SCHERING PLOUGH CORP
Form 10-K
February 27, 2009

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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**
**Form 10-K**

**þ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For fiscal year ended December 31, 2008**

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

**Commission file number 1-6571**
**SCHERING-PLOUGH CORPORATION**
*(Exact name of registrant as specified in its charter)*

| **New Jersey** | **22-1918501** |
|---|---|
| *(State or other jurisdiction of incorporation or organization)* | *(I.R.S. Employer Identification No.)* |
| **2000 Galloping Hill Road, Kenilworth, NJ** | **07033** |
| *(Address of principal executive offices)* | *(Zip Code)* |

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

**Securities registered pursuant to Section 12(b) of the Act:**

| **Title of Each Class** | **Name of Each Exchange on Which Registered** |
|---|---|
| Common Shares, $.50 par value | New York Stock Exchange |
| Mandatory Convertible Preferred Stock | New York Stock Exchange |

**Securities registered pursuant to section 12(g) of the Act:**
None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes þ No o

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No þ

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 the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. þ

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 þ Accelerated filer o Non-accelerated filer o Smaller reporting company o
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes o No þ

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of June 30, 2008 (the last business day of the registrant s most recently completed second fiscal quarter): $31,979,690,761

Common Shares outstanding as of January 31, 2009: 1,626,412,285

| **Documents Incorporated by Reference** | **Part of Form 10-K Incorporated into** |
|---|---|
| Schering-Plough Corporation s Proxy Statement for the 2009 Annual Meeting of Shareholders to be filed within 120 days after the close of the registrant s fiscal year (the Proxy Statement ) | Part III |

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## Part I

### Item 1. *Business*

**Overview of the Business**

Schering-Plough refers to Schering-Plough Corporation and its subsidiaries, except as otherwise indicated by the context. Schering Corporation, a predecessor company, was incorporated in New York in 1928 and New Jersey in 1935. The trademarks indicated by CAPITAL LETTERS in this 10-K are the property of, licensed to, promoted or distributed by Schering-Plough Corporation, its subsidiaries or related companies.

Schering-Plough is an innovation-driven, science-centered global health care company. Through its own biopharmaceutical research and collaborations with partners, Schering-Plough creates therapies that help save and improve lives around the world. Schering-Plough applies its research and development platform to prescription pharmaceuticals, animal health and consumer health care products. Schering-Plough s vision is to Earn Trust, Every Day with doctors, patients, customers, shareholders, employees and other stakeholders. Schering-Plough is based in Kenilworth, N.J., and its Web site is www.schering-plough.com.

In April 2003, the Board of Directors recruited Fred Hassan to join Schering-Plough as the new Chairman of the Board and Chief Executive Officer. With support from the Board, soon after he arrived in 2003, Hassan installed a new senior executive management team and initiated a strategic plan, with the goal of stabilizing, repairing and turning around Schering-Plough in order to build long-term shareholder value. That strategic plan, the Action Agenda, is a six- to eight-year, five-phase plan.

In 2008 and in the five years since Hassan and the new management team arrived, Schering-Plough made substantial progress. During 2008, in the fourth phase of the Action Agenda Build the Base Schering-Plough grew and broadened the base of marketed products, expanded the late-stage research and development project pipeline and made substantial progress with the integration of Organon BioSciences N.V. (OBS), purchased from Akzo Nobel in late 2007. That acquisition was transformative, giving Schering-Plough:

- Key new pipeline projects (including asenapine for schizophrenia and bipolar disease and sugammadex to reverse deep anesthesia);
- Key products in two new therapeutic areas Women s Health and Central Nervous System;
- A position as a leader in Animal Health by combining Schering-Plough Animal Health with Intervet;
- A leadership position in animal vaccines at Intervet and early-stage innovation capabilities in human vaccines at Nobilon;
- Additional state-of-the-art biologics capabilities;
- A substantial expansion to the Company s geographic footprint; and
- Significant talent, including in key research and development functions.

This strength gained from the progress in the Action Agenda was key for Schering-Plough during 2008, a period of challenge in the pharmaceutical industry (particularly in the U.S.) and the general economy. In addition, Schering-Plough faced particular challenges to the cholesterol products, ZETIA and VYTORIN, particularly in the U.S. as discussed in Item 3, Legal Proceedings.

In spite of these challenges, in 2008, Schering-Plough delivered strong operational performance but the stock price suffered significant pressure.

The Productivity Transformation Program announced in April of 2008 facilitated Schering-Plough s achievements in 2008. The goal of this program, which includes the ongoing integration of OBS, 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

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anticipated to be accomplished by the end of 2010 with the balance achieved by 2012. The targeted savings envisioned by this program include those resulting from the previously announced OBS integration synergies. 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.

In 2009, the environment continues to be challenging for all companies in all geographies, in part due to uncertainty in the stock markets and current credit conditions in financial markets. Further, pressures in the U.S. pharmaceutical market include uncertainty in the regulatory process for approving new drugs and new indications; reviewing labeling and indications for marketed products; and assessing information about risks associated with drugs. When human health is involved there is always a balance between the quest for new innovation, particularly to address urgent, unmet medical needs, and a desire to minimize risks. Currently, the balance is strongly skewed toward risk minimization in the U.S., resulting in longer delays in approving products, greater costs in clinical trials and post-marketing trials and increased scrutiny not only by patients, prescribers and regulatory agencies, but also the media. Further, 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.

**Segment Information**

Schering-Plough has three reportable segments: Prescription Pharmaceuticals, Animal Health and Consumer Health Care. The segment sales and profit/(loss) data that follow are consistent with Schering-Plough s current management reporting structure.

***Prescription Pharmaceuticals***

The Prescription Pharmaceuticals segment discovers, develops, manufactures and markets human pharmaceutical products. Within the Prescription Pharmaceuticals segment, Schering-Plough has a broad range of research projects and marketed products in six therapeutic areas: Cardiovascular, Central Nervous System, Immunology and Infectious Disease, Oncology, Respiratory and Women s Health. The Prescription Pharmaceuticals segment also includes Nobilon, a human vaccine development unit and Diosynth, a third-party manufacturing unit. Marketed products include the following:

*Cardiovascular Disease:* VYTORIN, a cholesterol-lowering tablet combining the dual action of ZETIA and Merck & Co., Inc. s (Merck) statin Zocor (simvastatin); ZETIA, a novel cholesterol-absorption inhibitor discovered by Schering-Plough scientists, for use as monotherapy or in combination with either statins or fenofibrate to lower cholesterol; INTEGRILIN Injection, a platelet receptor GP IIb/IIIa inhibitor for the treatment of patients with acute coronary syndrome and those undergoing percutaneous coronary intervention in the U.S., as well as for the prevention of early myocardial infarction in patients with acute coronary syndrome in most countries; and ORGARAN, a non-heparin antithrombotic.

*Central Nervous System:* REMERON, an antidepressant; ESMERON/ZEMURON, a muscle relaxant used in surgical procedures; SUBUTEX, a sublingual tablet formulation of buprenorphine; SUBOXONE, a sublingual tablet combination of buprenorphine and naloxone, marketed by Schering-Plough in certain countries outside the U.S. for the treatment of opiate addiction; NORCURON, a muscle relaxant and BRIDION (sugammadex), an anesthesia reversal agent launched in the European Union (EU) and other countries, and under U.S. review.

*Immunology and Infectious Disease:* REMICADE, an anti-TNF antibody marketed by Schering-Plough outside of the United States, Japan and certain Asian markets 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; PEGINTRON Powder for Injection, a pegylated interferon product for chronic hepatitis C; REBETOL Capsules, for use in combination with PEGINTRON or INTRON A for

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treating hepatitis C; AVELOX, which Schering-Plough only markets in the U.S., a broad-spectrum fluoroquinolone antibiotic for certain respiratory and skin infections; and NOXAFIL Oral Suspension, for prophylaxis (prevention) of invasive fungal infections in high-risk patients and the treatment of oropharyngeal candidiasis. It is also approved for the treatment of invasive fungal infections in markets outside the U.S.

*Oncology:* TEMODAR/TEMODAL for certain types of brain tumors, including newly diagnosed glioblastoma multiforme; CAELYX, a long-circulating pegylated liposomal formulation of the cancer drug doxorubicin marketed by Schering-Plough outside the U.S. for the treatment of certain ovarian cancers, Kaposi s sarcoma and metastatic breast cancer; and INTRON A injection, marketed for chronic hepatitis B and C and numerous anticancer indications worldwide, including as adjuvant therapy for malignant melanoma.

*Respiratory:* NASONEX, a once-daily, nasal-inhaled steroid for nasal allergy symptoms, including congestion, and for the treatment of nasal polyps in patients 18 years of age and older; CLARINEX/AERIUS/CLARITIN Rx, a non-sedating antihistamine for the treatment of allergic rhinitis; FORADIL AEROLIZER, a long-acting beta2-agonist marketed by Schering-Plough in the U.S. for the maintenance treatment of asthma and chronic obstructive pulmonary disease, and for the acute prevention of exercise- induced bronchospasm; ASMANEX TWISTHALER, an oral dry-powder corticosteroid inhaler for first-line maintenance treatment of asthma; and PROVENTIL HFA (albuterol) inhalation aerosol, for the relief of bronchospasm in patients 12 years or older.

*Women s Health:* FOLLISTIM/PUREGON, a fertility treatment; NUVARING, a vaginal contraceptive ring; LIVIAL, a menopausal therapy; MARVELON/DESOGEN, a low-dose combined oral contraceptive; MERCILON, a low-dose combined oral contraceptive; CERAZETTE, a progestin only oral contraceptive and IMPLANON, a single-rod subdermal contraceptive implant.

***Animal Health***

The Animal Health segment discovers, develops, manufactures and markets animal health products, including vaccines. Principal marketed products in this segment include:

*Livestock Products:* NUFLOR antibiotic range for use in cattle and swine; BOVILIS/VISTA vaccine lines for infectious diseases in cattle; BANAMINE bovine and swine anti-inflammatory; TRI-MERIT data management tool for cattle; ESTRUMATE for treatment of fertility disorders in cattle; REGUMATE/MATRIX fertility management for swine and horses; RESFLOR combination broad-spectrum antibiotic and non-steroidal anti-inflammatory drug for bovine respiratory disease; ZILMAX and REVALOR to improve production efficiencies in beef cattle; M+PAC swine pneumonia vaccine; PG 600 to stimulate fertility in swine and PORCILIS vaccine line for infectious diseases in swine.

*Poultry Products:* NOBILIS/INNOVAX vaccine lines for poultry; PARACOX and COCCIVAC coccidiosis vaccines for poultry.

*Companion Animal Products:* NOBIVAC/CONTINUUM vaccine lines for flexible dog and cat vaccination; OTOMAX/MOMETAMAX/POSATEX ear ointments for acute and chronic otitis; CANINSULIN/VETSULIN diabetes mellitus treatment for dogs and cats; PANACUR/SAFEGUARD broad-spectrum anthelmintic (de-wormer) for use in many animals; SCALIBOR/EXSPOT for protecting against bites from fleas, ticks, mosquitoes and sandflies; and HOMEAGAIN proactive U.S. pet recovery network.

*Aquaculture Products:* SLICE parasiticide for sea lice in salmon; AQUAVAC/NORVAX vaccines against bacterial and viral disease in fish; COMPACT PD vaccine for salmon; and AQUAFLOR antibiotic for farm-raised fish.

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***Consumer Health Care***

The Consumer Health Care segment develops, manufactures and markets Over-the-Counter (OTC), foot care and sun care products. Principal products in this segment include:

*Over-the-Counter Products:* CLARITIN non-sedating antihistamines; MIRALAX treatment for occasional constipation; CORICIDIN HBP decongestant-free cold/flu medicine for people with high blood pressure; AFRIN nasal decongestant spray; and CORRECTOL laxative tablets.

*Foot Care:* DR. SCHOLL S foot care products; LOTRIMIN topical antifungal products; and TINACTIN topical antifungal products and foot and sneaker odor/wetness products.

*Sun Care:* COPPERTONE sun care lotions, sprays, dry oils and lip-protection products and sunless tanning products; and SOLARCAINE sunburn relief products.

***Net sales by segment***

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2008 | 2007 | 2006 |
| | (Dollars in millions) | | |
| Prescription Pharmaceuticals | $ 14,253 | $ 10,173 | $ 8,561 |
| Animal Health | 2,973 | 1,251 | 910 |
| Consumer Health Care | 1,276 | 1,266 | 1,123 |
| Consolidated net sales | $ 18,502 | $ 12,690 | $ 10,594 |

***Profit /(loss) by segment***

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2008(1) | 2007(2) | 2006 |
| | (Dollars in millions) | | |
| Prescription Pharmaceuticals | $ 2,725 | $ (1,206) | $ 1,394 |
| Animal Health | 186 | (582) | 120 |
| Consumer Health Care | 271 | 275 | 228 |
| Corporate and other (including net interest (expense)/income of ($465) million, $150 million and $125 million in 2008, 2007 and 2006, respectively | (1,133) | 298 | (259) |
| Consolidated profit/(loss) before tax and cumulative effect of a change in accounting principle | $ 2,049 | $ (1,215) | $ 1,483 |

(1)

In 2008, the Prescription Pharmaceuticals segment s profit includes charges arising from purchase accounting items of $808 million. In 2008, the Animal Health segment s profit includes charges arising from purchase accounting items of $641 million.

(2) In 2007, the Prescription Pharmaceuticals segment s loss includes $3.4 billion of purchase accounting items, including acquired in-process research and development of $3.2 billion. In 2007, the Animal Health segment s loss includes $721 million of purchase accounting items, including acquired in-process research and development of $600 million.

Schering-Plough s net sales do not include sales of VYTORIN and ZETIA which are managed in the joint venture with Merck, as Schering-Plough accounts for this joint venture under the equity method of accounting (see Note 5, Equity Income, under Item 8, Financial Statements and Supplementary Data, for additional information). Equity income from the Merck/Schering-Plough joint venture is included in the Prescription Pharmaceuticals segment.

Corporate and other includes interest income and expense, foreign exchange gains and losses, currency option gains, headquarters expenses, special and acquisition-related charges and other miscellaneous items.

