercial paper borrowing and would increase the interest rate on a portion of Schering-Plough's short and long-term debt. As discussed above, Schering-Plough believes that existing cash and short-term investments, available credit facilities and cash generated from operations will allow Schering-Plough to fund its cash needs for the intermediate term.

**REGULATORY AND COMPETITIVE ENVIRONMENT IN WHICH SCHERING-PLOUGH OPERATES**

Schering-Plough is subject to the jurisdiction of various national, state and local regulatory agencies. The regulations to which Schering-Plough is subject are described in more detail in Part I, Item I, "Business," of Schering-Plough's 2008 10-K. Regulatory compliance is complex, as regulatory standards (including Good Clinical Practices, Good Laboratory Practices and Good Manufacturing Practices) vary by jurisdiction and are constantly evolving. Regulatory compliance is also costly. Regulatory compliance also impacts the timing needed to bring new drugs to market and to market drugs for new indications. Further, failure to comply with regulations can result in delays in the approval of drugs, seizure or recall of drugs, suspension or revocation of the authority necessary for the production and sale of

drugs, fines and other civil or criminal sanctions.

Regulatory compliance, and the cost of compliance failures, can have a material impact on Schering-Plough's results of operations, its cash flows or financial condition.

Much is still unknown about the science of human health and with every drug there are benefits and risks. Societal and governmental pressures are constantly shifting between the demand for innovation to meet urgent unmet medical needs and aversion to risk. These pressures impact the regulatory environment and the market for Schering-Plough's products.



**Table of Contents**

***Regulatory Compliance and Pharmacovigilance***

***Regulatory Inspections***

Schering-Plough is subject to pharmacovigilance reporting requirements in many countries and other jurisdictions, including the U.S., the EU, and the EU member states. The requirements differ from jurisdiction to jurisdiction, but all include requirements for reporting adverse events that occur while a patient is using a particular drug in order to alert the drug's manufacturer and the governmental agency to potential problems.

In February 2006, Schering-Plough began the Global Clinical Harmonization Program for building clinical excellence (in trial design, execution and tracking), which is strengthening Schering-Plough's scientific and compliance rigor on a global basis. In 2007, certain aspects of the Global Clinical Harmonization Program were implemented, and significant work was completed in 2008. Schering-Plough is committed to strong compliance in this area. Schering-Plough intends to continue upgrading skills, processes and systems in clinical practices and pharmacovigilance. Schering-Plough remains committed to accomplish this work and to invest significant resources in this area.

Like other pharmaceutical companies, Schering-Plough is subject to inspections by the FDA, the EMEA and other regulatory authorities. Possible actions include demands for improvements in reporting systems, criminal sanctions against Schering-Plough and/or responsible individuals and changes in the conditions of marketing authorizations for Schering-Plough's products.

***Regulatory Compliance and Post-Marketing Surveillance***

Schering-Plough engages in clinical trial research in many countries around the world. These clinical trial research activities must comply with stringent regulatory standards and are subject to inspection by U.S., EU and local country regulatory authorities. Failure to comply with current Good Clinical Practices or other applicable laws or regulations can result in delays in approval of clinical trials, suspension of ongoing clinical trials, delays in approval of marketing authorizations, criminal sanctions against Schering-Plough and/or responsible individuals, financial penalties, and changes in the conditions of marketing authorizations for Schering-Plough's products.

Clinical trials and post-marketing surveillance of certain marketed drugs of competitors within the industry have raised safety concerns that have led to recalls, withdrawals or adverse labeling of marketed products. In addition, these situations have raised concerns among some prescribers and patients relating to the safety and efficacy of pharmaceutical products in general. For the past several years, these occurrences have increased. In 2008, the intense media attention to the results of the ENHANCE clinical trial led to some concerns among patients and prescribers about ZETIA and VYTORIN (see discussion under Item 1, Financial Statements, Note 17, Legal, Environmental and Regulatory Matters—Litigation and Investigations relating to the Merck/Schering-Plough Cholesterol Joint Venture).

Following this wave of product withdrawals by other companies and other significant safety issues, health authorities such as the FDA, the EMEA and the PMDA have continued to increase their focus on safety when assessing the benefit/risk balance of drugs. The FDA, in particular, was granted new legislative authority in 2007 which included several provisions focused on drug safety and pharmacovigilance, including the ability to mandate labeling changes and require post-approval evaluations and studies. In addition, some health authorities appear to have become more cautious when making decisions about approvability of new products or indications and are re-reviewing select products that are already marketed, adding further to the uncertainties and potential delays in the regulatory approval processes. There also continues to be significant regulatory and legislative scrutiny, especially in the U.S., on advertising and promotion and in particular direct-to-consumer advertising.

Similarly, major health authorities, including the FDA, EMEA and PMDA, have also increased collaboration amongst themselves, especially with regard to the evaluation of safety and benefit/risk information. Media attention has also increased. In the current environment, a health authority regulatory action in one market, such as a safety labeling change, may have regulatory, prescribing and marketing implications in other markets to an extent not previously seen.

Some health authorities, such as the PMDA in Japan, have publicly acknowledged a significant backlog in workload due to resource constraints within their agency. Schering-Plough has recently received regulatory approvals for two products in Japan. However, for pending and new applications, the backlog makes timelines difficult to predict. While the PMDA has committed to correcting the backlog and has made some progress over the last two years, it is expected to continue for the foreseeable future.

## **Table of Contents**

These and other uncertainties inherent in government regulatory approval processes, including, among other things, delays in approval of new products, formulations or indications, new state marketing regulations, may also affect Schering-Plough's operations. The effect of regulatory approval processes on operations cannot be predicted.

Schering-Plough has nevertheless achieved a significant number of important regulatory approvals since 2004, including approvals for VYTORIN, BRIDION (in Europe), SIMPONI, SAPHRIS, NOXAFIL, CLARINEX D-24, CLARINEX REDITABS, CLARINEX D-12, SUBOXONE and new indications for TEMODAR and NASONEX. Since 2004, other significant approvals include ASMANEX DPI (Dry Powder for Inhalation) in the U.S., ASMANEX, PEGINTRON, ZETIA, TEMODAR, ESMERON/ESLAX, NASONEX, GANIREST and REMERON in Japan, and new indications for REMICADE. Schering-Plough also has a number of significant regulatory submissions filed in major markets awaiting approval, including sugammadex in the U.S.

Schering-Plough's personnel have regular, open dialogue with the FDA, EMEA and other regulators and review product labels and other materials on a regular basis and as new information becomes known.

### ***Regulatory Reform***

In the U.S., the Obama Administration has announced that health care reform, including regulation of pharmaceutical companies and their products, is a priority. A Secretary of the Department of Health and Human Services and an FDA Commissioner were confirmed in 2009. These individuals may initiate changes.

In addition, several states (e.g. California, Maine, Massachusetts, Minnesota, Nevada, Vermont, West Virginia) have enacted regulations that restrict certain sales and marketing activities and/or require tracking and disclosure of payments and other financial support to healthcare professionals. The regulations will impact certain marketing practices and potentially increase the cost of compliance. Similar regulations may be proposed by additional states and by the federal government.

The impact of such actions, as well as budget pressures on federal and state governments in the U.S., and potential changes in U.S. tax laws, cannot be predicted at this time.

### ***Pricing Pressures***

As described more specifically in Note 17, Legal, Environmental and Regulatory Matters, under Item 1, Financial Statements, the pricing, sales and marketing programs and arrangements, and related business practices of Schering-Plough and other participants in the health care industry are under increasing scrutiny from federal and state regulatory, investigative, prosecutorial and administrative entities. These entities include the Department of Justice and its U.S. Attorney's Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the FTC and various state Attorneys General offices. Many of the health care laws under which certain of these governmental entities operate, including the federal and state anti-kickback statutes and statutory and common law false claims laws, have been construed broadly by the courts and permit the government entities to exercise significant discretion. In the event that any of those governmental entities believes that wrongdoing has occurred, one or more of them could institute civil or criminal proceedings, which, if instituted and resolved unfavorably, could subject Schering-Plough to substantial fines, penalties and injunctive or administrative remedies, including exclusion from government reimbursement programs. Schering-Plough also cannot predict whether any investigations will affect its marketing practices or sales. Any such result could have a material adverse impact on Schering-Plough's results of operations, cash flows, financial condition, or its business.

In the U.S., many of Schering-Plough's pharmaceutical products are subject to increasingly competitive pricing as managed care groups, institutions, government agencies and other groups seek price discounts. For instance, third

party payors use formulary restrictions to control costs by negotiating discounted prices in exchange for inclusion in the formulary. A change in the formulary status of a product may impact the sales of that product. In the U.S. market, Schering-Plough and other pharmaceutical manufacturers are required to provide statutorily defined rebates to various government agencies in order to participate in Medicaid, the veterans health care program and other government-funded programs. The Medicare Prescription Drug Improvement and Modernization Act of 2003 contains a prescription drug benefit for individuals who are eligible for Medicare and has resulted in increased use of generics and increased purchasing power of those negotiating on behalf of Medicare recipients.

## **Table of Contents**

In most international markets, Schering-Plough operates in an environment of government mandated cost-containment programs. Several governments have placed restrictions on physician prescription levels and patient reimbursements; emphasized greater use of generic drugs; and enacted across-the-board price cuts as methods to control costs.

Since Schering-Plough is unable to predict the final form and timing of any future domestic or international governmental or other health care initiatives, including the passage of laws permitting the importation of pharmaceuticals into the U.S., their effect on operations and cash flows cannot be reasonably estimated. Similarly, the effect on operations and cash flows of future decisions of government entities, managed care groups and other groups concerning formularies and pharmaceutical reimbursement policies cannot be reasonably estimated.

## ***Competition***

The market for pharmaceutical products is competitive. Schering-Plough's operations may be affected by technological advances of competitors, industry consolidation, patents granted to competitors, competitive combination products, new products of competitors, new information from clinical trials of marketed products or post-marketing surveillance and generic competition as Schering-Plough's products mature. In addition, patent positions are increasingly being challenged by competitors, and the outcome can be highly uncertain. An adverse result in a patent dispute can preclude commercialization of products or negatively affect sales of existing products. The effect on operations of competitive factors and patent disputes cannot be predicted.

## **CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

Refer to Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, in Schering-Plough's 2008 10-K for disclosures regarding Schering-Plough's critical accounting policies and estimates.

Schering-Plough's rebate accruals for federal and state governmental programs, including Medicaid and Medicare Part D, at September 30, 2009 and 2008 were \$184 million and \$130 million, respectively. Commercial discounts, returns and other rebate accruals at September 30, 2009 and 2008 were \$402 million and \$419 million, respectively. These accruals are established in the period that the related revenue was recognized, resulting in a reduction to sales and the establishment of liabilities, which are included in total current liabilities, or in the case of returns and other receivable adjustments, an allowance provided against accounts receivable.

In the case of the governmental rebate programs, Schering-Plough's payments involve interpretations of relevant statutes and regulations. These interpretations are subject to challenges and changes in interpretive guidance by governmental authorities. The result of such a challenge or change could affect whether the estimated governmental rebate amounts are ultimately sufficient to satisfy Schering-Plough's obligations. Additional information on governmental inquiries focused in part on the calculation of rebates is contained in Note 21, Legal, Environmental and Regulatory Matters, under Item 8, Financial Statements and Supplementary Data in Schering-Plough's 2008 10-K. In addition, it is possible that, as a result of governmental challenges or changes in interpretive guidance, actual rebates could materially differ from amounts accrued.

**Table of Contents**

The following summarizes the activity in the accounts related to accrued rebates, sales returns and discounts for the nine months ended September 30, 2009 and 2008:

	<b>2009</b>	<b>2008</b>
	<b>(Dollars in millions)</b>	
Accrued rebates/returns/discounts, beginning of period	\$ 535	\$ 526
Provision for rebates	569	566
Adjustment to prior-year estimates	(10)	(7)
Payments	(551)	(544)
	8	15
Provision for returns	154	112
Purchase-accounting adjustments(1)		(9)
Adjustment to prior-year estimates	6	(4)
Returns	(108)	(91)
	52	8
Provision for discounts	690	665
Adjustment to prior-year estimates		(6)
Discounts granted	(699)	(659)
	(9)	
Accrued rebates/returns/discounts, end of period	\$ 586	\$ 549

- (1) For the nine months ended September 30, 2008, purchase-accounting adjustments include \$9 million related to the reversal of return reserves recorded as part of the purchase accounting for OBS. This reversal was recorded as a reduction to goodwill.

In formulating and recording the above accruals, management utilizes assumptions and estimates that include historical experience, wholesaler data, the projection of market conditions, the estimated lag time between sale and payment of a rebate, utilization estimates, and forecasted product demand amounts as discussed in Item 7 of Schering-Plough's 2008 10-K under Critical accounting policies and estimates Revenue Recognition.

As part of its review of these accruals, management performs a sensitivity analysis that considers differing assumptions, which are most subject to judgment in its rebate accrual calculation. Based upon Schering-Plough's sensitivity analysis, reasonably possible changes to assumptions related to rebate accruals for prior years could favorably or unfavorably impact 2009 net sales and income before taxes in an annual amount of approximately \$20 million. This sensitivity analysis excludes the potential impacts of a specific matter that involves interpretations of statutes and could have a favorable impact on net sales and income before taxes in future periods.

## DISCLOSURE NOTICE

### *Cautionary Statements Under the Private Securities Litigation Reform Act of 1995*

Management's Discussion and Analysis of Financial Condition and Results of Operations and other sections of this report, as well as other written reports and oral statements made from time to time by Schering-Plough, may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995.

Forward-looking statements do not relate strictly to historical or current facts and are based on current expectations or forecasts of future events. You can identify these forward-looking statements by their use of words such as anticipate, believe, could, estimate, expect, forecast, project, intend, plan, potential, will, and similar words. In particular, forward-looking statements include statements relating to Schering-Plough's plans; its strategies; timing and level of savings achieved from the Productivity Transformation Program; prospective products or product approvals; actions to enhance clinical, research and development, manufacturing and post-marketing systems; the potential of products and trending in therapeutic markets, including the cholesterol market; patent and other intellectual property protection; future performance or results of current and anticipated products; research and development programs and anticipated spending; estimates of rebates, discounts and returns; the outcome of contingencies such as litigation and investigations;

**Table of Contents**

and statements about the timing and potential benefits of the proposed merger between Merck and Schering-Plough and other statements that are not historical facts.