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The accounting policies used for segment reporting are the same as those described in Note 1, Summary of Significant Accounting Policies, under Item 8, Financial Statements and Supplementary Data .

In 2008, Corporate and other includes special and acquisition-related charges of $329 million, comprised of $54 million of integration-related costs and $275 million of employee termination costs related to the Productivity Transformation Program which includes the ongoing integration of OBS. It is estimated the charges relate to the reportable segments as follows: Prescription Pharmaceuticals $230 million, Animal Health $30 million, Consumer Health $2 million and Corporate and other $67 million.

In 2007, Corporate and other includes special and acquisition-related charges of $84 million, comprised of $61 million of integration-related costs for the OBS acquisition and $23 million of employee termination costs as part of integration activities. It is estimated the charges relate to the reportable segments as follows: Prescription Pharmaceuticals $27 million, Animal Health $11 million and Corporate and other $46 million.

In 2006, Corporate and other includes special charges of $102 million primarily related to changes to Schering-Plough s manufacturing operations in the U.S. and Puerto Rico announced in June 2006, all of which related to the Prescription Pharmaceuticals segment. Included in 2006 cost of sales were charges of approximately $146 million from the manufacturing streamlining actions which were primarily related to the Prescription Pharmaceuticals segment.

See Note 3, Special and Acquisition-Related Charges and Manufacturing Streamlining, under Item 8, Financial Statements and Supplementary Data, for additional information.

***Information About the Merck/Schering-Plough Joint Venture***

In May 2000, Schering-Plough and Merck entered into two separate sets of agreements to jointly develop and manage 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 that relies to the maximum degree possible on the respective infrastructures of the two companies. These agreements generally provide for equal sharing of development costs and for co-promotion of approved products by each company. During the second quarter of 2008 the joint venture related to the allergy/asthma drug was terminated in accordance with the agreements.

Pursuant to these cholesterol agreements, Schering-Plough granted the joint venture a limited but exclusive license to Schering-Plough s proprietary ezetimibe molecule and technology. The cholesterol agreements provide for Schering-Plough and Merck to develop and commercialize ezetimibe in the cholesterol management field through the joint venture:

i. as a once-daily monotherapy (marketed 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 marketed 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 joint venture. See Note 5, Equity Income, under Item 8, Financial Statements and Supplementary Data, for additional information regarding the profits and costs sharing and accounting as provided by the agreements.

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The allergy/asthma agreements provided for the joint development and marketing by the companies of a once-daily, fixed-combination tablet containing loratadine/montelukast. 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. As a result of the termination of the respiratory joint venture, Schering-Plough received payments totaling $105 million which Schering-Plough recognized in equity income during 2008.

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

***Information About the Centocor Licenses***

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, a fully human monoclonal antibody which has been filed for approval in Europe. 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 golimumab, extending Schering-Plough s exclusive rights to market REMICADE to match the duration of Schering-Plough s exclusive marketing rights for golimumab. Effective upon regulatory approval of golimumab in the EU, Schering-Plough s marketing rights for both products will extend for 15 years after the first commercial sale of golimumab within the EU. Centocor will receive a progressively increased share of profits on Schering-Plough s distribution of both products in the Schering-Plough marketing territory between 2010 and 2014, and the share of profits will remain fixed thereafter for the remainder of the term. The changes to the duration of REMICADE marketing rights and the profit sharing arrangement for the products are all conditioned on approval of golimumab being granted prior to September 1, 2014. Schering-Plough may independently develop and market golimumab for a Crohn s disease indication in its territories, with an option for Centocor to participate. In addition, Schering-Plough and Centocor agreed to utilize an autoinjector device in the commercialization of golimumab and further agreed to share its development costs.

**Global Operations**

A majority of Schering-Plough s operations are outside the U.S. With the acquisition of OBS in late 2007, Schering-Plough s global operations in Prescription Pharmaceuticals and Animal Health increased.

Non-U.S. activities are carried out primarily through wholly-owned subsidiaries wherever market potential is adequate and circumstances permit. In addition, Schering-Plough is represented in some markets through licensees or other distribution arrangements.

Currently, Schering-Plough has business operations in more than 140 countries.

For additional information on global operations, see Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations, and the segment information described above in this 10-K.

***Net sales by geographic area***

| | 2008 | 2007 | 2006 |
|---|---|---|---|
| | (Dollars in millions) | | |
| United States | $ 5,556 | $ 4,597 | $ 4,192 |
| Europe and Canada | 8,903 | 5,500 | 4,403 |
| Latin America | 1,987 | 1,359 | 990 |
| Asia Pacific | 2,056 | 1,234 | 1,009 |
| Consolidated net sales | $ 18,502 | $ 12,690 | $ 10,594 |

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Schering-Plough has subsidiaries in more than 55 countries outside the United States. Net sales are presented in the geographic area in which Schering-Plough s customers are located. The following countries accounted for 5 percent or more of consolidated net sales during any of the past three years:

| | 2008 | | 2007 | | 2006 | |
|---|---|---|---|---|---|---|
| | Net Sales | % of Consolidated Net Sales | Net Sales | % of Consolidated Net Sales | Net Sales | % of Consolidated Net Sales |
| | (Dollars in millions) | | | | | |
| Total International net sales | $ 12,946 | 70% | $ 8,093 | 64% | $ 6,402 | 60% |
| France | 1,369 | 7% | 965 | 8% | 809 | 8% |
| Japan | 1,008 | 5% | 709 | 6% | 669 | 6% |
| Germany | 835 | 5% | 473 | 4% | 408 | 4% |
| Canada | 774 | 4% | 578 | 5% | 478 | 5% |

***Net sales by customer***

Sales to a single customer that accounted for 10 percent or more of Schering-Plough s consolidated net sales during any of the past three years were as follows:

| | 2008 | | 2007 | | 2006 | |
|---|---|---|---|---|---|---|
| | Net Sales | % of Consolidated Net Sales | Net Sales | % of Consolidated Net Sales | Net Sales | % of Consolidated Net Sales |
| | (Dollars in millions) | | | | | |
| McKesson Corporation | $ 1,923 | 10% | $ 1,526 | 12% | $ 1,159 | 11% |
| Cardinal Health | 1,168 | 6% | 1,196 | 9% | 1,019 | 10% |

***Supplemental sales information***

Sales of products comprising 10 percent or more of Schering-Plough s U.S. or international sales for the year ended December 31, 2008, were as follows:

| | Amount | Percentage of applicable sales |
|---|---|---|
| | (Dollars in millions) | |
| **U.S.** | | |
| NASONEX | $ 644 | 12% |
| **International** | | |
| REMICADE | $ 2,118 | 16% |

Schering-Plough s net sales do not include sales of VYTORIN and ZETIA which are managed in the joint venture with Merck, as Schering-Plough accounts for this joint venture under the equity method of accounting.

***Long-lived assets by geographic location***

| | 2008 | 2007 | 2006 |
|---|---|---|---|
| | (Dollars in millions) | | |
| United States | $ 2,792 | $ 2,863 | $ 2,547 |
| Netherlands | 1,244 | 1,320 | 1 |
| Ireland | 689 | 719 | 488 |
| Singapore | 816 | 822 | 824 |
| Other | 1,572 | 1,599 | 804 |
| Total | $ 7,113 | $ 7,323 | $ 4,664 |

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Long-lived assets shown by geographic location are primarily properties. The significant increase in long-lived assets from 2006 to 2007 is due to the OBS acquisition.

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

**Research and Development**

Schering-Plough s research activities are primarily aimed at discovering and developing new prescription products and enhancements to existing human prescription products of medical and commercial significance. However, Schering-Plough s research and development platform also supports its Animal Health and Consumer Health Care products, and often a research and development project will have application in more than one product segment.

Significant work by the current management team to increase productivity and efficiency in research activities as part of the Action Agenda has produced tangible results. Schering-Plough has increased the number of new molecular entities in Phase III from three in 2004 to eight at year-end 2008, with four more in pre-registration, for a total of 12 in late-stage development.

Company-sponsored research and development expenditures were $3.5 billion, $2.9 billion and $2.2 billion in 2008, 2007 and 2006, respectively. As a percentage of consolidated net sales, research and development expenditures represented approximately 19 percent, 23 percent and 21 percent in 2008, 2007 and 2006, respectively.

Schering-Plough s research activities are concentrated in the six therapeutic areas of focus: Cardiovascular, Central Nervous System, Immunology and Infectious Disease, Oncology, Respiratory and Women s Health. Schering-Plough s research activities include significant biotechnology, immunology and vaccine development efforts, reflecting a portfolio balance between small molecule and biologic products. Research activities include expenditures for both internal research efforts and research collaborations with various partners.

While a number of pharmaceutical compounds are in varying stages of development, it cannot be predicted when or if these compounds will become available for commercial sale. Schering-Plough s product pipeline lists significant products in development and is available on Schering-Plough s web site at www.schering-plough.com. Due to the nature of the development and approval process as well as the fact that human health is involved and the science of human health is constantly evolving the status of any compounds in development is subject to change. Schering-Plough does not assume any duty to update this information.

Schering-Plough has six research and development projects which have been granted fast-track designation by the FDA including: a novel thrombin receptor antagonist for acute coronary syndrome and secondary prevention of subsequent cardiovascular events; boceprevir (a protease inhibitor compound) for hepatitis C; vicriviroc (a CCR5 receptor antagonist) for the treatment of HIV; preladenant (A2a Adenosine receptor antagonist) for the treatment of Parkinson s disease; SCH 900518 (a next generation protease inhibitor compound) for hepatitis C; and an IV formulation of posaconazole (currently approved in many countries for the treatment and prophylaxis of certain fungal infections). Of these products, three are in Phase III clinical testing phase: thrombin receptor antagonist, boceprevir and vicriviroc. Significant expenditures would be required to progress these through development, due to the large number of patients necessary for Phase III trials.

Schering-Plough continues to expect research and development expenses to increase over the next several years. The primary reason is that Schering-Plough s pipeline is larger because the new management team has focused on making research and development more productive and because additional pipeline projects were added in the OBS acquisition. Other reasons include the need for larger clinical trials, more frequent clinical trials and longer clinical

trials in the current global regulatory environment. Research and development activities typically continue after a product has been marketed. One reason is to develop new indications for the product. Another reason is to further understand the benefit or risks that may become known as more people use a product for a longer period of time, requiring the need for incremental safety or efficacy testing.

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The regulatory authorities around the world are placing increasing emphasis on post-approval commitments in the form of new studies, registries, etc. after initial approval.

**Patents, Trademarks and Other Intellectual Property Rights**

***Overview***

Intellectual property protection is critical to Schering-Plough s ability to successfully commercialize its product innovations. Schering-Plough owns, has applied for, or has licensed rights to, a large number of patents, both in the U.S. and in other countries, relating to compounds, formulations, uses, and manufacturing processes. There is no assurance that the patents Schering-Plough is seeking will be granted or that the patents Schering-Plough has been granted would be found valid if challenged. Moreover, patents relating to particular formulations, uses, or processes do not preclude other manufacturers from employing alternative processes or from marketing alternative formulations or uses that might successfully compete with Schering-Plough s patented products.

Outside the U.S., the standard of intellectual property protection for pharmaceuticals varies widely. While many countries have reasonably strong patent laws, other countries currently provide little or no effective protection for inventions or other intellectual property rights. Under the Trade-Related Aspects of Intellectual Property Agreement (TRIPs) administered by the World Trade Organization (WTO), more than 140 countries have now agreed to provide non-discriminatory protection for most pharmaceutical inventions and to assure that adequate and effective rights are available to all patent owners. It is possible that changes to this agreement will be made in the future that will diminish or further delay its implementation in developing countries. It is too soon to assess how much, if at all, Schering-Plough will be impacted commercially from these changes.

When a product patent expires, the patent holder often loses effective market exclusivity for the product. This can result in a rapid, sharp and material decline in sales of the formerly patented product, particularly in the U.S. However, in some cases the innovator company can obtain additional commercial benefits through manufacturing trade secrets; later-expiring patents on processes, uses, or formulations; trademark use; or exclusivity that may be available under pharmaceutical regulatory laws.

***Schering-Plough s Intellectual Property Portfolio***

Patent protection for certain Schering-Plough compounds, formulations, processes and uses are important to Schering-Plough s business and financial results. For many of Schering-Plough s products, in addition to patents on the compound, Schering-Plough holds other patents on manufacturing processes, formulations, or uses that may extend exclusivity beyond the expiration of the compound patent.

Schering-Plough s subsidiaries own (or have licensed rights under) a number of patents and patent applications, both in the U.S. and abroad. Patents and patent applications relating to Schering-Plough s significant products, including, without limitation, VYTORIN, ZETIA, REMICADE, NASONEX, FOLLISTIM/PUREGON, NUVARING, TEMODAR, PEGINTRON and CLARINEX, are of material importance to Schering-Plough.

Worldwide, Schering-Plough sells all major products under trademarks that also are material in the aggregate to its business and financial results. Trademark protection varies throughout the world, with protection continuing in some countries as long as the mark is used and in other countries as long as it is registered. Registrations are normally for fixed but renewable terms.

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

The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as Hatch-Waxman, made a complex set of changes to both patent and new drug approval laws in the U.S. Before Hatch-Waxman, no drug could be approved without providing the FDA complete safety and efficacy studies, known as a complete New Drug Application (NDA). Hatch-Waxman authorized the FDA to approve generic versions of innovative medicines without such information upon the filing of an Abbreviated New Drug

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Application (ANDA). In an ANDA, the generic manufacturer must demonstrate only bioequivalence between the generic version and the NDA-approved drug not safety and efficacy. Hatch-Waxman provides for limited patent term restoration to partially make up for patent term lost during the time an NDA-approved drug is in regulatory review. NDA-approved drugs also receive a limited period of data exclusivity which prevents the approval of ANDA applications for specific time periods after approval of the NDA-approved drug.

Absent a successful patent challenge, the FDA cannot approve an ANDA until after the innovator s patents that are listed by the innovator in the FDA Orange Book expire. However, a generic manufacturer may file an ANDA seeking approval after the expiration of the applicable data exclusivity, and alleging that one or more of the patents listed in the innovator s NDA are invalid or not infringed. This allegation is commonly known as a Paragraph IV certification. The innovator must then file suit against the generic manufacturer to protect its patents. If one or more of the NDA-listed patents are successfully challenged, the first filer of a Paragraph IV certification may be entitled to a 180-day period of market exclusivity over all other generic manufacturers. 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, certain generic companies have elected to launch generic products at risk while patent litigation is ongoing and before a decision is reached by the court.