Any or all forward-looking statements here or in other publications may turn out to be wrong. There are no guarantees about Schering-Plough's financial and operational performance or the performance of Schering-Plough's stock. Schering-Plough does not assume the obligation to update any forward-looking statement. Many factors could cause actual results to differ materially from Schering-Plough'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. Although it is not possible to predict or identify all such factors, we refer you to Part II, Item 1A, "Risk Factors," of this 10-Q for identification of important factors with respect to risks and uncertainties.

**Item 3. *Quantitative and Qualitative Disclosures about Market Risk***

Schering-Plough is exposed to market risk primarily from changes in foreign currency exchange rates and, to a lesser extent, from interest rates and equity prices. The impact of currency is more pronounced on products and businesses that are concentrated in Europe.

Refer to Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," in Schering-Plough's 2008 10-K for further discussion of market risks.

**Item 4. *Controls and Procedures***

Management, including the chief executive officer and the chief financial officer, has evaluated Schering-Plough's disclosure controls and procedures as of the end of the quarterly period covered by this 10-Q and has concluded that Schering-Plough's disclosure controls and procedures are effective. They also concluded that there were no changes in Schering-Plough's internal control over financial reporting that occurred during Schering-Plough's most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, Schering-Plough's internal control over financial reporting. As part of the changing business environment in which Schering-Plough operates, Schering-Plough is replacing and upgrading a number of information systems including integrating the Organon BioSciences N.V. human and animal health businesses. The overall integration process is continuing during 2009.



**Table of Contents****PART II. OTHER INFORMATION**

The following table sets forth the United States and European Union scheduled patent expiration dates for material patents held by Schering-Plough. We refer you to *Patent Challenges Under the Hatch-Waxman Act* below for a discussion of pending Paragraph IV Certification proceedings.

<b>PRODUCT</b>	<b>PATENT EXPIRATION</b>	
	<b>US</b>	<b>EU</b>
REMICADE	No Rights	Aug 2014
NASONEX	Apr 2018	Jan 2015
TEMODAR	Feb 2014	Expired
PEGINTRON		
(Conjugate)	Jan 2015	Dec 2018
(Mature INF-alpha)	Aug 2020	Expired
ZETIA	Apr 2017	Oct 2017
VYTORIN	Apr 2017	Apr 2019
CLARINEX/AERIUS		
(Composition)	Expired	Feb 2010
(Formulation/Use)	2014-2020	Jul 2019
CLARITIN/OTC		
(Extended Release Formulation)	Oct 2012	Oct 2013
(Syrup Formulation)	Jun 2018	May 2019
FOLLISTIM/PUREGON	Jun 2015	Aug 2009
NUVARING		
(Delivery System)	Apr 2018	Apr 2018
AVELOX	Mar 2014	No Rights
INTEGRILIN	Nov 2014 – Sep 2015	No Rights
REBETOL	Expired	Expired
CAELYX	No Rights	2010
INTRON A	Aug 2020	Expired
PROVENTIL/ALBUTEROL		
(Formulation)	Jul 2010	NA
REMERON		
(ODT Formulation)	Jan 2010	Sep 2010
SUBUTEX/SUBOXONE	No Rights	Expired
ASMANEX DPI		
(Formulation)	Sep 2018	Mar 2018
ELOCON	Expired	Expired
CERAZETTE		
(Dose Regimen)	Not marketed	Dec 2012
NOXAFIL	Jul 2019	Dec 2019
IMPLANON		
(Use)	Sep 2009	NA
(Delivery system)	Expired	Jul 2013
MERCILON/MARVELON		
(Formulation)	Sep 2012	Revoked

LIVIAL	Not marketed	Mar 2010
ZEMURON	Expired	Expired
FORADIL		
(Use)	Jan 2018	No Rights
(Device)	Mar 2019	No Rights

Note: Compound patent unless otherwise noted.

**Table of Contents**

**Item 1. *Legal Proceedings***

Material pending legal proceedings involving Schering-Plough are described in Part I, Item 3, *Legal Proceedings*, of the 2008 10-K. The following discussion is limited to material developments to previously reported proceedings and new material legal proceedings, which Schering-Plough, or any of its subsidiaries, became a party during the quarter ended September 30, 2009, or subsequent thereto, but before the filing of this report. This section should be read in conjunction with Part I, Item 3, *Legal Proceedings* in the 2008 10-K.

***Patent Matters***

***Patent Challenges Under the Hatch-Waxman Act***

While Schering-Plough does not currently believe that any pending Paragraph IV certification proceeding under the Hatch-Waxman Act is material, because there is frequently media and investor interest in such proceedings, Schering-Plough is listing the pending proceedings each quarter. Currently, the following are pending:

in July 2007, Schering-Plough and its licensor, Cancer Research Technologies, Limited, filed a patent infringement action against companies seeking approval of a generic version of certain strengths of TEMODAR capsules. The trial concluded April 2, 2009. A decision has not yet been rendered;

in March 2007, Schering-Plough and an entity jointly owned with Merck filed a patent infringement action against companies seeking approval of a generic version of ZETIA;

in September 2006 and dates thereafter, Schering-Plough filed patent infringement actions against companies seeking approval of generic versions of CLARINEX Tablets, CLARINEX Reditabs, CLARINEX D24, and CLARINEX D12. Schering-Plough has settled with all defendants. Under the terms of the settlements generic versions of CLARINEX Reditabs, CLARINEX D24, and CLARINEX D12 will be launched no earlier than January 2012 and a generic version of the CLARINEX tablet will be launched no earlier than July 2012, assuming certain conditions are met;

on February 18, 2009 Schering-Plough and its licensor filed patent infringement actions against companies seeking approval of a generic version of INTEGRILIN; and

on June 30, 2009, Schering-Plough, Bayer Schering Pharma AG, and Bayer Healthcare Pharmaceuticals filed a patent infringement action against companies seeking approval of a generic version of LEVITRA.

***Securities and Class Action Litigation***

***Litigation and Investigations relating to the Merck/Schering-Plough Cholesterol Joint Venture***

On July 15, 2009, Schering-Plough and Merck announced a settlement with a multistate group of 36 Attorneys General that was investigating whether the companies violated state consumer protection laws in connection with the ENHANCE clinical trial or the promotion and marketing of VYTORIN. As part of the civil resolution of these investigations, the companies agreed to reimburse the 35 states and the District of Columbia for their collective investigative costs, which total \$5.4 million. The payments under this settlement will be made by the Merck/Schering-Plough Pharmaceuticals cholesterol joint venture. The settlement agreement does not require any further payment.

With respect to VYTORIN and ZETIA, the agreement also includes voluntary assurances of compliance by the companies, including assurances that the companies will continue to comply with various laws and regulations, such as the U.S. Food and Drug Administration (FDA) Amendments Act, the Food, Drug and Cosmetic Act, and various laws requiring truthful and non-misleading marketing of products.