Schering-Plough s 10-Ks and 10-Qs include a listing of Hatch-Waxman Act challenges to its patents in the Legal Proceedings section.

**Marketing Activities and Competition**

Schering-Plough, through its marketing organization and its trained professional sales representatives, introduces and makes known its prescription drugs to health care providers (such as physicians and pharmacists), hospitals, pharmacy benefit managers, managed care organizations, employers, buying groups and government agencies. Schering-Plough also introduces and makes known its prescription products through journal advertising, direct mail advertising, and the distribution of samples to physicians. Schering-Plough communicates directly to consumers in the U.S. through television, radio, Internet, print and other advertising media. Schering-Plough believes that this advertising can benefit the public health by increasing awareness about diseases, educating patients about treatment options, and motivating patients to engage in a dialogue about health concerns with their physicians. Schering-Plough sells prescription drugs to wholesale and specialty distributors, hospitals, certain managed care organizations, retail and specialty pharmacists and government agencies.

Schering-Plough, through its trained professional sales representatives, promotes its animal health products to veterinarians, distributors and animal producers.

Schering-Plough sells over-the-counter (OTC), foot care and sun care products through wholesale and retail drug, food chain and mass merchandiser outlets. Schering-Plough promotes directly to the consumer through television, radio, Internet, print and other advertising media. Where appropriate, Schering-Plough seeks regulatory approval to switch prescription products to over-the-counter status. In this way, the OTC marketplace is another means of maximizing the return on investments in discovery and development.

The pharmaceutical industry is highly competitive and includes other large companies, some significantly larger than Schering-Plough, with substantial resources for research, product development, advertising, promotion and field selling support. Competitive pressures have intensified as pressures in the environment have intensified.

There are numerous domestic and international competitors in this industry. Some of the principal competitive techniques used by Schering-Plough for its products include research and development of new, innovative and improved products, varied dosage forms and strengths and switching prescription products to non-prescription status.

In the U.S., many of Schering-Plough s products are subject to increasingly competitive pricing as managed care groups, institutions, federal and state government entities and agencies and buying groups seek price discounts and rebates. Governmental, third-party payers, practices of U.S. pharmacists

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and other pressures toward the dispensing of generic products may significantly reduce the sales of certain products when they, or competing products in the same therapeutic category, are no longer protected by patents or exclusivity available under pharmaceutical regulatory laws. Outside the U.S. there are similar competitive pressures. Additionally, in Europe and some other international markets, the government regulates pharmaceutical prices and access to control costs for government sponsored healthcare systems. There is a possibility, that in the U.S., the Medicare Act could be amended to allow the federal government to negotiate prices directly with manufacturers. Additionally, several states are considering price controls or access constraints under the Medicaid program.

**Government Regulation**

Each of Schering-Plough s major business segments is subject to significant regulation in multiple jurisdictions. This section describes the general regulatory framework. Additional information about the cost of regulatory compliance and specific impacts on Schering-Plough s business and financial condition are described under the heading Regulatory And Competitive Environment In Which Schering-Plough Operates in Management s Discussion and Analysis later in this 10-K. Additional information about other regulatory matters can be found in Note 21, Legal, Environmental and Regulatory Matters, under Item 8, Financial Statements and Supplementary Data.

In the prescription pharmaceuticals segment, regulations apply at all phases of the business, including:

- regulatory requirements to conduct, and standards for, clinical trials (for example, requiring the use of Good Clinical Practices or GCPs), which apply at the research and development stage;
- regulatory requirements to conduct, and standards for, post-approval clinical trials;
- required regulatory approval to begin marketing a new drug or to market an existing drug product for new indications;
- regulations prescribing the manner in which drugs are manufactured, packaged, labeled, advertised, marketed and distributed;
- regulations impacting the pricing of drugs;
- regulatory requirements to assess and report adverse impacts and side effects of drugs used in clinical trials, as well as marketed drugs, called pharmacovigilance; and
- the ability of regulatory authorities to remove a product from the market, modify its approved uses/labeling or recall certain batches of products.

In the U.S., the national regulation of all phases of the prescription drug business except pricing is centralized at the FDA. The FDA is responsible for protecting the U.S. public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products and medical devices. Generally, there is free market pricing in the U.S., although the Centers for Medicare and Medicaid Services (CMS) and Medicare Part B and D include provisions about pricing drugs for the elderly, disabled and indigent who receive federal prescription benefits. Schering-Plough is also committed to complying with voluntary best practices of the Pharmaceutical Research and Manufacturers of America (PhRMA), a trade industry group of which it is a member, regarding marketing and advertising practices.

In the EU, including Schering-Plough s key markets in the United Kingdom, France, Germany and Italy, there is regulation at the local country level and additional regulation at the EU level, through the European Medicines Agency (EMEA). Pharmaceutical products are regulated at both of these levels through various national, mutual

recognition or centralized regulatory procedures. The EMEA coordinates the evaluation and supervision of the majority of medicinal products throughout the EU. There is no pan-EU market pricing system; however, individual member states have various systems/agencies that regulate price at a local level.

In Japan, there is regulation through the Pharmaceuticals and Medical Device Agency (PMDA). The PMDA regulates pharmaceuticals and medical devices from development through post-marketing use. The Japanese government regulates the pricing/reimbursement of pharmaceutical products in Japan through a

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complicated pricing process that includes benchmarks with prices in other western countries such as the U.S., Canada and select EU countries.

There is increasing pressure from governmental bodies in all major markets, as well as from third-party payors, for the pharmaceutical industry to bring products to market that provide differentiation versus existing products. This can lead to more expensive and scientifically challenging clinical trials in order to generate this type of data for new products versus marketed comparators.

In the U.S., the focus on product differentiation and reliance on comparator data will be accelerated by new federal grants provided through the stimulus package for comparative effectiveness reviews ($1.1 billion) and health information technology ($2.0 billion), coupled with $17 billion in bonus payments through Medicare and Medicaid to physicians and hospitals that adopt health information technology improvements. It is difficult to predict the speed of change or the degree of impact this new spending will have regarding pharmaceutical markets and branded pharmaceutical products.

For a description of the prescription pricing pressures refer to Pricing Pressures in Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations.

**Raw Materials**

Raw materials essential to Schering-Plough s operations are available in adequate quantities from a number of potential suppliers. Energy is expected to be available to Schering-Plough in sufficient quantities to meet its operating requirements.

**Seasonality**

Certain of Schering-Plough s products, particularly the respiratory and sun care products, are seasonal in nature. Seasonal patterns do not have a material effect on the consolidated operations of Schering-Plough.

**Environment**

To date, environmental matters have not had a material effect on Schering-Plough s operations or financial position. These matters include compliance with federal, state and local laws regarding discharge of materials into the environment, or protection of the environment and climate change.

**Employees**

At December 31, 2008, Schering-Plough had approximately 51,000 employees worldwide, with approximately 15,000 employees in the United States and approximately 36,000 employees outside the United States.

**Available Information**

Schering-Plough s 10-Ks, 10-Qs, 8-Ks and amendments to those reports that are filed with or furnished to the U.S. Securities and Exchange Commission (SEC) are available free of charge on Schering-Plough s web site as soon as reasonably practicable after such materials are electronically filed with the SEC. Schering-Plough s Internet address is www.schering-plough.com. Since Schering-Plough began this practice in the third quarter of 2002, each such report has been available on Schering-Plough s web site within 24 hours of filing. Reports filed by Schering-Plough with the SEC may be read and copied at the SEC s Public Reference Room at 100 F Street, NE, Washington, DC 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330.

The SEC also maintains an Internet site at www.sec.gov that contains reports, proxies and information statements and other information regarding issuers that file electronically with the SEC.

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

Schering-Plough s future operating results and cash flows may differ materially from the results described in this 10-K due to risks and uncertainties related to Schering-Plough s business, including those discussed

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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.

***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

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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 refer to Legal Proceedings in Item 3 in this 10-K 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. See Patent Challenges Under the Hatch-Waxman Act in Item 3, 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.

In addition to legislation concerning price controls, other trends could adversely affect Schering-Plough s sales and profit margins. These trends include legislative or regulatory action relating to pharmaceutical pricing and reimbursement, health care reform initiatives, drug importation legislation and involuntary approval of medicines for OTC use. These trends also include non-governmental initiatives and practices such as consolidation among

customers, managed care practices and health care costs containment. Increasingly, market approval, reimbursement of products, prescribers practices and policies of third-party payors may be

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influenced by health technology assessments by the National Institute for Health and Clinical Excellence in the UK and other such organizations.

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.

***Through the acquisition of OBS, Schering-Plough acquired marketed products and pipeline projects in new therapeutic areas, including women s health and central nervous system, each of which carry unique risks and uncertainties which could have a negative impact on future results of operations and cash flows.***

With its acquisition of OBS, Schering-Plough acquired products in additional therapeutic areas. Each therapeutic area presents a different risk profile, including different benefits and safety issues that must be balanced by Schering-Plough and regulators as various research and development and marketing decisions are made; unique product liability risks; different patient and prescriber priorities; and different societal pressures. While adding new therapeutic areas may strengthen Schering-Plough s business by increasing sales and profits; making the combined company more relevant to patients and prescribers; and diversifying enterprise risk across more areas, such positives may not outweigh the additional risk in a particular therapeutic area or could result in unanticipated costs that could have a significant adverse impact on results of operations and cash flows.

***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.

***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

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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.

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 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.

***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, 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 Item 3 in this 10-K 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 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.

There was significant negative media surrounding the release of the ENHANCE results. As the Merck/Schering-Plough cholesterol joint venture s ENHANCE and SEAS clinical trial results are further reviewed, VYTORIN and ZETIA may receive additional media attention, in connection with these and other clinical

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trials, which could lead to reduced sales, or affect enrollment in clinical trials. 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.

***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

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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 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.

***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 are outside the U.S. With the acquisition of OBS in late 2007, Schering-Plough s global operations in Prescription Pharmaceuticals and Animal Health increased. Acquisitions, such as the recently completed purchase of OBS, further expanded the size, scale and scope of Schering-Plough s global

operations. Risks inherent in conducting a global business include:

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

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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.

***The integration of the businesses of Schering-Plough and OBS to create a combined company is a complex process and may be subject to unforeseen developments, which could have an adverse impact on the results of future operations.***

As the two companies are combined, the workforces of Schering-Plough and OBS will continue to face uncertainties until the completion of the integration phase. Cultural integration particularly in trans-Atlantic transactions are complex and can take several years. Although substantial progress has been made towards completing the integration phase of the OBS acquisition as quickly as possible, it is difficult to predict how long the integration phase will last.

The workforces of both companies are learning to use new processes as work is integrated and streamlined. Further, for those employees of the new combined company who have not in the past worked for a U.S.-based global company, the applicable regulatory requirements are different in a number of respects. While substantial efforts are being made to facilitate smooth execution of integration including thorough training and transparent and motivational employee communications there may be an increased risk of slower execution of various work processes, repeated execution to achieve quality standards and reputational harm in the event of a compliance failure with new and complex regulatory requirements, even if such a failure were inadvertent. Any such events could have an adverse impact on the results of future operations.

***The acquisition of OBS expanded Schering-Plough s animal health business worldwide, which increases the risk that negative events in the animal health industry could have a negative impact on future results of operations.***

Through the acquisition of OBS s animal health business, Schering-Plough s global Animal Health business is a more significant business segment. The combined company s 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.

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***The acquisition of OBS increased Schering-Plough s biologics human and animal health product offerings, including animal health vaccines. 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 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.

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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 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, new tax laws and revised tax law interpretations in domestic and foreign jurisdictions.

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**Item 1B.** ***Unresolved Staff Comments***

None.

**Item 2.** ***Properties***

Schering-Plough s corporate and global pharmaceutical headquarters are located in Kenilworth, New Jersey. Schering-Plough s Animal Health global headquarters is located in Boxmeer, the Netherlands. Principal U.S. research facilities are located in Kenilworth, Union and Summit, New Jersey; Palo Alto, California; and Nebraska (Animal Health). Principal research facilities outside the U.S. are located in the Netherlands and Scotland. Principal manufacturing facilities are as follows:

| Location | Product Type |
|---|---|
| Belgium | Pharmaceuticals |
| Brazil | Pharmaceuticals, Animal Health |
| Cleveland, Tennessee, U.S.A. | Consumer Products |
| France | Pharmaceuticals |
| Ireland | Pharmaceuticals, Consumer Products, Animal Health |
| Kenilworth, New Jersey, U.S.A. | Pharmaceuticals, Consumer Products |
| Mexico | Pharmaceuticals |
| Millsboro, Delaware, U.S.A. | Animal Health |
| Netherlands | Pharmaceuticals, Animal Health |
| Omaha, Nebraska, U.S.A. | Animal Health |
| Puerto Rico | Pharmaceuticals |
| Research Triangle Park, North Carolina, U.S.A. | Pharmaceuticals |
| Singapore | Pharmaceuticals |

Schering-Plough owns the majority of its properties. In general, the properties are adequately maintained and suitable for their purposes.

As discussed in more detail in Part II of this 10-K, certain of Schering-Plough s manufacturing sites operate below capacity. In April 2008, Schering-Plough announced as part of the Productivity Transformation Program that there would be a reduction in the number of plants worldwide, with the goal of creating a more focused and high-efficiency network of plants by 2012. Analysis of the optimal configuration of plants is ongoing.

**Item 3.** ***Legal Proceedings***

Material pending legal proceedings, other than ordinary routine litigation incidental to the business, to which Schering-Plough Corporation or any of its subsidiaries or to which any of their property is subject, are disclosed below.

Additional information on legal proceedings, including important financial information, can be found in Note 21, Legal, Environmental and Regulatory Matters, contained in Item 8, Financial Statements and Supplementary Data.

***Patent Matters***

As described in Patents, Trademarks, and Other Intellectual Property Rights under Item 1, Business, of this 10-K, intellectual property protection is critical to Schering-Plough s ability to successfully commercialize its product innovations. The potential for litigation regarding Schering-Plough s intellectual property rights always exists and may be initiated by third parties attempting to abridge Schering-Plough s rights, as well as by Schering-Plough in protecting its rights. Patent matters described below have a potential material effect on Schering-Plough.

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*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. Trial is scheduled to begin on March 20, 2009 in the U.S. District Court for the District of Delaware;

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 the majority of companies and continues to litigate with the three remaining 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; and

on February 18, 2009 Schering-Plough and its licensor filed a patent infringement action against a company seeking approval of a generic version of INTEGRILIN.

***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

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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 is scheduled to be presented for final approval at a hearing on June 1, 2009.

*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, retired Chairman, CEO and President Richard Jay Kogan, 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.

*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.

*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. Please refer to Legal Proceedings in Item 3 in Schering-Plough s 2007 10-K/A and Part II, Item 1, Legal Proceedings, in the Forms 10-Q for the periods ending March 31, 2008, June 30, 2008 and September 30, 2008. Also see Part II, OTHER INFORMATION, Recent Cholesterol Clinical Trials, in the Forms 10-Q for the periods ending June 30, 2008 and September 30, 2008.

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-K, Schering-Plough, the 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

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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.

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.

***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. This refund litigation has been tried in Newark District court and a decision has not yet been rendered. Schering-Plough s tax reserves were adequate to cover the above-mentioned payments.

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***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 of 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 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.

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.

**Item 4.** ***Submission of Matters to a Vote of Security Holders***

Not applicable.

**Executive Officers of the Registrant**

Listed below are the executive officers and corporate officers of Schering-Plough as of February 27, 2009. Unless otherwise indicated, each has held the position indicated for the past five years. Officers serve for one year and until their successors have been duly appointed.

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| Name | Title | Age |
|---|---|---|
| Robert J. Bertolini* | Executive Vice President and Chief Financial Officer(1) | 47 |
| John M. Carroll | Vice President, Global Internal Audits(2) | 48 |
| C. Ron Cheeley* | Senior Vice President, Global Human Resources(3) | 58 |
| Carrie S. Cox* | Executive Vice President and President, Global Pharmaceuticals(4) | 51 |
| William J. Creelman | Vice President, Tax(5) | 54 |
| Fred Hassan* | Chairman and Chief Executive Officer(6) | 63 |
| Maria Teresa Hilado | Vice President and Treasurer(7) | 44 |
| Steven H. Koehler* | Vice President and Controller(8) | 58 |
| Thomas P. Koestler, Ph.D.* | Executive Vice President and President, Schering-Plough Research Institute(9) | 57 |
| Raul E. Kohan* | Senior Vice President and President, Intervet/Schering-Plough Animal Health(10) | 56 |
| Ian A.T. McInnes, Ph.D. | Senior Vice President and President, Global Supply Chain(11) | 56 |
| Lori Queisser* | Senior Vice President, Global Compliance and Business Practices(12) | 48 |
| Thomas J. Sabatino, Jr.* | Executive Vice President and General Counsel(13) | 50 |
| Karl D. Salnoske | Vice President and Chief Information Officer(14) | 55 |
| Brent Saunders* | Senior Vice President and President, Consumer Health Care(15) | 39 |
| Susan Ellen Wolf | Corporate Secretary, Associate General Counsel and Vice President, Governance(16) | 54 |

* Officers as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934.

(1) Mr. Bertolini joined Schering-Plough in 2003 as Executive Vice President and Chief Financial Officer. Mr. Bertolini was a partner at PricewaterhouseCoopers from 1993 to 2003.

(2) Mr. Carroll joined Schering-Plough in 2006 as Vice President, Global Internal Audits. Mr. Carroll was Vice President and General Auditor of American Standard Companies from 2005 to 2006, General Auditor of American Standard Companies from 2002 to 2005.

(3) Mr. Cheeley joined Schering-Plough in 2003 as Senior Vice President, Global Human Resources. Mr. Cheeley was Group Vice President, Global Compensation and Benefits of Pharmacia Corporation from 1998 to 2003.

(4) Ms. Cox joined Schering-Plough in 2003 as Executive Vice President and President, Global Pharmaceuticals. Ms. Cox was Executive Vice President and President, Global Prescription Business of Pharmacia Corporation from 1999 to 2003.

(5) Mr. Creelman joined Schering-Plough in 2004 as Vice President, Tax. Mr. Creelman was Senior Tax Counsel of Pfizer from 2003 to 2004. Mr. Creelman was Assistant Vice President International Tax of CIGNA Corporation from 2002 to 2003.

(6) Mr. Hassan joined Schering-Plough in 2003 as Chairman of the Board and Chief Executive Officer. Mr. Hassan was Chairman of the Board and Chief Executive Officer of Pharmacia Corporation from 2001 to 2003.

(7)

Ms. Hilado joined Schering-Plough in May 2008 as Vice President and Treasurer. Ms. Hilado was Assistant Treasurer for General Motors Corporation from January 2006 to April 2008, and Chief Financial Officer of GMAC Commercial Finance from 2001 to 2005.

(8) Mr. Koehler joined Schering-Plough in 2006 as Vice President and Controller. Mr. Koehler was Senior Vice President, Chief Financial Officer and Treasurer from 2004 to 2006, and Vice President, Chief Financial Officer, Treasurer and Corporate Secretary from 2002 to 2004 of The Medicines Company.

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(9) Dr. Koestler was named Executive Vice President and President of Schering-Plough Research Institute in September 2006. Dr. Koestler was Executive Vice President, Global Development of Schering-Plough Research Institute from 2005 to September 2006; Executive Vice President of Schering-Plough Research Institute from 2003 to 2005, and Senior Vice President, Global Regulatory Affairs of Pharmacia Corporation from 2001 to 2003.

(10) Mr. Kohan was named Senior Vice President and President, Intervet/Schering-Plough Animal Health in October 2008. Mr. Kohan was Deputy Head of Animal Health and Senior Vice President, Corporate Excellence and Administrative Services of Schering-Plough Corporation from the end of 2007 to October 2008. Mr. Kohan was Senior Vice President and President Animal Health from February 2007 to October 2007 and Group Head of Global Specialty Operations and President, Animal Health from 2003 to 2007.

(11) Dr. McInnes was named Senior Vice President and President, Global Supply Chain in February 2008. Dr. McInnes joined Schering-Plough in 2004 as Senior Vice President, Global Supply Chain. Dr. McInnes was Senior Vice President, Global Supply Chain of Pharmacia Corporation from 1994 to 2003 and Executive Vice President, Supply Chain, Watson Pharmaceuticals, Inc. from 2003 to 2004.

(12) Ms. Queisser joined Schering-Plough in February 2007 as Senior Vice President, Global Compliance and Business Practices. Ms. Queisser was Vice President, Chief Compliance Officer of Eli Lilly Company from October 2002 to February 2007.

(13) Mr. Sabatino joined Schering-Plough in 2004 as Executive Vice President and General Counsel. Mr. Sabatino was Senior Vice President and General Counsel of Baxter International, Inc. from 2001 to 2004.

(14) Mr. Salnoske joined Schering-Plough in 2004 as Vice President and Chief Information Officer. Mr. Salnoske was CEO of Adaptive Trade from 2001 to 2004.

(15) Mr. Saunders joined Schering-Plough in 2003 as Senior Vice President, Global Compliance and Business Practices. Mr. Saunders was a partner at PricewaterhouseCoopers prior to joining Schering-Plough in 2003.

(16) Ms. Wolf was named Vice President, Corporate Secretary and Associate General Counsel in 2004. She held various positions in Schering-Plough s Law Department from 2002 to 2004.

## Part II

### Item 5. *Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities*

The principal market for Schering-Plough s common stock is the New York Stock Exchange. Additional information required by this Item is incorporated by reference from the table captioned Quarterly Data (unaudited) under Item 8, Financial Statements and Supplementary Data.

The following table provides information with respect to purchases by Schering-Plough of its common shares during the fourth quarter of 2008.

**ISSUER PURCHASES OF EQUITY SECURITIES**

| Period | Total Number of Shares Purchased(1) | Average Price Paid per Share | Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs | Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs |
|---|---|---|---|---|
| October 1, 2008 through October 31, 2008 | 1,644 | $ 13.08 | N/A | N/A |
| November 1, 2008 through November 30, 2008 | 18,611 | $ 14.49 | N/A | N/A |
| December 1, 2008 through December 31, 2008 | 18,881 | $ 15.45 | N/A | N/A |
| **Total October 1, 2008 through December 31, 2008** | **39,136** | **$ 14.89** | **N/A** | **N/A** |

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(1) All of the shares included in the table above 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, pursuant to Schering-Plough s stock incentive program.

**Performance Graph**

**Comparison of Cumulative Total Return**

| | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 |
|---|---|---|---|---|---|---|
| Schering-Plough Corporation | 100 | 122 | 123 | 140 | 160 | 104 |
| Composite Peer Group | 100 | 92 | 89 | 103 | 109 | 90 |
| S&P 500 Index | 100 | 111 | 116 | 134 | 142 | 90 |

The graph above assumes a $100 investment on December 31, 2003, and reinvestment of all dividends, in each of Schering-Plough s Common Shares, the S&P 500 Index, and a composite peer group of the major U.S.-based pharmaceutical companies, which are: Abbott Laboratories, Bristol-Myers Squibb Company, Johnson & Johnson, Eli Lilly and Company, Merck, Pfizer Inc. and Wyeth.

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**Item 6.** ***Selected Financial Data***

| | 2008(1) | 2007(1) | 2006 | 2005 | 2004 |
|---|---|---|---|---|---|
| | (In millions, except per share figures and percentages) | | | | |
| **Operating Results** | | | | | |
| Net sales | $ 18,502 | $ 12,690 | $ 10,594 | $ 9,508 | $ 8,272 |
| Equity (income) | (1,870) | (2,049) | (1,459) | (873) | (347) |
| Income/(loss) before income taxes and cumulative effect of a change in accounting principle(2) | 2,049 | (1,215) | 1,483 | 497 | (168) |
| Net income/(loss)(2) | 1,903 | (1,473) | 1,143 | 269 | (947) |
| Net income/(loss) available to common shareholders(2) | 1,753 | (1,591) | 1,057 | 183 | (981) |
| Diluted earnings/(loss) per common share(2) | 1.07 | (1.04) | 0.71 | 0.12 | (0.67) |
| Basic earnings/(loss) per common share(2) | 1.08 | (1.04) | 0.71 | 0.12 | (0.67) |
| Research and development expenses | 3,529 | 2,926 | 2,188 | 1,865 | 1,607 |
| Acquired in-process research and development | | 3,754 | | | |
| Depreciation and amortization expenses | 2,175 | 861 | 568 | 486 | 453 |
| **Financial Position and Cash Flows** | | | | | |
| Property, net | $ 6,833 | $ 7,016 | $ 4,365 | $ 4,487 | $ 4,593 |
| Total assets | 28,117 | 29,156 | 16,071 | 15,469 | 15,911 |
| Long-term debt(3) | 7,931 | 9,019 | 2,414 | 2,399 | 2,392 |
| Shareholders equity | 10,529 | 10,385 | 7,908 | 7,387 | 7,556 |
| Capital expenditures | 747 | 618 | 458 | 478 | 489 |
| **Financial Statistics** | | | | | |
| Net income/(loss) as a percent of net sales | 10.3% | (11.6)% | 10.8% | 2.8% | (11.4)% |
| Return on average shareholders equity | 18.1% | (16.1)% | 14.9% | 3.6% | (12.7)% |
| Net book value per common share(4) | $ 6.13 | $ 6.07 | $ 5.10 | $ 4.77 | $ 4.91 |
| **Other Data** | | | | | |
| Cash dividends per common share | $ 0.26 | $ 0.25 | $ 0.22 | $ 0.22 | $ 0.22 |
| Cash dividends paid on common shares | 422 | 382 | 326 | 324 | 324 |
| Cash dividends paid on preferred shares | 150 | 99 | 86 | 86 | 30 |
| Average shares outstanding used in calculating diluted earnings/(loss) per common share | 1,635 | 1,536 | 1,491 | 1,484 | 1,472 |
| Average shares outstanding used in calculating basic earnings/(loss) per common share | 1,625 | 1,536 | 1,482 | 1,476 | 1,472 |
| Common shares outstanding at year-end | 1,626 | 1,621 | 1,487 | 1,479 | 1,474 |

(1) Operating results and other financial information reflects the operations of the OBS business subsequent to the acquisition on November 19, 2007, including the impacts of purchase accounting in accordance with

SFAS No. 141, Business Combinations.

(2) 2008, 2007, 2006, 2005, and 2004 include special and acquisition-related charges and manufacturing streamlining costs of $329, $84, $248, $294, and $153, respectively. See Note 3, Special and Acquisition-Related Charges and Manufacturing Streamlining, for additional information on these charges that were incurred in 2008, 2007 and 2006. The special charges incurred in 2005 of $294 million included litigation charges of $250 million, employee termination costs of $28 million and asset impairment and other charges of $16 million. The special charges incurred in 2004 included $119 million of employee termination costs and $34 million for asset impairment and related charges.

(3) The increase in long-term debt in 2007, as compared to 2006, primarily reflects the financing of the OBS acquisition.

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(4) Assumes conversion of all 2007 mandatory convertible preferred stock into approximately 91 million common shares in 2008 and 2007. Assumes conversion of all 2004 mandatory convertible preferred stock into approximately 65 million common shares in 2006, 69 million common shares in 2005 and 65 million common shares in 2004. In 2007, the 2004 mandatory convertible preferred stock converted into common shares.

## Item 7. *Management s Discussion and Analysis of Financial Condition and Results of Operations*

## EXECUTIVE SUMMARY

### 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., golimumab, sugammadex in the U.S., thrombin receptor antagonist, vicriviroc, boceprevir and asenapine), 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.