On August 5, 2009, Schering-Plough, Merck and the cholesterol joint venture entered into settlement agreements resolving for a total fixed amount of \$41.5 million, civil class action litigation relating to the purchase or use of VYTORIN and ZETIA. The cholesterol joint venture recorded these charges in the second quarter 2009.

The settlements resolve all but one of the class action lawsuits (including claims for attorneys' fees, costs and nongovernmental liens) that seek economic damages related to the purchase of VYTORIN and ZETIA. The settlements were reached with plaintiffs seeking to represent proposed classes of consumers, insurers and other entities and with a separate group of independently represented health plans that purchased, used or paid money

## **Table of Contents**

towards the purchase of VYTORIN or ZETIA from the time of the products' introduction to the market. The agreement with the proposed classes is subject to court approval and certain conditions related to participation. The agreement with the independently represented health plans is not a class settlement and does not require court approval.

See Schering-Plough's 2008 10-K, Item 3, Legal Proceedings—Litigation and Investigations relating to the Merck/Schering-Plough Cholesterol Joint Venture for further information about the Merck/Schering-Plough cholesterol joint venture's ENHANCE clinical trials and related matters.

### *Legal Proceedings Related to the Merck Combination*

*Class Action Suits.* Since the announcement of the proposed combination, several putative class action lawsuits seeking to enjoin the merger, among other things, have been filed on behalf of shareholders of Schering-Plough in federal and state court.

On April 30, 2009, the federal actions were consolidated. On July 23, 2009, Schering-Plough entered into an agreement regarding a settlement of the consolidated federal class action for certain disclosures relating to the proposed merger. See Schering-Plough's Form 8-K filed July 24, 2009. The agreement to make the additional disclosures does not constitute an acknowledgment that the additional disclosures are required under any applicable state or federal law, statute, rule or regulation. The parties also agreed that plaintiffs' counsel may apply to the Court for an award of attorneys' fees and costs.

Two additional putative class action complaints have been filed on behalf of public shareholders of Merck. On June 4, 2009, plaintiffs filed a consolidated class action complaint seeking, among other things, class action status, an order preliminarily and permanently enjoining the proposed combination, rescission of the combination if it is consummated, and attorneys' fees and expenses. On July 23, 2009, Schering-Plough and Merck entered into an agreement regarding a settlement of these consolidated actions for certain disclosures relating to the proposed merger which had previously been made. The agreement to make the additional disclosures does not constitute an acknowledgment that the additional disclosures are required under any applicable state or federal law, statute, rule or regulation. The parties also agreed that plaintiffs' counsel may apply to the court for an award of attorneys' fees and costs.

*Centocor Distribution Agreement.* On May 27, 2009, Centocor, a wholly owned subsidiary of Johnson & Johnson, delivered to Schering-Plough a notice initiating an arbitration proceeding to resolve whether, as a result of the proposed merger between Schering-Plough and Merck, Centocor is permitted to terminate Schering-Plough's rights to distribute and commercialize REMICADE and golimumab (SIMPONI) in certain territories. The arbitration process involves a number of steps, including the selection of an independent arbitrator, information exchanges and hearings, before a final decision will be reached. The arbitration process is expected to continue in 2010.

### ***Tax Matters***

In October 2001, IRS auditors asserted that two interest rate swaps that Schering-Plough entered into with an unrelated party should be recharacterized as loans from affiliated companies, resulting in additional tax liability for the 1991 and 1992 tax years. In September 2004, Schering-Plough made payments to the IRS in the amount of \$194 million for income tax and \$279 million for interest. Schering-Plough filed refund claims for the tax and interest with the IRS in December 2004. Following the IRS's denial of Schering-Plough's claims for a refund, Schering-Plough filed suit in May 2005 in the U.S. District Court for the District of New Jersey for refund of the full amount of the tax and interest. On August 28, 2009, the District Court ruled in the Government's favor. Schering Plough is considering its options, including appealing the decision. Schering-Plough's tax reserves were adequate to cover the

above-mentioned payments.

**Item 1A. *Risk Factors***

Schering-Plough's future operating results and cash flows may differ materially from the results described in this 10-Q due to risks and uncertainties related to Schering-Plough's business, including those discussed below. In addition, these factors represent risks and uncertainties that could cause actual results to differ materially from those implied by forward-looking statements contained in this report.

## **Table of Contents**

***Key Schering-Plough products generate a significant amount of Schering-Plough's profits and cash flows, and any events that adversely affect the markets for its leading products could have a material and negative impact on results of operations and cash flows.***

Schering-Plough's ability to generate profits and operating cash flow depends largely upon the continued profitability of Schering-Plough's cholesterol franchise, consisting of VYTORIN and ZETIA, and other key products such as REMICADE, TEMODAR, NASONEX, PEGINTRON, CLARINEX, FOLLISTIM, CLARITIN, REMERON and NUVARING. As a result of Schering-Plough's dependence on key products, any event that adversely affects any of these products or the markets for any of these products could have a significant impact on results of operations and cash flows. These events could include loss of patent protection, increased costs associated with manufacturing, generic or OTC availability of Schering-Plough's product or a competitive product, the discovery of previously unknown side effects, increased competition from the introduction of new, more effective treatments and discontinuation or removal from the market of the product for any reason.

***There is a high risk that funds invested in research will not generate financial returns because the development of novel drugs requires significant expenditures with a low probability of success.***

There is a high rate of failure inherent in the research to develop new drugs to treat diseases. As a result, there is a high risk that funds invested by Schering-Plough in research programs will not generate financial returns. This risk profile is compounded by the fact that this research has a long investment cycle. To bring a pharmaceutical compound from the discovery phase to market may take a decade or more and failure can occur at any point in the process, including later in the process after significant funds have been invested.

***Schering-Plough's success is dependent on the successful development and marketing of new products, which are subject to substantial risks.***

Products that appear promising in development may fail to reach market for numerous reasons, including the following:

findings of ineffectiveness, superior safety or efficacy of competing products, or harmful side effects in clinical or pre-clinical testing;

failure to receive the necessary regulatory approvals, including delays in the approval of new products and new indications, and increasing uncertainties about the time required to obtain regulatory approvals and the benefit/risk standards applied by regulatory agencies in determining whether to grant approvals;

lack of economic feasibility due to manufacturing costs or other factors; and

preclusion from commercialization by the proprietary rights of others.

***Intellectual property protection for innovation is an important contributor to Schering-Plough's profitability. Generic forms of Schering-Plough's products may be introduced to the market as a result of the expiration of patents covering Schering-Plough's products, a successful challenge to Schering-Plough's patents, or the at-risk launch of a generic version of a Schering-Plough product, which may have a material and negative effect on results of operations.***

Intellectual property protection is critical to Schering-Plough's ability to successfully commercialize its products. Patents relating to Schering-Plough's significant products may be of material importance to Schering-Plough. Upon the expiration or the successful challenge of Schering-Plough's patents covering a product, competitors may introduce

lower-priced generic or similar branded versions of that product, which may include Schering-Plough's well-established products.

A generic manufacturer may file an Abbreviated New Drug Application seeking approval after the expiration of the applicable data exclusivity and alleging that one or more of the patents listed in the innovator's New Drug Application are invalid, not infringed or unenforceable. This allegation is commonly known as a Paragraph IV certification. The innovator then has the ability to file suit against the generic manufacturer to enforce its patents. Generic manufacturers have used Paragraph IV certifications extensively to challenge patents on a wide array of innovative pharmaceuticals, and it is anticipated that this trend will continue. In recent years, some generic manufacturers have launched generic versions of products before the ultimate resolution of patent litigation (commonly known as "at-risk" product launches). Generic entry may result in the loss of a significant portion of sales or downward pressures on the prices at which Schering-Plough offers formerly patented products. Please



## **Table of Contents**

refer to Legal Proceedings in Part II, Item 1 in this 10-Q for descriptions of pending intellectual property litigation.

Additionally, certain foreign governments have indicated that compulsory licenses to patents may be granted in the case of national emergencies, which could diminish or eliminate sales and profits from those regions and negatively affect Schering-Plough's results of operations. Further, recent court decisions relating to other companies' U.S. patents, potential U.S. legislation relating to patent reform, as well as regulatory initiatives may result in further erosion of intellectual property protection.

***Patent disputes can be costly to prosecute and defend and adverse judgments could result in damage awards, increased royalties and other similar payments and decreased sales.***

Patent positions can be highly uncertain and patent disputes in the pharmaceutical industry are not unusual. An adverse result in a patent dispute involving Schering-Plough's patents, or the patents of its collaborators, may lead to a determination by a court that the patent is not infringed, is invalid, and/or is unenforceable. Such an adverse determination could lead to Schering-Plough's loss of market exclusivity. An adverse result in a patent dispute alleging that Schering-Plough has infringed patents held by a third party may lead to a determination by a court that the patent is infringed, valid, and enforceable. Such an adverse determination may preclude the commercialization of Schering-Plough's products and/or may lead to significant financial damages for past and ongoing infringement. Due to the uncertainty surrounding patent litigation, parties may settle patent disputes by obtaining a license under mutually agreeable terms in order to decrease risk of an interruption in manufacturing and/or marketing of its products.

The potential for litigation regarding Schering-Plough's intellectual property rights always exists and litigation may be initiated by third parties attempting to abridge Schering-Plough's rights. Even if Schering-Plough is ultimately successful in a particular dispute, Schering-Plough may incur substantial costs in defending its patents and other intellectual property rights. Please refer to Patent Challenges Under the Hatch-Waxman Act in Part II, Item 1, Legal Proceedings for a list of current Paragraph IV certifications for Schering-Plough products.

***Multi-jurisdictional regulations, including those establishing Schering-Plough's ability to price products, may negatively affect Schering-Plough's sales and profit margins.***

Schering-Plough faces increasing pricing pressure globally from managed care organizations, institutions and government agencies and programs that could negatively affect Schering-Plough's sales and profit margins. For example, in the U.S., the Medicare Prescription Drug Improvement and Modernization Act of 2003 contains a prescription drug benefit for individuals who are eligible for Medicare. The prescription drug benefit became effective on January 1, 2006, and has resulted in increased use of generics and increased purchasing power of those negotiating on behalf of Medicare recipients, which in turn has resulted in increased price pressure on Schering-Plough's products.

The U.S. government is considering a number of legislative and regulatory proposals that could adversely affect Schering-Plough's sales and profit margins. Legislative and regulatory actions under consideration in the U.S. include health care reform initiatives that could significantly alter the market for pharmaceuticals (such as private health insurance expansion, the creation of competing public health insurance plans, a variety of proposals that would reduce government expenditures for prescription drugs to help finance healthcare reform, or, less likely, the eventual transition of the U.S. multiple payer system to a single payer system). Other actions under consideration include proposals for government intervention in pharmaceutical pricing, changes in government reimbursement, an accelerated approval process for follow-on biologics, legalization of commercial drug importation into the U.S., and involuntary approval of medicines for OTC use. In addition, individual states have enacted or proposed regulations that restrict certain sales and marketing activities and/or require tracking and disclosure of payments and other financial support to healthcare professionals. Similar regulations may be proposed at the federal level. Such

regulations could adversely affect Schering-Plough's sales and profit margins. Non-governmental trends include consolidation among customers, expansion of managed care practices, and more aggressive pursuit of health care cost containment. Globally, market approval, reimbursement of products, prescribers' practices and policies of third-party payors may be influenced by health technology assessments performed by governmental bodies, such as the National Institute for Health and Clinical Excellence in the UK, or diverse private sector entities, such as the Blue Cross Blue Shield Technology Assessment Center.

## **Table of Contents**

In the U.S., as a result of the government's efforts to reduce health care expenditures and other payors' efforts to reduce health care costs, Schering-Plough faces increased pricing pressure as payors continue to seek price discounts with respect to Schering-Plough's products.

In other countries, many governmental agencies strictly control, directly or indirectly, the prices at which pharmaceutical products are sold. In these markets, cost control methods including restrictions on physician prescription levels and patient reimbursements; emphasis on greater use of generic drugs; and across-the-board price cuts may decrease revenues internationally.

### ***Market forces continue to evolve and can impact Schering-Plough's ability to sell products or the price Schering-Plough can charge for products.***

A number of intermediaries are involved between drug manufacturers, such as Schering-Plough, and patients who use the drugs. These intermediaries impact the patient's ability, and their prescribers' ability, to choose and pay for a particular drug, which may adversely affect sales of a particular Schering-Plough drug. These intermediaries include health care providers, such as hospitals and clinics; payors and their representatives, such as employers, insurers, managed care organizations and governments; and others in the supply chain, such as pharmacists and wholesalers. Examples include: payors that require a patient to first fail on one or more generic, or less expensive branded drugs, before reimbursing for a more effective, branded product that is more expensive; payors that are increasing patient co-payment amounts; hospitals that stock and administer only a generic product to in-patients; managed care organizations that may penalize doctors who prescribe outside approved formularies which may not include branded products when a generic is available; and pharmacists who receive larger revenues when they dispense a generic drug over a branded drug. Further, the intermediaries are not required to routinely provide transparent data to patients comparing the effectiveness of generic and branded products or to disclose their own economic benefits that are tied to steering patients toward, or requiring patients to use, generic products rather than branded products. Reports on comparative effectiveness of alternative treatments, prepared as a result of the additional \$1.1 billion in federal financing under the American Recovery and Reinvestment Act (ARRA) of 2009, could begin to appear for therapeutic categories in which Schering-Plough has significant medications and could alter intermediary and patient perceptions of the value of leading Schering-Plough products, affecting health plan coverage and reimbursement and overall market share for these products. In the U.S., possible enactment of health care reform could result in a significant restructuring of intermediaries between manufacturers and patients and their economic incentives, resulting in adverse effects on Schering-Plough's results of operations, cash flows and financial condition.