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. Over the past five years, sales of Schering-Plough pharmaceutical products across an array of therapeutic areas showed strong growth compared to prior periods and other pharmaceutical companies. Schering-Plough s pharmaceutical sales and marketing activities were further expanded in newer markets. This geographic diversity adds to growth and makes performance less sensitive to any one geographic area. Substantial progress was made with the integration of Organon BioSciences N.V. (OBS), purchased from Akzo Nobel in late 2007. That acquisition was transformative, giving Schering-Plough:

Key new pipeline projects (including asenapine for schizophrenia and bipolar disease and sugammadex to reverse deep anesthesia);

Key products in two new therapeutic areas Women s Health and Central Nervous System;

A position as a leader in Animal Health by combining Schering-Plough Animal Health with Intervet;

A leadership position in animal vaccines at Intervet and early-stage innovation capabilities in human vaccines at Nobilon;

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Additional state-of-the-art biologics capabilities;

A substantial expansion to the Company s geographic footprint; and

Significant talent, including in key research and development functions.

In April 2008, Schering-Plough announced the Productivity Transformation Program (PTP). The goal of this program, which includes the ongoing integration of OBS, 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 with the balance achieved by 2012. The targeted savings envisioned by this program include those resulting from the previously announced OBS integration synergies. 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.

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.

The pharmaceutical industry is under increasing political and regulatory pressure, particularly in the United States and Schering-Plough and the Merck/Schering-Plough Cholesterol Joint Venture have encountered specific challenges during 2008, as explained in more detail in Item 3, Legal Proceedings, Litigation and Investigations relating to the Merck/Schering-Plough Cholesterol Joint Venture.

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, including those relating to the Merck/Schering-Plough Cholesterol Joint Venture.

***Results and Highlights of Schering-Plough s performance in 2008 are as follows:***

Schering-Plough s net sales for 2008 were $18.5 billion, an increase of $5.8 billion, or 46 percent, as compared to 2007. This increase in net sales was primarily due to the contribution of the products from OBS during 2008.

For 2008, net sales outside the U.S. totaled $12.9 billion. This approximated 70 percent of consolidated net sales.

Net income available to common shareholders for 2008 was $1.8 billion which includes a gain on the divestitures of certain Animal Health products.

Increased sales in 2008, of pharmaceutical products such as REMICADE, TEMODAR and NASONEX as well as increased sales in the Animal Health segment contributed favorably to Schering-Plough s overall operating results. Overall operating results also benefited from the increased sales of OBS products.

Global combined net sales of Schering-Plough s cholesterol franchise products, VYTORIN and ZETIA, decreased 11 percent during 2008 as compared 2007. Combined net sales of the products VYTORIN and ZETIA in the U.S. decreased 24 percent during 2008 as compared to 2007.

**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

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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 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 this 10-K, and the change of control provision relating to REMICADE and golimumab is contained in the contract with Centocor, filed as Exhibit 10(v) in this 10-K.

**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 of 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 sales of VYTORIN and ZETIA for 2008, decreased 11 percent as compared to 2007. During 2008, total combined sales of VYTORIN and ZETIA in the U.S. declined 24 percent as compared to 2007. During 2008, total combined sales of VYTORIN and ZETIA outside the U.S. increased 30 percent as compared to 2007. As of December 2008, total combined prescription share for VYTORIN and ZETIA in the U.S. was down versus December 2007 from 16.9 percent to 10.1 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, which was approved in Japan in April 2007 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.

**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, a fully human monoclonal antibody which has been filed for approval in Europe. 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 golimumab, extending Schering-Plough s rights to exclusively market REMICADE to match the duration of Schering-Plough s exclusive marketing rights for

golimumab. Effective upon regulatory approval of golimumab in the EU, Schering-Plough s marketing rights for both products will extend for 15 years after the first commercial sale of golimumab within the EU. Centocor will receive a progressively increased share of profits on Schering-Plough s distribution of both products in the Schering-Plough marketing territory between 2010 and 2014, and the share of profits will remain fixed thereafter for the remainder of the term. The changes to the duration of REMICADE marketing rights and the profit sharing arrangement for the products are all

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conditioned on approval of golimumab being granted prior to September 1, 2014. Schering-Plough may independently develop and market golimumab for a Crohn s disease indication in its territories, with an option for Centocor to participate. In addition, Schering-Plough and Centocor agreed to utilize an autoinjector device in the commercialization of golimumab and further agreed to share its development costs.

**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 reductions in the number of Schering-Plough manufacturing facilities 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. 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.

**OBS Acquisition**

On November 19, 2007, Schering-Plough acquired OBS for a purchase price of approximately Euro 11 billion in cash, or approximately $16.1 billion.

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Commencing from the acquisition date, OBS s assets acquired and liabilities assumed, as well as the results of OBS s operations, are included in Schering-Plough s consolidated financial statements. There were approximately one and one-half months of results of operations relating to OBS included in Schering-Plough s Statement of Consolidated Operations for the year ended December 31, 2007.

The impact of purchase accounting resulted in the following non-cash charges in 2008 and 2007:

Acquired In-Process Research and Development (IPR&D), which was a one-time charge of approximately $3.8 billion in 2007.

Amortization of inventory adjusted to fair value of approximately $1.1 billion was charged to Cost of Sales ($889 million in 2008 and $258 million in 2007).

Amortization of acquired intangible assets adjusted to fair value, of which $6.8 billion will be amortized over a weighted average life of 15 years to Cost of Sales ($527 million in 2008 and $65 million in 2007).

Incremental depreciation relating to the adjustment in fair value on property, plant and equipment of approximately $900 million that will be depreciated primarily to Cost of Sales over the lives of the applicable property ($33 million in 2008 and $3 million in 2007).

**DISCUSSION OF OPERATING RESULTS**

The results of operations in 2008 and 2007 discussed below include OBS s product sales and expenses as well as certain non-cash charges relating to purchase accounting associated with the OBS acquisition.

***Net Sales***

Consolidated net sales in 2008 were $18.5 billion, an increase of $5.8 billion or 46 percent as compared to 2007. Consolidated net sales in 2008 included $5.4 billion of net sales of products from OBS. The increase was primarily due to the acquisition of OBS, on November 19, 2007. Foreign exchange had an estimated 3% favorable impact on sales in 2008. Since the acquisition of OBS, a greater proportion of Schering-Plough s sales are denominated in Euros. Net sales outside the U.S. are approximately 70 percent of consolidated net sales.

Consolidated net sales in 2007 were $12.7 billion, an increase of $2.1 billion or 20 percent compared to 2006. Consolidated net sales in 2007 included $626 million of net sales of products from OBS related to the period subsequent to the acquisition. The increase primarily reflected the growth in sales volumes of REMICADE, TEMODAR, NASONEX and AVELOX as well as contributions from Animal Health and Consumer Health Care and an estimated favorable impact of 4 percent from foreign exchange.

A significant portion of U.S. net sales are made to major pharmaceutical and health care product distributors and major retail chains. 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 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, 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. This

prescription drug benefit became effective on January 1, 2006 and is resulting 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 may and 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.

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Net sales for the years ended December 31, 2008, 2007, and 2006 were as follows:

| | 2008 | 2007 | 2006 | % Increase (Decrease) 2008/2007 | % Increase (Decrease) 2007/2006 |
|---|---|---|---|---|---|
| | (Dollars in millions) | | | | |
| **PRESCRIPTION PHARMACEUTICALS** | **$ 14,253** | **$ 10,173** | **$ 8,561** | **40%** | **19%** |
| REMICADE | 2,118 | 1,648 | 1,240 | 28% | 33% |
| NASONEX | 1,155 | 1,092 | 944 | 6% | 16% |
| TEMODAR | 1,002 | 861 | 703 | 16% | 22% |
| PEGINTRON | 914 | 911 | 837 | | 9% |
| CLARINEX/AERIUS | 790 | 799 | 722 | (1)% | 11% |
| FOLLISTIM/PUREGON(1) | 577 | 57 | | N/M | N/M |
| NUVARING(1) | 440 | 45 | | N/M | N/M |
| CLARITIN Rx | 425 | 391 | 356 | 9% | 10% |
| AVELOX | 376 | 384 | 304 | (2)% | 26% |
| INTEGRILIN | 314 | 332 | 329 | (5)% | 1% |
| CAELYX | 297 | 257 | 206 | 16% | 25% |
| REBETOL | 260 | 277 | 311 | (6)% | (11)% |
| ZEMURON(1) | 253 | 25 | | N/M | N/M |
| REMERON(1) | 239 | 33 | | N/M | N/M |
| INTRON A | 234 | 233 | 237 | | (2)% |
| SUBUTEX/SUBOXONE | 230 | 220 | 203 | 5% | 8% |
| ASMANEX | 180 | 162 | 103 | 11% | 57% |
| Other Pharmaceutical | 4,449 | 2,446 | 2,066 | N/M | 18% |
| **ANIMAL HEALTH** | **2,973** | **1,251** | **910** | **138%** | **37%** |
| **CONSUMER HEALTH CARE** | **1,276** | **1,266** | **1,123** | **1%** | **13%** |
| OTC | 680 | 682 | 558 | | 22% |
| Foot Care | 357 | 345 | 343 | 3% | 1% |
| Sun Care | 239 | 239 | 222 | | 8% |
| **CONSOLIDATED NET SALES** | **$ 18,502** | **$ 12,690** | **$ 10,594** | **46%** | **20%** |

(1) Products acquired in OBS acquisition on November 19, 2007

N/M Not a meaningful percentage.

Sales of Prescription Pharmaceuticals in 2008 totaled $14.3 billion, a $4.1 billion or 40 percent increase compared to 2007. Included in 2008 and 2007 are $3.5 billion and $409 million of net sales related to Organon, the human health business of OBS. Sales of Prescription Pharmaceuticals in 2007 totaled $10.2 billion, a $1.6 billion or 19 percent increase compared to 2006.

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 28 percent to $2.1 billion in 2008 as compared to 2007 driven by continued

market growth, expanded penetration in certain indications and a favorable impact from foreign exchange. International net sales increased 33 percent in 2007 to $1.6 billion as compared to 2006, due to greater demand, expanded use across indications and a favorable impact from foreign exchange. REMICADE is an anti-TNF antibody, marketed by Schering-Plough outside of the U.S., Japan and certain Asian markets. Competitive products for the indications referred to above have been introduced during 2007 and 2008.

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Global net sales of NASONEX Nasal Spray, a once-daily corticosteroid nasal spray for allergies, rose 6 percent to $1.2 billion in 2008 as compared to 2007 due to increased sales in the international market and 16 percent to $1.1 billion in 2007 as compared to 2006, as the product captured greater U.S. and international market share in 2007. Competitive products have been introduced in 2007 and 2008.

Global net sales of TEMODAR, a treatment for certain types of brain tumors, increased 16 percent to $1 billion in 2008 as compared to 2007 due to increased sales across geographic regions. Global net sales increased 22 percent to $861 million in 2007 as compared to 2006 due to increased sales across geographic markets, including Japan, where the product was launched in September 2006. TEMODAR will lose patent exclusivity in the EU in 2009.

Global net sales of PEGINTRON Powder for Injection, a pegylated interferon product for treating hepatitis C, were essentially flat in 2008 as compared to 2007, including a favorable impact of foreign exchange. Global net sales increased 9 percent to $911 million in 2007 as compared to 2006 due to higher sales in Latin America and emerging markets across Europe, and tempered by lower sales in Japan due to increased competition and a decrease in the U.S. market size.

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, in 2008 decreased 1 percent to $790 million as compared to 2007 primarily due to lower sales in the United States. Global net sales in 2007 increased 11 percent to $799 million as compared to 2006 primarily due to higher sales in international markets.

Global net sales of FOLLISTIM/PUREGON, a recombinant follicle-stimulating hormone for treating infertility, were $577 million in 2008 and $57 million for 2007 (which represent sales from the date of the OBS acquisition on November 19, 2007 through December 31, 2007). FOLLISTIM/PUREGON will lose patent exclusivity in the EU in 2009.

Global net sales of NUVARING, a contraception product, were $440 million for 2008 and $45 million for 2007 (which represent sales from the date of the OBS acquisition on November 19, 2007 through December 31, 2007).

International net sales of prescription CLARITIN increased 9 percent to $425 million in 2008 as compared to 2007, primarily due to higher sales in Japan and favorable foreign exchange. Sales in 2007 increased 10 percent to $391 million as compared to 2006, reflecting growth in Latin America, Asia Pacific and Japan.

Net sales of AVELOX, a fluoroquinolone antibiotic for the treatment of certain respiratory and skin infections, marketed in the U.S. by Schering-Plough as a result of its license agreement with Bayer, decreased 2 percent to $376 million in 2008 as compared to 2007, reflecting a decline in the U.S. respiratory tract infection market. Net sales in 2007 increased 26 percent to $384 million in 2007 as compared to $304 million in 2006, primarily as a result of increased market share.

Global net sales of INTEGRILIN Injection, a glycoprotein platelet aggregation inhibitor for the treatment of patients with acute coronary syndrome, that is sold primarily in the U.S. by Schering-Plough, decreased 5 percent to $314 million in 2008 as compared to 2007. During 2007, sales increased 1 percent to $332 million as compared to 2006.

International net sales of CAELYX, for the treatment of ovarian cancer, metastatic breast cancer and Kaposi s sarcoma, increased 16 percent to $297 million in 2008 as compared to 2007 primarily due to higher sales across Europe and favorable foreign exchange. Sales in 2007 increased 25 percent to $257 million as compared to 2006 primarily due to increased sales in Latin America and a favorable impact from foreign exchange.

Global 2008 net sales of REBETOL Capsules, for use in combination with PEGINTRON or INTRON A for treating hepatitis C, decreased 6 percent to $260 million as compared to 2007 due to lower sales in Japan and continued generic competition. Global net sales in 2007 decreased 11 percent to $277 million as compared to 2006 due to lower patient enrollment in Japan and increased generic competition.

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Global net sales of ZEMURON, a muscle relaxant used in surgical procedures, were $253 million in 2008 and $25 million in 2007 (which represent sales from the date of the OBS acquisition on November 19, 2007, through December 31, 2007). ZEMURON lost patent exclusivity in the U.S. in October 2008 and will lose patent exclusivity in the EU in 2009.

Global net sales of REMERON, an antidepressant, were $239 million in 2008 and $33 million in 2007 (which represent sales from the date of the OBS acquisition on November 19, 2007, through December 31, 2007).

Global net sales of INTRON A Injection, for chronic hepatitis B and C and other antiviral and anticancer indications, were essentially flat in 2008 as compared to 2007 and decreased 2 percent in 2007 to $233 million as compared to 2006. The decrease in 2007 as compared to 2006 was due to the conversion to PEGINTRON for treating hepatitis C in Japan.