### ***Government investigations involving Schering-Plough could lead to the commencement of civil and/or criminal proceedings involving the imposition of substantial fines, penalties and injunctive or administrative remedies, including exclusion from government reimbursement programs, which could give rise to other investigations or litigation by government entities or private parties.***

Schering-Plough cannot predict whether future or pending investigations to which it may become subject would lead to a judgment or settlement involving a significant monetary award or restrictions on its operations.

The pricing, sales and marketing programs and arrangements and related business practices of Schering-Plough and other participants in the health care industry are under increasing scrutiny from federal and state regulatory, investigative, prosecutorial and administrative entities. These entities include the Department of Justice and its U.S. Attorneys' Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the Federal Trade Commission and various state Attorneys General offices. Many of the health care laws under which certain of these governmental entities operate, including the federal and state anti-kickback statutes and statutory and common law false claims laws, have been construed broadly by the courts and permit the government entities to exercise significant discretion. In the event that any of those governmental entities believes that wrongdoing has

occurred, one or more of them could institute civil or criminal proceedings which, if resolved unfavorably, could subject Schering-Plough to substantial fines, penalties and injunctive or administrative remedies, including exclusion from government reimbursement programs. In addition, an adverse outcome to a government investigation could prompt other government entities to commence investigations of Schering-Plough or cause those entities or private parties to bring civil claims against it. Schering-Plough also cannot predict whether any investigations will affect its marketing practices or sales. Any such result could have a material adverse impact on Schering-Plough's results of operations, cash flows, financial condition, or its business.

**Table of Contents**

A number of governmental entities in the U.S. have made inquiries or initiated investigations into the timing and disclosures relating to the ENHANCE clinical trial. These include several letters from Congress, investigations by state Attorneys General offices, and requests for information from U.S. Attorneys' Offices and the Department of Justice.

Regardless of the merits or outcomes of any investigation, government investigations are costly, divert management's attention from Schering-Plough's business and may result in substantial damage to Schering-Plough's reputation.

See Schering-Plough's 2008 10-K, Item 3, Legal Proceedings—Litigation and Investigations relating to the Merck/Schering-Plough Cholesterol Joint Venture and Part II, Item 1, Legal Proceedings in this 10-Q for further information about the Merck/Schering-Plough cholesterol joint venture's ENHANCE clinical trials and related matters.

***There are other legal matters in which adverse outcomes could negatively affect Schering-Plough's results of operations, cash flows, financial condition, or business.***

Unfavorable outcomes in other pending litigation matters, or in future litigation, including litigation concerning product pricing, securities law violations, product liability claims, ERISA matters, patent and intellectual property disputes, arbitration over the right to retain products, and antitrust matters could preclude the commercialization of products, negatively affect the profitability of existing products and subject Schering-Plough to substantial fines, penalties and injunctive or administrative remedies, including exclusion from government reimbursement programs. Any such result could materially and adversely affect Schering-Plough's results of operations, cash flows, financial condition, or business.

Further, aggressive plaintiffs counsel often file litigation on a wide variety of allegations whenever there is media attention or negative discussion about the efficacy or safety of a product and whenever the stock price is volatile; even when the allegations are groundless, Schering-Plough may need to expend considerable funds and other resources to respond to such litigation.

Please refer to Legal Proceedings in Part II, Item 1 in this 10-Q for descriptions of significant pending litigation.

***Issues concerning the Merck/Schering-Plough Cholesterol Joint Venture's clinical trials could have a material adverse effect on the joint venture's sales of VYTORIN and ZETIA, which in turn could have a material adverse impact on Schering-Plough's financial condition.***

See Schering-Plough's 2008 10-K, Item 3, Legal Proceedings—Litigation and Investigations relating to the Merck/Schering-Plough Cholesterol Joint Venture for further information about the Merck/Schering-Plough cholesterol joint venture's ENHANCE clinical trials and related matters. Current or future investigations, analysis of the ENHANCE, SEAS, or other clinical trials, data by various agencies, litigation concerning the sale and promotion of these products, or the securities and other class action litigation relating to such matters could, if resolved unfavorably to Schering-Plough or the joint venture, have a material adverse effect on Schering-Plough's results of operations, cash flow and financial position.

***Schering-Plough and third parties acting on its behalf are subject to governmental regulations, and the failure to comply with, as well as the costs of compliance with, these regulations may adversely affect Schering-Plough's results of operations, cash flow and financial position.***

Manufacturing and research practices of Schering-Plough and third parties acting on its behalf must meet stringent regulatory standards and are subject to regular inspections. The cost of regulatory compliance, including that associated with compliance failures, can materially affect Schering-Plough's results of operations, cash flow and

financial position. Failure to comply with regulations, which include pharmacovigilance reporting requirements and standards relating to clinical, laboratory and manufacturing practices, can result in suspension or termination of clinical studies, delays or failure in obtaining the approval of drugs, seizure or recalls of drugs, suspension or revocation of the authority necessary for the production and sale of drugs, withdrawal of approval, fines and other civil or criminal sanctions.

Schering-Plough also is subject to other regulations, including environmental, health and safety, and labor regulations.

**Table of Contents**

***Developments following regulatory approval may adversely affect sales of Schering-Plough's products.***

Even after a product reaches market, certain developments following regulatory approval, including results in post-marketing Phase IV trials, may decrease demand for Schering-Plough's products, including the following:

- the re-review of products that are already marketed;
- new scientific information and evolution of scientific theories;
- the recall or loss of marketing approval of products that are already marketed;
- changing government standards or public expectations regarding safety, efficacy or labeling changes; and
- greater scrutiny in advertising and promotion.

In the past several years, clinical trials and post-marketing surveillance of certain marketed drugs of competitors within the industry have raised safety concerns that have led to recalls, withdrawals or adverse labeling of marketed products. Clinical trials and post-marketing surveillance of certain marketed drugs also have raised concerns among some prescribers and patients relating to the safety or efficacy of pharmaceutical products in general that have negatively affected the sales of such products. In addition, increased scrutiny of the outcomes of clinical trials have led to increased volatility in market reaction. Further, these matters often attract litigation and, even where the basis for the litigation is groundless, considerable resources may be needed to respond.

In addition, following the wake of product withdrawals of other companies and other significant safety issues, health authorities such as the FDA, the EMEA and the PMDA have increased their focus on safety when assessing the benefit/risk balance of drugs. Some health authorities appear to have become more cautious when making decisions about approvability of new products or indications and are re-reviewing select products that are already marketed, adding further to the uncertainties in the regulatory processes. There is also greater regulatory scrutiny, especially in the U.S., on advertising and promotion and in particular, direct-to-consumer advertising.

If previously unknown side effects are discovered or if there is an increase in negative publicity regarding known side effects of any of Schering-Plough's products, it could significantly reduce demand for the product or require Schering-Plough to take actions that could negatively affect sales, including removing the product from the market, restricting its distribution or applying for labeling changes. Further, in the current environment in which all pharmaceutical companies operate, Schering-Plough is at risk for product liability claims for its products.