International net sales of SUBUTEX/SUBOXONE, for the treatment of opiate addiction, increased 5 percent to $230 million in 2008 as compared to 2007. Sales increased 8 percent to $220 million in 2007 as compared to 2006. The increases in 2008 and 2007 resulted primarily from the benefit of foreign exchange.

Global net sales of ASMANEX, an orally inhaled steroid for asthma, were up 11 percent to $180 million in 2008 as compared to 2007 primarily due to market share growth in the U.S. Sales increased to $162 million in 2007 as compared to 2006 due to the increase in sales in the U.S.

Other pharmaceutical net sales include a large number of lower sales volume prescription pharmaceutical products and included $2.0 billion and $249 million of net sales from OBS products for 2008 and 2007, respectively. 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.

Global net sales of Animal Health products increased 138 percent to approximately $3.0 billion in 2008 as compared to 2007. Included in global Animal Health net sales are $1.9 billion related to Intervet, the animal health business of OBS. Global net sales in 2008 benefited from solid growth in all geographic areas, led by the cattle, poultry and companion animal product lines, coupled with a positive impact from foreign currency exchange rates. Global net sales increased 37 percent in 2007 to $1.3 billion as compared to 2006, reflecting strong growth of core brands across most geographic and species areas led by higher sales of companion animal products and the inclusion of Intervet sales. The Animal Health segment s sales are 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, increased 1 percent or $10 million as compared to 2007. The increase in 2008 was mainly due to higher sales of MiraLAX, which was launched in February 2007 as the first Rx-to-OTC switch in the laxative category in more than 30 years, offset by lower sales of other OTC products. OTC CLARITIN sales decreased 12 percent to $405 million in 2008 as compared to 2007 as a result of increased competition from private-label products. Global net sales in 2007 increased 13 percent or $143 million as compared to 2006 reflecting an increase in sales of sun care products and DR. SCHOLL S products and the launch of MiraLAX. In addition, sales of OTC CLARITIN increased 18 percent to $462 million in 2007 as compared to 2006 due to sales growth across all product forms. Net sales of sun care products increased $17 million or 8 percent in 2007 as compared to 2006, primarily due to the success of COPPERTONE CONTINUOUS SPRAY products launched in 2005. The consumer health care market is highly competitive, with heavy advertising to consumers and frequent competitive product introductions, including a former prescription antihistamine that was launched for OTC sales in early 2008, and the impact of U.S. consumers purchasing patterns.

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

A summary of costs, expenses and equity income for the years ended December 31, 2008, 2007 and 2006 is as follows:

| | | | | % Increase (Decrease) | |
|---|---|---|---|---|---|
| | **2008** | **2007** | **2006** | **2008/2007** | **2007/2006** |
| | **(Dollars in millions)** | | | | |
| Gross margin | 60.5% | 65.3% | 65.1% | (4.8)% | 0.2% |
| Selling, general and administrative (SG&A) | $ 6,823 | $ 5,468 | $ 4,718 | 24.8% | 15.9% |
| Research and development (R&D) | 3,529 | 2,926 | 2,188 | 20.6% | 33.7% |
| Acquired in-process research and development (IPR&D) | | 3,754 | | N/M | N/M |
| Other expense/(income), net | 335 | (683) | (135) | N/M | N/M |
| Special and acquisition-related charges | 329 | 84 | 102 | N/M | N/M |
| Equity income | (1,870) | (2,049) | (1,459) | (9)% | 40.4% |

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. 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 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 was 60.5 percent in 2008 as compared to 65.3 percent in 2007. Gross margin in 2008 and 2007 was unfavorably impacted by $1.4 billion and $326 million, respectively, of purchase accounting adjustments included in cost of sales. These purchase accounting adjustments were a result of the amortization of fair values of primarily inventories and intangible assets acquired as part of the OBS acquisition. Gross margin in 2007, when compared to 2006, benefited from realized cost savings of approximately $100 million from manufacturing streamlining in 2006, the non-recurrence of $146 million of charges associated with the aforementioned manufacturing streamlining actions and favorable product mix.

*Selling, general and administrative*

Selling, general and administrative expenses (SG&A) increased 25 percent to $6.8 billion in 2008 as compared to 2007. The increase in SG&A is primarily due to the inclusion of expenses from OBS and the impact of foreign exchange partially offset by the Productivity Transformation Program savings.

SG&A increased 16 percent to $5.5 billion in 2007 as compared to 2006, reflecting higher promotion spending, ongoing investments in emerging markets and an unfavorable impact from foreign exchange.

*Research and development*

Research and development (R&D) spending increased 21 percent to $3.5 billion in 2008 as compared to 2007. Included in R&D in 2007 were upfront payments of $197 million mainly related to certain licensing transactions. The increase in R&D spending versus 2007 also reflects increased spending as a result of the OBS acquisition, as well as higher spending for clinical trials and related activities and investments to build greater breadth and capacity to support Schering-Plough s expanding global R&D pipeline. In 2007, R&D spending increased 34 percent to $2.9 billion as compared to 2006. The 2007 increase was due to higher costs associated with clinical trials, as well as building greater breadth and capacity to support Schering-Plough s pipeline. Changes in R&D spending also reflect the timing of Schering-Plough s funding of both internal

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research efforts and research collaborations with various partners to discover and develop a steady flow of innovative products.

To maximize its chances for the successful development of new products, Schering-Plough began a Development Excellence initiative in 2005 to build talent and critical mass, create a uniform level of excellence and deliver on high-priority programs within R&D. In 2006, Schering-Plough began a Global Clinical Harmonization Program to maximize and globalize the quality of clinical trial execution, pharmacovigilance and regulatory processes. Beginning in 2007, certain aspects of the Global Clinical Harmonization Program have been implemented and continue to be integrated into the processes of OBS.

*Other expense/(income), net*

Other expense/(income), net is comprised of the following for the years ended December 31:

| | 2008 | 2007 | 2006 |
|---|---|---|---|
| | (Dollars in millions) | | |
| Interest cost incurred | $ 555 | $ 263 | $ 184 |
| Less: amount capitalized on construction | (19) | (18) | (12) |
| Interest expense | 536 | 245 | 172 |
| Interest income | (71) | (395) | (297) |
| Foreign exchange losses/(gains), net | 47 | (37) | 2 |
| Gain on sale of divested products | (160) | | |
| Realized gain on foreign currency options, net | | (510) | |
| Ineffective portion of interest rate swaps | | 7 | |
| Other, net | (17) | 7 | (12) |
| Total other expense/(income), net | $ 335 | $ (683) | $ (135) |

Schering-Plough had $335 million of other expense, net, for 2008 and $683 million of other income, net, for 2007. Interest expense was higher in 2008 due to the issuance of new debt in connection with the acquisition of OBS in the second half of 2007. Other expense, net, for 2008 includes $160 million ($149 million after tax) of gain on sale of the divestitures of certain Animal Health products as required by regulatory agencies in U.S. and Europe in connection with the acquisition of OBS. In addition, during 2008, Schering-Plough recognized a gain of $17 million ($12 million after tax) on the sale of a manufacturing site. Other income, net, for 2007 included net realized gains on foreign currency options of $510 million related to the OBS acquisition. The increase in Other income, net, in 2007 compared to 2006 also reflected higher interest income due to higher balances of cash equivalents and short-term investments partially offset by higher interest expense due to the issuance of new debt.

*Special and acquisition-related charges and manufacturing streamlining*

2008 Special and acquisition-related charges

Special and acquisition-related charges relate to the Productivity Transformation Program activities which include the ongoing integration of the OBS business. Special and acquisition-related charges for 2008 were $329 million. The costs for 2008 included $275 million of employee termination costs. The remaining charges of $54 million related to

integration activities.

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The following table summarizes the charges, cash payments and liabilities related to the Productivity Transformation Program, which includes the ongoing integration of OBS, through December 31, 2008:

| | Employee Termination Costs | Acquisition-Related Liabilities: Employee Termination Costs | Acquisition-Related Liabilities: Other Exit Costs |
|---|---|---|---|
| | (Dollars in millions) | | |
| Accrued liability at December 31, 2007 | $ 23 | $ 151 | $ |
| Charges(a) | 254 | 21 | |
| Purchase price allocation items(b) | | (3) | 50 |
| Cash payments | (154) | (169) | (18) |
| Accrued liability at December 31, 2008 | $ 123 | $ | $ 32 |

(a) Recorded to special and acquisition-related charges.

(b) Recorded as part of purchase accounting. Included in acquisition-related liabilities at December 31, 2008 are costs to exit certain activities of OBS.

2007 Special and acquisition-related charges

During the year ended December 31, 2007, Schering-Plough incurred $84 million of special and acquisition-related charges, comprised of $61 million of integration-related costs for the OBS acquisition and $23 million of employee termination costs as part of integration activities.

2006 manufacturing streamlining

During 2006, Schering-Plough implemented changes to its manufacturing operations in Puerto Rico and New Jersey that have streamlined its global supply chain and further enhanced Schering-Plough s long-term competitiveness. These changes resulted in the phase-out and closure of Schering-Plough s manufacturing operations in Manati, Puerto Rico, and additional workforce reductions in Las Piedras, Puerto Rico, and New Jersey.

*Special charges:* Special charges in 2006 related to the changes in Schering-Plough s manufacturing operations totaled $102 million. These charges consisted of approximately $47 million of severance and $55 million of fixed asset impairments.

*Cost of Sales:* Included in 2006 cost of sales was approximately $146 million consisting of $93 million of accelerated depreciation, $46 million of inventory write-offs, and $7 million of other charges related to the closure of Schering-Plough s manufacturing facilities in Manati, Puerto Rico.

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The following table summarizes activities reflected in the consolidated financial statements related to changes to Schering-Plough s manufacturing operations which were completed in 2006:

| | Charges included in Cost of sales | Special charges | Total charges | Cash payments | Non-cash charges | Accrued Liability |
|---|---|---|---|---|---|---|
| | | | (Dollars in millions) | | | |
| Accrued liability at January 1, 2006 | | | | | | $ |
| Severance | $ | $ 47 | $ 47 | $ (35) | $ | 12 |
| Asset impairments | | 55 | 55 | | (55) | |
| Accelerated depreciation | 93 | | 93 | | (93) | |
| Inventory write-offs | 46 | | 46 | | (46) | |
| Other | 7 | | 7 | (2) | (5) | |
| Total | $ 146 | $ 102 | $ 248 | $ (37) | $ (199) | |
| Accrued liability at December 31, 2006 | | | | | | $ 12 |
| Severance | | | | $ (12) | | (12) |
| Accrued liability at December 31, 2007 | | | | | | $ |

*Equity income*

Sales of the Merck/Schering-Plough Cholesterol Joint Venture totaled $4.6 billion, $5.2 billion and $3.9 billion in 2008, 2007 and 2006, respectively. The sales decrease in 2008 was due primarily to lower market share in the U.S. partially offset by continued growth in international markets. The sales growth in 2007, as compared to 2006, was due primarily to an increase in market share.

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. 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.

The allergy/asthma agreements provided for the joint development and marketing by the companies of a once-daily, fixed-combination tablet containing loratadine/montelukast. In April 2008, the Merck/Schering-Plough joint venture received a not-approvable letter from the 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. As a result of the

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termination of the respiratory joint venture, Schering-Plough received payments totaling $105 million, which Schering-Plough recognized during 2008 in equity income.

Equity income from the Merck/Schering-Plough joint venture totaled $1.9 billion, $2.0 billion and $1.5 billion in 2008, 2007, and 2006, respectively. The decrease in 2008 equity income amounts compared to 2007 reflects sales declines of VYTORIN and ZETIA in the U.S. partially offset by sales growth internationally and receipt of $105 million from the termination of the respiratory joint venture. The increase in 2007 equity income as compared to 2006 reflected increased sales of VYTORIN and ZETIA during 2007 as compared to 2006.

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

*Provision for income taxes*

Tax expense was $146 million, $258 million and $362 million in 2008, 2007 and 2006, respectively. The 2008 and 2007 tax provision amounts included tax benefits of $344 million and $89 million, respectively, related to the amortization of fair values of certain assets acquired as part of the OBS acquisition and other purchase-accounting related items. The tax provisions in 2008, 2007 and 2006 do not include any benefit related to U.S. operating losses. During 2004, Schering-Plough established a valuation allowance on its net U.S. deferred tax assets, including the benefit of U.S. operating losses, as management concluded that it is not more likely than not that the benefit of the U.S. net deferred tax assets can be realized. At December 31, 2008, Schering-Plough continues to maintain a valuation allowance against its U.S. net deferred tax assets. Schering-Plough expects to report a U.S. Net Operating Loss (NOL) carryforward of $1.3 billion on its tax return for the year ended December 31, 2008. 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 implemented the provisions of FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes, (FIN 48) as of January 1, 2007. As required by FIN 48, the cumulative effect of applying the provisions of the interpretation was reported as an adjustment to Schering-Plough s retained earnings balance as of January 1, 2007. Schering-Plough reduced its January 1, 2007 retained earnings by $259 million as a result of the adoption of FIN 48.

Schering-Plough s unrecognized tax benefits result primarily from the varying application of statutes, regulations and interpretations and include exposures on intercompany terms of cross border arrangements and utilization of cash held by foreign subsidiaries (investment in U.S. property) as well as Schering-Plough s tax matters litigation (see Note 21, Legal, Environmental and Regulatory Matters , under Item 8, Financial Statements and Supplementary Data ). At December 31, 2008 and 2007, the total amount of unrecognized tax benefits was $994 million and $859 million, respectively, which includes tax liabilities as well as reductions to deferred tax assets carrying a full valuation allowance. At December 31, 2008 and 2007, approximately $596 million and $535 million, respectively, of total unrecognized tax benefits, if recognized, would affect the effective tax rate. Management believes it is reasonably possible that total unrecognized tax benefits could decrease over the next twelve-month period up to approximately $625 million. This would be primarily attributable to a decision in the tax matter currently being litigated in Newark District Court for which a decision has not yet been rendered, possible final resolution of Schering-Plough s 1997 through 2002 examination by the IRS and appeals and possible resolutions of various other matters. However, the timing of the ultimate resolution of Schering-Plough s tax matters and the payment and receipt of related cash is dependent on a number of factors, many of which are outside Schering-Plough s control.