***New products and technological advances developed by Schering-Plough's competitors may negatively affect sales.***

Schering-Plough operates in a highly competitive industry. Schering-Plough competes with a large number of multinational pharmaceutical companies, biotechnology companies and generic pharmaceutical companies. Many of Schering-Plough's competitors have been conducting research and development in areas served both by Schering-Plough's current products and by those products Schering-Plough is in the process of developing. Competitive developments that may impact Schering-Plough include technological advances by, patents granted to, and new products developed by competitors or new and existing generic, prescription and/or OTC products that compete with products of Schering-Plough or the Merck/Schering-Plough Cholesterol Joint Venture. In addition, it is possible that doctors, patients and providers may favor those products offered by competitors due to safety, efficacy, pricing or reimbursement characteristics, and as a result Schering-Plough will be unable to maintain its sales for such products.

***Competition from third parties may make it difficult for Schering-Plough to acquire or license new products or product candidates (regardless of stage of development) or to enter into such transactions on terms that permit Schering-Plough to generate a positive financial impact.***

Schering-Plough depends on acquisition and in-licensing arrangements as a source for new products. Opportunities for obtaining or licensing new products are limited, however, and securing rights to them typically requires substantial amounts of funding or substantial resource commitments. Schering-Plough competes for these opportunities against many other companies and third parties that have greater financial resources and greater ability to make other resource commitments. Schering-Plough may not be able to acquire or license new products, which could adversely impact Schering-Plough and its prospects. Schering-Plough may also have difficulty acquiring or licensing new products on acceptable terms. To secure rights to new products, Schering-Plough may



**Table of Contents**

have to make substantial financial or other resource commitments that could limit its ability to produce a positive financial impact from such transactions.

***Schering-Plough relies on third-party relationships for its key products, and the conduct and changing circumstances of such third parties may adversely impact the business.***

Schering-Plough has several relationships with third parties on which Schering-Plough depends for many of its key products. Very often these third parties compete with Schering-Plough or have interests that are not aligned with the interests of Schering-Plough. Notwithstanding any contracts Schering-Plough has with these third parties, Schering-Plough may not be able to control or influence the conduct of these parties, or the circumstances that affect them, either of which could adversely impact Schering-Plough.

The relationships are long-standing and, as the third party's work and Schering-Plough's work evolves, priorities and alignments also change. At times new issues develop that were not anticipated at the time contracts were negotiated. These new issues, and related uncertainties in the contracts, also can adversely impact Schering-Plough.

Please refer to "Legal Proceedings" in Part II, Item 1 in this 10-Q for a description of the Centocor arbitration relating to the rights to distribute and commercialize REMICADE and golimumab (SIMPONI) in certain territories.

***Schering-Plough's global operations expose Schering-Plough to additional risks, and any adverse event could have a material negative impact on results of operations.***

A majority of Schering-Plough's operations (based on total revenue) are outside the U.S. Risks inherent in conducting a global business include:

changes in medical reimbursement policies and programs and pricing restrictions in key markets;

multiple regulatory requirements that could restrict Schering-Plough's ability to manufacture and sell its products in key markets;

trade protection measures and import or export licensing requirements;

diminished protection of intellectual property in some countries; and

possible nationalization and expropriation.

In addition, there may be changes to Schering-Plough's business and political position if there is instability, disruption or destruction in a significant geographic region, regardless of cause, including war, terrorism, riot, civil insurrection or social unrest; and natural or man-made disasters, including famine, flood, fire, earthquake, storm or disease.

***Negative events in the animal health industry could have a negative impact on future results of operations.***

Future sales of key animal health products could be adversely impacted by a number of risk factors including certain risks that are specific to the animal health business. For example, the outbreak of disease carried by animals, such as Bovine Spongiform Encephalopathy (BSE) or mad cow disease, could lead to their widespread death and precautionary destruction as well as the reduced consumption and demand for animals, which could adversely impact Schering-Plough's results of operations. Also, the outbreak of any highly contagious diseases near Schering-Plough's main production sites could require Schering-Plough to immediately halt production of vaccines at such sites or force Schering-Plough to incur substantial expenses in procuring raw materials or vaccines elsewhere. Other risks specific

to animal health include epidemics and pandemics, government procurement and pricing practices, weather and global agribusiness economic events. As the Animal Health segment of Schering-Plough's business becomes more significant, the impact of any such events on future results of operations would also become more significant.

**Table of Contents**

***Biologics carry unique risks and uncertainties, which could have a negative impact on future results of operations.***

The successful development, testing, manufacturing and commercialization of biologics, particularly human and animal health vaccines, is a long, expensive and uncertain process. There are unique risks and uncertainties with biologics, including:

There may be limited access to and supply of normal and diseased tissue samples, cell lines, pathogens, bacteria, viral strains and other biological materials. In addition, government regulations in multiple jurisdictions such as the U.S. and European states within the EU, could result in restricted access to, or transport or use of, such materials. If Schering-Plough loses access to sufficient sources of such materials, or if tighter restrictions are imposed on the use of such materials, Schering-Plough may not be able to conduct research activities as planned and may incur additional development costs.

The development, manufacturing and marketing of biologics are subject to regulation by the FDA, the EMEA and other regulatory bodies. These regulations are often more complex and extensive than the regulations applicable to other pharmaceutical products. For example, in the U.S., a Biologics License Application, including both preclinical and clinical trial data and extensive data regarding the manufacturing procedures, is required for human vaccine candidates and FDA approval for the release of each manufactured lot.

Manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies to handle living micro-organisms. Each lot of an approved biologic must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing biologics requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in backorders on certain products, lot failures, product recalls or spoilage. When changes are made to the manufacturing process, Schering-Plough may be required to provide pre-clinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes.

Biologics are frequently costly to manufacture because production ingredients are derived from living animal or plant material, and most biologics cannot be made synthetically. In particular, keeping up with the demand for vaccines may be difficult due to the complexity of producing vaccines.

The use of biologically derived ingredients can lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination. Any of these events could result in substantial costs.

There currently is no process in the U.S. for the submission or approval of generic biologics based upon abbreviated data packages or a showing of sameness to another approved biologic, but there is public dialogue at the FDA and in Congress regarding the scientific and statutory basis upon which such products, known as biosimilars or follow-on biologics, could be approved and marketed in the U.S. Schering-Plough cannot be certain when Congress will create a statutory pathway for the approval of biosimilars, and Schering-Plough cannot predict what impact, if any, the approval of biosimilars would have on the sales of Schering-Plough products in the U.S. In Europe, however, the EMEA has issued guidelines for approving biological products through an abbreviated pathway, and biosimilars have been approved in Europe. If a biosimilar version of one of Schering-Plough's products were approved in Europe, it could have a negative effect on sales of the product.

***Schering-Plough is exposed to market risk from fluctuations in currency exchange rates and interest rates.***

Schering-Plough operates in multiple jurisdictions and, as such, virtually all sales are denominated in currencies of the local jurisdiction. Additionally, Schering-Plough has entered and will enter into acquisition, licensing, borrowings or other financial transactions that may give rise to currency and interest rate exposure.

Since Schering-Plough cannot, with certainty, foresee and mitigate against such adverse fluctuations, fluctuations in currency exchange rates and interest rates could negatively affect Schering-Plough's results of operations, financial position and cash flows.

In order to mitigate against the adverse impact of these market fluctuations, Schering-Plough will from time to time enter into hedging agreements. While hedging agreements, such as currency options and interest rate

**Table of Contents**

swaps, limit some of the exposure to exchange rate and interest rate fluctuations, such attempts to mitigate these risks are costly and not always successful.

***The current stock market and credit market conditions are extremely volatile and unpredictable. It is difficult to predict whether these conditions will continue or worsen, and, if so, whether the conditions would impact Schering-Plough and whether such impact could be material.***

Schering-Plough has exposure to many different industries and counterparties, including commercial banks, investment banks, suppliers and customers (which include wholesalers, managed care organizations and governments) that may be unstable or may become unstable in the current economic environment. Any such instability may impact these parties' ability to fulfill contractual obligations to Schering-Plough or they might limit or place burdensome conditions upon future transactions with Schering-Plough. Customers may also reduce spending during times of economic uncertainty. Also, it is possible that suppliers may be negatively impacted. In such events, there could be a resulting material and adverse impact on operations and results of operations.

Although Schering-Plough currently has no plan to access the equity or debt markets to meet capital or liquidity needs, constriction and volatility in these markets may restrict future flexibility to do so if unforeseen capital or liquidity needs were to arise.

Further, the current conditions have resulted in severe downward pressure on the stock and credit markets, which could further reduce the return available on invested corporate cash, reduce the return on investments held by the pension plans and thereby potentially increase funding obligations, all of which if severe and sustained could have material and adverse impacts on Schering-Plough's results of operations, financial position and cash flows.

***Insurance coverage for product liability may be limited, cost prohibitive or unavailable.***

Schering-Plough maintains insurance coverage with such deductibles and self-insurance to reflect market conditions (including cost and availability) existing at the time it is written, and the relationship of insurance coverage to self-insurance varies accordingly. For certain products, third-party insurance is increasingly cost prohibitive, available on more limited terms than past coverage, or unavailable. Schering-Plough self-insures substantially all of its risk as it relates to products' liability, as the availability of commercial insurance has become more restrictive. Schering-Plough continually assesses the best way to provide for its insurance needs.

***Schering-Plough is subject to evolving and complex tax laws, which may result in additional liabilities that may affect results of operations.***

Schering-Plough is subject to evolving and complex tax laws in the jurisdictions in which it operates. Significant judgment is required for determining Schering-Plough's tax liabilities, and Schering-Plough's tax returns are periodically examined by various tax authorities. Schering-Plough believes that its accrual for tax contingencies is adequate for all open years based on past experience, interpretations of tax law, and judgments about potential actions by tax authorities; however, due to the complexity of tax contingencies, the ultimate resolution of any tax matters may result in payments greater or less than amounts accrued.

In addition, Schering-Plough may be impacted by changes in tax laws including tax rate changes, changes to the laws related to the remittance of foreign earnings (deferral), or other limitations impacting the US tax treatment of foreign earnings, new tax laws, and revised tax law interpretations in domestic and foreign jurisdictions.

***The anticipated combination of Merck with Schering-Plough creates unique risks in the time leading up to closing, and there are also risks of completing the conditions to closing.***

The Agreement of Merger dated March 8, 2009 relating to the proposed combination of Merck with Schering-Plough (the combination ) generally requires Schering-Plough to operate its business in the ordinary course pending consummation of the proposed combination, but restricts Schering-Plough, without Merck's consent, from taking certain specified actions until the combination is complete or the Agreement is terminated. Further, until key personnel are notified that they will have a job that they desire with the combined company, there is a risk of losing these key employees, even when there are retention arrangements in place. Additional efforts are needed by every person working at Schering-Plough to prevent a loss of momentum, including in research and development work on the pipeline; sales and marketing efforts relating to current marketed products, as well as the launch of new products; to continue with productivity initiatives, including the Productivity

**Table of Contents**

Transformation Program and to avoid disruption of relationships with important stakeholders, including patients, prescribers, clinical trial investigators, private and government customers, suppliers, distributors and regulatory authorities.

Until antitrust and other regulatory approvals, are obtained, it cannot be certain that the transaction will close. Schering-Plough will incur significant transaction costs relating to the proposed combination, whether or not the proposed combination is completed. Additionally, matters relating to the combination (including integration planning) may require substantial commitments of time and resources by Schering-Plough, which could otherwise have been devoted to other beneficial opportunities.

While Schering-Plough's executive management team has deep experience in managing mergers and acquisitions, including complex transactions in the pharmaceutical industry (which will help maintain focus and momentum in the time before closing), many external people, organizations and events will impact the process, events and time it takes to reach closing. Any loss of business opportunities, key personnel or momentum could have material adverse impacts on future business, and as a result future sales and earnings either for Schering-Plough if the proposed combination were not completed or for the combined company. Further, uncertainties about whether the proposed combination will close could impact the stock prices of Schering-Plough and Merck.

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

This table provides information with respect to purchases by Schering-Plough of its common shares during the third quarter of 2009.

<b>Period</b>	<b>Total Number of Shares Purchased</b>	<b>Average Price Paid per Share</b>	<b>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs</b>	<b>Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs</b>
July 1, 2009 through July 31, 2009	5,521(1)	\$ 24.81	N/A	N/A
August 1, 2009 through August 31, 2009	8,885(1)	\$ 26.51	N/A	N/A
September 1, 2009 through September 30, 2009	3,050(1)	\$ 27.79	N/A	N/A
<b>Total July 1, 2009 through September 30, 2009</b>	17,456(1)	\$ 26.20	N/A	N/A

- (1) All of the shares included in the table above were repurchased pursuant to Schering-Plough's stock incentive program and represent shares delivered to Schering-Plough by option holders for payment of the exercise price and tax withholding obligations in connection with stock options and stock awards.

**Table of Contents****Item 6. Exhibits**

<b>Exhibit Number</b>	<b>Description</b>	<b>Location</b>
12	Computation of Ratio of Earnings to Fixed Charges.	Attached
15	Awareness letter.	Attached
31.1	Sarbanes-Oxley Act of 2002, Section 302 Certification for Chairman of the Board and Chief Executive Officer.	Attached
31.2	Sarbanes-Oxley Act of 2002, Section 302 Certification for Executive Vice President and Chief Financial Officer.	Attached
32.1	Sarbanes-Oxley Act of 2002, Section 906 Certification for Chairman of the Board and Chief Executive Officer.	Attached
32.2	Sarbanes-Oxley Act of 2002, Section 906 Certification for Executive Vice President and Chief Financial Officer.	Attached
101	The following materials from Schering-Plough Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 2009, formatted in XBRL (Extensible Business Reporting Language): (i) the Statements of Condensed Consolidated Operations, (ii) the Statements of Condensed Consolidated Cash Flows, (iii) the Condensed Consolidated Balance Sheets, and (iv) Notes to Condensed Consolidated Financial Statements, tagged as blocks of text.	Attached



**Table of Contents**

**SIGNATURES**

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

SCHERING-PLOUGH CORPORATION  
(Registrant)

By /s/ Steven H. Koehler  
Steven H. Koehler  
Vice President and Controller  
(Duly Authorized Officer  
and Chief Accounting Officer)

Date: October 29, 2009