Schering-Plough includes interest expense or income as well as potential penalties on uncertain tax positions as a component of income tax expense in the Statement of Consolidated Operations. The total amount of interest expense related to uncertain tax positions for the years ended December 31, 2008 and 2007 was $63 million and $50 million,

respectively. The total amount of accrued interest related to uncertain tax positions at December 31, 2008 and 2007 was $245 million and $197 million, respectively, and is included in other accrued liabilities.

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During the second quarter of 2007, the IRS completed its examination of Schering-Plough s 1997-2002 federal income tax returns. Schering-Plough is seeking resolution of an issue raised during this examination through the IRS administrative appeals process. In July 2007, Schering-Plough made a payment of $98 million to the IRS pertaining to the 1997-2002 examination. Schering-Plough s tax returns are open for examination with the IRS for the 1997 through 2008 tax years. During 2008, the IRS commenced its examination of the 2003 2006 federal income tax returns. This examination is expected to be completed in 2010. For most of its other significant tax jurisdictions (U.S., state and foreign), Schering-Plough s income tax returns are open for examination for the period 2000 through 2008.

*Net income/(loss) available to common shareholders*

Schering-Plough had a net income/(loss) available to common shareholders of $1.8 billion, $(1.6) billion and $1.1 billion for 2008, 2007 and 2006, respectively. Net income/(loss) available to common shareholders for 2008 and 2007 included approximately $1.1 billion and $4.0 billion, respectively, of charges related to purchase accounting for the OBS acquisition, Net income/(loss) available to common shareholders for 2008, 2007 and 2006 included the deduction of preferred stock dividends of $150 million, $118 million and $86 million, respectively, related to the 2004 and 2007 mandatory convertible preferred shares. The loss in 2007 was due to the impact of purchase accounting items from the OBS acquisition and increased interest expense as a result of the issuance of debt in the second half of 2007. These amounts were partially offset by the impacts of a gain on currency options in the 2007 period and a gain on the divestitures of certain Animal Health products in the 2008 period.

Net income/(loss) available to common shareholders for 2008, 2007 and 2006 also included special and acquisition-related charges and manufacturing streamlining costs of approximately $329 million, $84 million and $248 million, respectively. See Note 3, Special and Acquisition-Related Charges and Manufacturing Streamlining, under Item 8, Financial Statements and Supplementary Data, for additional information.

**LIQUIDITY AND FINANCIAL RESOURCES**

***Discussion of Cash Flow***

| | For the Years Ended December 31, | | |
|---|---|---|---|
| | **2008** | **2007** | **2006** |
| | **(Dollars in millions)** | | |
| Cash flow provided by operating activities | $ 3,364 | $ 2,630 | $ 2,161 |
| Cash flow used for investing activities | (532) | (13,156) | (2,908) |
| Cash flow (used for)/provided by financing activities | (1,660) | 10,089 | (1,361) |

*Operating Activities*

In 2008, operating activities provided $3.4 billion of cash, compared with net cash provided by operations of $2.6 billion in 2007. The increase is primarily due to the inclusion of the OBS business and the absence of special and acquisition-related payments in 2007 associated with the settlement of an investigation by the U.S. Attorney s Office for the District of Massachusetts involving certain of Schering-Plough s sales, marketing and clinical trial practices and programs (the Massachusetts Investigation).

In 2007, net cash provided by operating activities was $2.6 billion, an increase of $0.4 billion as compared to 2006. The increase was primarily due to a net realized gain of $510 million from foreign currency options relating to the

OBS acquisition, higher net sales and equity income, partially offset by payments of $435 million for the settlement of the Massachusetts Investigation and $98 million for tax and interest due in connection with an examination by the IRS of Schering-Plough s 1997-2002 federal income tax returns.

During 2007, as part of an overall risk management strategy and in consideration of various preliminary financing scenarios associated with the acquisition of OBS, Schering-Plough purchased euro-denominated currency options (derivatives) for aggregate premiums of approximately $165 million and received proceeds of

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$675 million upon the termination of these options, resulting in a net realized gain of $510 million. These derivatives were short-term (trading) in nature and did not hedge a specific financing or investment transaction. Accordingly, the cash impacts of these derivatives were classified as operating cash flows in the Statement of Consolidated Cash Flows.

*Investing Activities*

Net cash used for investing activities during 2008 was $532 million and primarily relates to capital expenditures of $747 million partially offset by the proceeds from divested products of $241 million.

Net cash used for investing activities in 2007 was $13.2 billion, primarily consisting of $15.8 billion of net cash used to purchase OBS. In addition, the source of cash for investing activities in 2007 included a net reduction of short-term investments of $3.3 billion partially offset by $618 million of capital expenditures. Net cash used for investing activities during 2006 was $2.9 billion primarily related to the net purchases of short-term investments of $2.4 billion previously invested in cash equivalents and $458 million of capital expenditures.

*Financing Activities*

Net cash used for financing activities was $1.7 billion for 2008, compared to $10.1 billion of cash provided by financing activities for 2007. Uses of cash for financing activities for 2008 included the pay down of euro-denominated long-term debt of Euro 600 million and other debt payments (total payments $929 million), payment of dividends on common and preferred shares of $572 million and pay down of commercial paper and other short-term debt outstanding of $169 million.

Net cash provided by financing activities for 2007 included net proceeds on the issuance of common and preferred shares of approximately $1.5 billion and $2.4 billion, respectively, and net proceeds of approximately $6.4 billion on the issuance of long-term debt. Net cash provided by financing activities in 2007 also included $225 million of proceeds from stock option exercises offset by the payment of dividends on common and preferred shares of $481 million. Net cash used for financing activities during 2006 was $1.4 billion, which included the payment of dividends on common and preferred shares of $412 million and the repayment of $1.0 billion of bank debt and short-term commercial paper borrowings.

*Other Discussion of Cash Flows*

Schering-Plough expects to contribute approximately $350 million to its retirement plans during 2009, including approximately $200 million to the U.S. Schering-Plough Retirement Plan.

At December 31, 2008 and 2007, Schering-Plough had net debt (total debt less cash, cash equivalents, short-term investments and marketable securities) of $4.8 billion and $7.1 billion, respectively. Cash generated from operations, available cash and short-term investments and available credit facilities are expected to provide Schering-Plough with the ability to fund cash needs for the intermediate term.

***Borrowings and Credit Facilities***

On September 17, 2007, Schering-Plough issued $1.0 billion aggregate principal amount of 6.00 percent senior unsecured notes due 2017 and $1.0 billion aggregate principal amount of 6.55 percent senior unsecured notes due 2037. The net proceeds from this offering were approximately $2.0 billion. Interest on the notes is payable semi-annually. The effective interest rate on the 6.00 percent senior unsecured notes and the 6.55 percent senior unsecured notes, which incorporates the initial discount and debt issuance fees, is 6.13 percent and 6.67 percent,

respectively. The interest rate payable on these notes is not subject to adjustment. The notes generally restrict Schering-Plough from creating or assuming liens or entering into sale and leaseback transactions unless the aggregate outstanding indebtedness secured by any such liens and related to any such sale and leaseback transactions does not exceed 10 percent of consolidated net tangible assets. These notes are redeemable in whole or in part, at Schering-Plough s option at any time, at a redemption price equal to the greater of (1) 100 percent of the principal amount of such notes and (2) the sum of the present values of the

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remaining scheduled payments of principal and interest discounted to the redemption date on a semiannual basis using the rate of Treasury Notes with comparable remaining terms plus 25 basis points for the 2017 notes or 30 basis points for the 2037 notes. If a change of control triggering event occurs, under certain circumstances, as defined in the prospectus, holders of the notes will have the right to require Schering-Plough to repurchase all or any part of the notes for a cash payment equal to 101 percent of the aggregate principal amount of the notes repurchased plus accrued and unpaid interest, if any, to the date of purchase.

On October 1, 2007, Schering-Plough issued Euro 500 million aggregate principal amount of 5.00 percent senior unsecured euro-denominated notes due 2010 and Euro 1.5 billion aggregate principal amount of 5.375 percent senior unsecured euro-denominated notes due 2014. The net proceeds from this offering were approximately $2.8 billion. Interest on the notes is payable annually. The effective interest rate on the 5.00 percent senior unsecured euro-denominated notes and the 5.375 percent senior unsecured euro-denominated notes, which incorporates the initial discount, debt issuance fees and the impact of interest rate hedges, is 5.10 percent and 5.46 percent, respectively. The interest rate payable on these notes is not subject to adjustment. The notes generally restrict Schering-Plough from creating or assuming liens or entering into sale and leaseback transactions unless the aggregate outstanding indebtedness secured by any such liens and related to any such sale and leaseback transactions does not exceed 10 percent of consolidated net tangible assets. These notes are redeemable in whole or in part, at Schering-Plough s option at any time, at a redemption price specified in the prospectus. If a change of control triggering event occurs, under certain circumstances, as defined in the prospectus, holders of the notes will have the right to require Schering-Plough to repurchase all or any part of the notes for a cash payment equal to 101 percent of the aggregate principal amount of the notes repurchased plus accrued and unpaid interest, if any, to the date of purchase. Schering-Plough used the net proceeds from these notes to fund a portion of the purchase price for the OBS acquisition.

On October 24, 2007, Schering-Plough entered into a five-year senior unsecured euro-denominated term loan facility with a syndicate of banks. On October 31, 2007, Schering-Plough drew Euro 1.1 billion ($1.6 billion) on this term loan to fund a portion of the purchase price for the OBS acquisition. This term loan has a floating interest rate and requires Schering-Plough to maintain a net debt to total capital ratio of no more than 65 percent through 2009 and 60 percent thereafter, in which net debt equals total debt less cash, cash equivalents, short-term investments and marketable securities and total capital equals the sum of total debt and total shareholders equity excluding the cumulative effect of acquired in-process research and development in connection with any acquisition consummated after the closing of the term loan. The term loan also generally restricts Schering-Plough from creating or assuming liens or entering into sale and leaseback transactions unless the aggregate outstanding indebtedness secured by any such liens and related to any such sale and leaseback transactions does not exceed 12 percent of consolidated net tangible assets. At February 27, 2009, the outstanding balance on the euro-denominated term loan was Euro 450 million.

The reported U.S. dollar amounts of the outstanding debt balance and interest expense on the euro-denominated notes and euro-denominated term loan will fluctuate due to the impact of foreign currency translation.

On November 26, 2003, Schering-Plough issued $1.25 billion aggregate principal amount of 5.3 percent senior unsecured notes due 2013 and $1.15 billion aggregate principal amount of 6.5 percent senior unsecured notes due 2033. The interest rates payable on the notes are subject to adjustment. In connection with ratings downgrades in 2004, on December 1, 2004, the interest rate payable on the notes due 2013 increased from 5.3 percent to 5.55 percent, and the interest rate payable on the notes due 2033 increased from 6.5 percent to 6.75 percent. The interest rate payable on a particular series of notes will return to 5.3 percent and 6.5 percent, respectively, and the rate adjustment provisions will permanently cease to apply if, the notes are subsequently rated above Baa1 by Moody s and BBB+ by S&P. If the rating assigned to the notes by either Moody s or S&P is downgraded below A3 or A-, respectively, the interest rate payable on that series of notes would increase. See Note 15, Borrowings and Other Commitments, under

Item 8, Financial Statements and Supplementary Data, for additional information.

On August 9, 2007, Schering-Plough entered into a $2.0 billion revolving credit agreement with a syndicate of banks and terminated its $1.5 billion credit facility that was due to mature in May 2009. This credit facility has a floating interest rate, matures in August 2012 and requires Schering-Plough to maintain a

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net debt to total capital ratio of no more than 65 percent through 2009 and 60 percent thereafter, in which net debt equals total debt less cash, cash equivalents, short-term investments and marketable securities and total capital equals the sum of total debt and total shareholders equity excluding the cumulative effect of acquired in-process research and development in connection with any acquisition consummated after the closing of the credit facility. The credit facility also generally restricts Schering-Plough from creating or assuming liens or entering into sale and leaseback transactions unless the aggregate outstanding indebtedness secured by any such liens and related to any such sale and leaseback transactions does not exceed 12 percent of consolidated net tangible assets. This credit line is available for general corporate purposes and is considered primarily as support to Schering-Plough s commercial paper borrowings. Borrowings under this credit facility may be drawn by the U.S. parent company or by its wholly-owned international subsidiaries when accompanied by a parent guarantee. This facility does not require compensating balances; however, a nominal commitment fee is paid. At December 31, 2008 and 2007, no borrowings were outstanding under this facility.

At December 31, 2008 and 2007, short-term borrowings, including the credit facilities mentioned above, totaled $245 million and $461 million, respectively. There was no outstanding commercial paper at December 31, 2008. The weighted-average interest rate for short-term borrowings at December 31, 2008 and 2007 was 7.1 percent and 7.9 percent, respectively.

Schering-Plough s senior unsecured euro-denominated notes and euro-denominated term loan have been designated as, and are effective as, economic hedges of the net investment in a foreign operation. In accordance with SFAS No. 52, Foreign Currency Translation (SFAS 52), the foreign currency transaction gains or losses on these euro-denominated debt instruments are included in foreign currency translation adjustment within other comprehensive income.

***Credit Ratings***

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

| Senior Unsecured Credit Ratings | Long-term | Short-term | Long-Term Review Status |
|---|---|---|---|
| Moody s Investors Service | Baa1 | P-2 | Stable |
| Standard and Poor s | A– | A-2 | Stable |
| Fitch Ratings | BBB+ | F-2 | Stable |

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 August 2008, Standard and Poor s and Fitch Ratings changed their Long Term Review Status from negative watch to stable. In April 2008, Moody s Investor Service had changed its Long Term Review Status from stable to negative outlook, and Fitch Ratings changed its Long Term Review Status from stable to negative watch. In March 2008, Standard and Poor s had changed its Long Term Review Status from stable to negative watch.

Schering-Plough paid down its entire commercial paper borrowings of $149 million during 2008. 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

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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.

***Mandatory Convertible Preferred Stock***

On August 15, 2007, Schering-Plough issued 10,000,000 shares of 6 percent Mandatory Convertible Preferred Stock (the 2007 Preferred Stock) with a face value of $2.5 billion. Net proceeds to Schering-Plough were approximately $2.4 billion after deducting commissions, discounts and other underwriting expenses. Schering-Plough used the net proceeds from the sale of the 2007 Preferred Stock to fund a portion of the purchase price for the OBS acquisition.

Each share of the 2007 Preferred Stock will automatically convert into between 7.4206 and 9.0909 common shares of Schering-Plough depending on the average closing price of Schering-Plough s common shares over the 20 trading day period ending on the third trading day prior to the mandatory conversion date of August 13, 2010, as defined in the prospectus. The preferred shareholders may elect to convert at any time prior to August 13, 2010, at the minimum conversion ratio of 7.4206 common shares per share of the 2007 Preferred Stock. Additionally, if at any time prior to the mandatory conversion date the closing price of Schering-Plough s common shares exceeds $50.53 (for at least 20 trading days within a period of 30 consecutive trading days), Schering-Plough may elect to cause the conversion of all, but not less than all, of the 2007 Preferred Stock then outstanding at the same minimum conversion ratio of 7.4206 common shares for each share of 2007 Preferred Stock.

The 2007 Preferred Stock accrues dividends at an annual rate of 6 percent on shares outstanding. The dividends are cumulative from the date of issuance and, to the extent Schering-Plough is legally permitted to pay dividends and the Board of Directors declares a dividend payable, Schering-Plough will pay dividends on each dividend payment date. The dividend payment dates are February 15, May 15, August 15 and November 15 of each year.

During the year ended December 31, 2007, all shares of 6 percent Mandatory Convertible Preferred Stock issued on August 10, 2004 (the 2004 Preferred Stock) were converted into 64,584,929 shares of Schering-Plough common stock.

***Equity Issuance and Treasury Shares***

On August 15, 2007, Schering-Plough issued 57,500,000 common shares from treasury shares at $27.50 per share. Net proceeds to Schering-Plough were approximately $1.5 billion after deducting commissions, discounts and other underwriting expenses. Schering-Plough used the net proceeds from the sale of the common shares to fund a portion of the purchase price for the OBS acquisition. See Note 2, Acquisition, under Item 8, Financial Statements and Supplementary Data.

***Contractual Obligations and Off-Balance Sheet Arrangements***

Schering-Plough has various contractual obligations that are reported as liabilities in the Consolidated Balance Sheets and others that are not required to be recognized as liabilities such as certain purchase

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commitments and other executory contracts. The following table summarizes payments due by period under Schering-Plough s known contractual obligations at December 31, 2008.

| | Payments Due by Period | | | | |
|---|---|---|---|---|---|
| | Total | 2009 | 2010-2011 | 2012-2013 | 2014 and Thereafter |
| | (Dollars in millions) | | | | |
| Short-term borrowings and current portion of long-term debt | $ 245 | $ 245 | $ | $ | $ |
| Long-term debt obligations | 7,931 | | 722 | 1,973 | 5,236 |
| Interest related to debt obligations | 5,568 | 479 | 853 | 794 | 3,442 |
| Operating lease obligations | 558 | 165 | 218 | 99 | 76 |
| Purchase obligations(1) | 2,780 | 2,601 | 125 | 38 | 16 |
| Deferred compensation plan obligations | 153 | 74 | 20 | 25 | 34 |
| Other obligations(2) | 1,506 | 846 | 258 | 200 | 202 |
| Total | $ 18,741 | $ 4,410 | $ 2,196 | $ 3,129 | $ 9,006 |

(1) Purchase obligations include advertising and research contracts, capital expenditure commitments and other inventory and expense items. Potential milestone payments of approximately $2 billion were not included in the contractual obligations table as they are contingent on the achievement of various research and development (approximately $370 million), regulatory approval (approximately $630 million) or sales-based (approximately $1 billion) milestones. Research, development and regulatory milestones depend upon future clinical developments as well as regulatory agency actions which may never occur. Sales-based milestones are contingent on generating levels of sales of current or future products that have not yet been achieved.

(2) This caption includes obligations, based on undiscounted amounts, for estimated payments under certain of Schering-Plough s pension plans, preferred stock dividends, management s estimate of the current portion of unrecognized tax benefits and other contractual obligations.

**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 this 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 adversity to risk. These pressures impact the regulatory environment and the market for Schering-Plough s products.

**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

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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 continued in 2008 and is expected to continue for several years. 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 3, Legal Proceedings, 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. This backlog has caused long regulatory review times for new indications and products and has added to the uncertainty in predicting approval timelines in these markets. 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.

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In the U.S., the new Presidential Administration has announced that health care reform, including regulation of pharmaceutical companies and their products, is a priority. The Administration has not yet named a Health and Human Services Secretary or the FDA Commissioner, who may initiate further change. The impact of such actions, as well as budget pressures on governments in the U.S. and other nations, cannot be predicted at this time.

These and other uncertainties inherent in government regulatory approval processes, including, among other things, delays in approval of new products, formulations or indications, 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), NOXAFIL, CLARINEX D-24, CLARINEX REDITABS, CLARINEX D-12, SUBOXONE and new indications for TEMODAR and NASONEX. Other significant approvals since 2004 include ASMANEX DPI (Dry Powder for Inhalation) in the U.S., PEGINTRON, ZETIA, TEMODAR, ESMERON/ESLAX, NASONEX and GANIREST in Japan, and new indications for REMICADE. Schering-Plough also has a number of significant regulatory submissions filed in major markets awaiting approval, including golimumab in Europe, sugammadex in the U.S. and SAPHRIS (asenapine) 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.

***Pricing Pressures***

As described more specifically in Note 21, Legal, Environmental and Regulatory Matters, under Item 8, Financial Statements and Supplementary Data, 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.

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.

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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.

**2009 OUTLOOK**

Schering-Plough does not provide numeric guidance. However, the following outlook may be helpful to readers in assessing future prospects.

Uncertainties in the financial and credit markets, along with generally difficult business conditions, have contributed recently to pressures on companies in the U.S., including pharmaceutical companies. While further development of these economic effects, along with potential for healthcare reforms at the federal or state level in the U.S. are difficult to predict, Schering-Plough plans to remain flexible in managing its business in the face of these challenges.

Given the current uncertainties in the cholesterol markets, it remains difficult to predict the long-term performance of the cholesterol franchise. Currently, Schering-Plough believes that 2009 U.S. sales of VYTORIN and ZETIA are expected to be lower than in 2008 while international sales, excluding the impact of foreign exchange, should continue to grow.

For the full year 2009, Schering-Plough currently expects R&D spending to grow in the mid single-digit range.

The risks set forth in Item 1A. Risk Factors of this 10-K could cause actual results to differ materially from the expectation provided in this section.

**IMPACT OF RECENTLY ISSUED ACCOUNTING STANDARDS**

In September 2006, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 157, Fair Value Measurements. The standard defines fair value, establishes a framework for measuring fair value in accordance with U.S. Generally Accepted Accounting Principles, and expands disclosures about fair value measurements. The standard codifies the definition of fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The standard clarifies the principle that fair value should be based on the assumptions market participants would use when pricing the asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. For calendar-year companies, the standard became effective January 1, 2008 (see Note 17, Fair Value Measurements in Item 8, Financial Statements and Supplementary Data ) except for non-financial items measured on a non-recurring basis for which it is effective beginning January 1, 2009. The implementation of this standard did not have a material impact on Schering-Plough s financial statements. Based on Schering-Plough s current

financial position, the impact of the provisions of this standard that are effective January 1, 2009 is not expected to be material.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities-Including an Amendment of FASB Statement No. 115 (SFAS 159), which permits

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entities to choose to measure many financial instruments and certain other items at fair value. SFAS 159 also includes an amendment to SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities, which applies to all entities with available-for-sale and trading securities. For calendar-year companies, the standard became effective January 1, 2008. Schering-Plough chose not to elect the fair value option prescribed by SFAS 159. As a result, the implementation of this standard did not have a material impact on Schering-Plough s financial statements.

In December 2007, the FASB issued EITF Issue No. 07-1, Accounting for Collaborative Arrangements, which is effective for calendar-year companies beginning January 1, 2009. The Task Force 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 impact of this standard on the consolidated financial statements is not expected to be material.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), Business Combinations, (SFAS 141R). For calendar-year companies, the standard is applicable to new business combinations occurring on or after January 1, 2009. SFAS 141R 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, SFAS 141R will require 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 standard will also impact certain unresolved matters related to purchase transactions consummated prior to the effective date of the standard. The impact of this standard on the consolidated financial statements is not expected to be material, but this standard may have an effect on accounting for future business combinations.

In December 2007, the FASB issued SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements An Amendment of ARB No. 51, which is effective for calendar-year companies beginning January 1, 2009. The standard establishes new accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. The impact of this standard on the consolidated financial statements is not expected to be material.

In March 2008, the FASB issued SFAS No. 161, Disclosures about Derivative Instruments and Hedging Activities An Amendment of FASB Statement No. 133, which is effective for calendar-year companies beginning January 1, 2009. The standard enhances required disclosures regarding derivatives and hedging activities. The impact of this standard on the consolidated financial statements is not expected to be material.

In April 2008, the FASB issued FASB Staff Position (FSP) No. FAS 142-3, Determination of the Useful Life of Intangible Assets (FSP 142-3). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, Goodwill and Other Intangible Assets (SFAS 142). FSP 142-3 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 impact of this standard on the consolidated financial statements is not expected to be material.

In May 2008, the FASB issued SFAS No. 162, The Hierarchy of Generally Accepted Accounting Principles. This standard identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements that are presented in conformity with generally accepted accounting principles (GAAP) in the United States (the GAAP hierarchy). SFAS No. 162 became effective on November 15, 2008. The implementation of this standard did not have a material impact on Schering-Plough s financial statements.

In June 2008, the FASB issued FSP EITF No. 03-6-1, Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities. The FSP addresses whether instruments granted in share-based payment transactions are participating securities prior to vesting and therefore need to be included in the earnings allocation in calculating earnings per share under the two-class method described

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in SFAS No. 128, Earnings per Share. The FSP requires companies to treat unvested share-based payment awards that have non-forfeitable rights to dividend or dividend equivalents as a separate class of securities in calculating earnings per share. The FSP is effective for calendar-year companies beginning January 1, 2009. The impact of this standard on the consolidated financial statements is not expected to be material.

In October 2008, the FASB issued FSP 157-3 Determining Fair Value of a Financial Asset in a Market That Is Not Active (FSP 157-3). FSP 157-3 clarified the application of SFAS No. 157 in an inactive market. It demonstrated how the fair value of a financial asset is determined when the market for that financial asset is inactive. FSP 157-3 was effective upon issuance, including prior periods for which financial statements had not been issued. The implementation of this standard did not have a material impact on Schering-Plough s financial statements.

In December 2008, the FASB issued FSP No. FAS 140-4 and FIN 46(R)-8, Disclosures by Public Entities (Enterprises) about Transfers of Financial Assets and Interest in Variable Interest Entities. FSP No. FAS 140-4 and FIN 46(R)-8 requires enhanced disclosures about transfers of financial assets and interests in variable interest entities. The FSP is effective for interim and annual periods ending after December 15, 2008. Since the FSP requires only additional disclosures concerning transfers of financial assets and interest in variable interest entities, adoption of this FSP did not affect Schering-Plough s disclosures.

**CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

The following accounting policies and estimates are considered significant because changes to certain judgments and assumptions inherent in these policies could affect Schering-Plough s financial statements:

Revenue Recognition

Rebates, Discounts and Returns

Provision for Income Taxes

Acquisitions and Impairment of Goodwill, Intangible Assets and Property

Accounting for Pensions and Post-retirement Benefit Plans

Accounting for Legal and Regulatory Matters

***Revenue Recognition***

Schering-Plough s pharmaceutical products are sold to direct purchasers, which include wholesalers, retailers and certain health maintenance organizations. Price discounts and rebates on such sales are paid to federal and state agencies, other indirect purchasers and other market participants such as managed care organizations that indemnify beneficiaries of health plans for their pharmaceutical costs and pharmacy benefit managers.

Schering-Plough recognizes revenue when title and risk of loss pass to the purchaser and when reliable estimates of the following can be determined:

i. commercial discount and rebate arrangements;

ii. rebate obligations under certain federal and state governmental programs; and

iii. sales returns in the normal course of business.

Revenue recognition also requires that there is reasonable assurance of collection of sales proceeds.

When recognizing revenue, Schering-Plough estimates and records the applicable commercial and governmental discounts and rebates as well as sales returns that have been or are expected to be granted or made for products sold during the period. These amounts are deducted from sales for that period. If reliable estimates of these items cannot be made, Schering-Plough defers the recognition of revenue. Estimates recorded in prior periods are re-evaluated as part of this process.

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Revenue recognition for new products is based on specific facts and circumstances including estimated acceptance rates from established products with similar marketing characteristics. Absent the ability to make reliable estimates of rebates, discounts and returns, Schering-Plough would defer revenue recognition.

Product discounts granted are based on the terms of arrangements with wholesalers, managed care organizations and government purchasers and certain other market conditions. Rebates are estimated based on sales and contract terms, historical experience, trend analysis and projected market conditions in the various markets served. Schering-Plough evaluates market conditions for products or groups of products primarily through the analysis of third party demand and market research data, as well as internally generated information. Data and information provided by purchasers and obtained from third parties are subject to inherent limitations as to their accuracy and validity.

Sales returns are estimated and recorded based on historical sales and returns information, analysis of recent wholesale purchase information, consideration of stocking levels at wholesalers and forecasted demand amounts. Products that exhibit unusual sales or return patterns due to dating, competition including expected generic introductions, or other marketing matters are specifically investigated and analyzed as part of the formulation of return reserves.

Schering-Plough s agreements with the major U.S. pharmaceutical wholesalers address a number of commercial issues, such as product returns, timing of payment, processing of chargebacks and the quantity of inventory held by these wholesalers. With respect to the quantity of inventory held by these wholesalers, these agreements provide a financial disincentive for these wholesalers to acquire quantities of product in excess of what is necessary to meet current patient demand. Through the use of these agreements, Schering-Plough expects to avoid situations where Schering-Plough s shipments of product are not reflective of current demand.

***Rebates, Discounts and Returns***