

SCHERING PLOUGH CORP

Form 10-K

February 29, 2008

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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, 2007**

**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**  
*(State or other jurisdiction of  
incorporation or organization)*

**22-1918501**  
*(I.R.S. Employer  
Identification No.)*

**2000 Galloping Hill Road, Kenilworth, NJ**  
*(Address of principal executive offices)*

**07033**  
*(Zip Code)*

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

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

| <b>Title of Each Class</b>            | <b>Name of Each Exchange on Which Registered</b> |
|---------------------------------------|--|
| Common Shares, \$.50 par value        | New York Stock Exchange                          |
| Mandatory Convertible Preferred Stock | New York Stock Exchange                          |
| Preferred Share Purchase Rights*      | New York Stock Exchange                          |

\* At the time of filing, the Rights were not traded separately from the Common Shares.

**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 ☐ No ☐

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 ☐ No ☐

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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 ☒ No ☐

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. ☒

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):

|   |  |                                  |
|---|--|----------------------------------|
|   | Non-accelerated Filer <input type="checkbox"/> |                                  |
|   | (Do not check if a smaller reporting           | Smaller reporting                |
| Large Accelerated Filer <input checked="" type="checkbox"/> | company) <input type="checkbox"/>              | company <input type="checkbox"/> |
| Accelerated Filer <input type="checkbox"/>                  |  |                                  |

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

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, 2007 (the last business day of the registrant's most recently completed second fiscal quarter): \$45,516,213,799

Common Shares outstanding as of January 31, 2008: 1,621,353,851

**Documents Incorporated by Reference**

**Part of Form 10-K  
Incorporated into**

Schering-Plough Corporation Proxy Statement for  
the  
Annual Meeting of Shareholders on May 16, 2008

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 human prescription, animal health and consumer products. Schering-Plough's vision is to Earn Trust, Every Day with the 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](http://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 2007 and in the four years since Hassan and the new management team arrived, Schering-Plough made substantial progress. During 2007, 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 closed the transformative acquisition of Organon BioSciences N.V. (OBS) from Akzo Nobel. In acquiring OBS, Schering-Plough gained both the Organon human prescription business and the Intervet animal health business.

This additional strength is key for Schering-Plough in the current environment. The pharmaceutical industry continues to be subject to ever-more critical scrutiny, where challenges can arise in presenting scientific data in an objective manner. Schering-Plough believes that new scientific data are best presented and discussed at appropriate scientific and medical forums.

As explained in more detail later in this 10-K, in early 2008, Schering-Plough encountered such a challenge when results of a Merck/Schering-Plough Pharmaceuticals (the Merck/Schering-Plough cholesterol joint venture ) clinical trial, called ENHANCE, and joint venture products ZETIA and VYTORIN became the subject of much media scrutiny prior to presentation of the trial results in appropriate medical forums. Results are scheduled to be presented at an American College of Cardiology meeting on March 30, 2008. While the trial failed to show a statistically significant difference between treatment groups for the primary endpoint the mean change in the intima-media thickness measured at three sites in the carotid arteries (the right and left common carotid, internal carotid and carotid bulb) in patients with Heterozygous Familial Hypercholesterolemia the trial did demonstrate VYTORIN's effectiveness compared to simvastatin at lowering LDL cholesterol (often known as bad cholesterol ). Medical experts and health advisory groups have long recognized high LDL cholesterol as a significant cardiovascular risk factor and recommended increasingly aggressive treatment of high cholesterol for certain patients. Lowering LDL cholesterol, along with a healthy diet and lifestyle changes, remains the cornerstone of lipid treatment for patients at risk for heart

disease. Clinical studies have demonstrated that VYTORIN lowers patients' LDL cholesterol more than rosuvastatin, atorvastatin and simvastatin at the doses studied and was able to get more patients to their LDL cholesterol goals (as defined by ATP III). While it is too early to tell the impact of the joint venture's ENHANCE trial results on the joint venture's cholesterol business, Schering-Plough's diversified group of products and geographic areas, as well as its highly experienced executive team, gives Schering-Plough additional strength that will be helpful in weathering this situation.

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### **Segment Information**

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

#### ***Human Prescription Pharmaceuticals***

The Human Prescription Pharmaceuticals segment discovers, develops, manufactures and markets human pharmaceutical products. Within the Human Prescription Pharmaceutical 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 Human 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 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 United States, 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 United States for the treatment of opiate addiction; and NORCURON, a muscle relaxant.

*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; AVELOX, which is only marketed 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 Capsules 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 United States 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, a non-sedating antihistamine for the treatment of allergic rhinitis; FORADIL AEROLIZER, a long-acting beta2-agonist marketed by Schering-Plough in the United States 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 Solution, 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; and IMPLANON, a single-rod subdermal contraceptive implant.



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### ***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 bovine and swine antibiotic; BOVILIS/VISTA vaccine lines for infectious diseases in cattle; BANAMINE bovine and swine anti-inflammatory; TRI-MERIT, data management tool for cattle; REGUMATE/MATRIX fertility management for swine and horses; RESFLOR combination broad-spectrum antibiotic and non-steroidal anti-inflammatory drug for bovine respiratory disease; M+PAC swine pneumonia vaccine 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:* GALAXY/QUANTUM/PROCYON/ECLIPSE/INTRA-TRAC vaccine line for dogs and cats, NOBIVAC/CONTINUUM vaccine lines for flexible dog and cat vaccination; OTOMAX/MOMETAMAX canine otic 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, dog collar/spot on protecting against bites from fleas, ticks, mosquitoes and sandflies; HOMEAGAIN proactive U.S. pet recovery network; and ZUBRIN, an anti-inflammatory/analgesic for dogs.

*Aquaculture Products:* NORVAX/MINOVA vaccines against bacterial and viral disease in fish, SLICE parasiticide for sea lice in salmon and AQUAFLO antibiotic for farm-raised fish.

### ***Consumer Health Care***

The Consumer Health Care segment develops, manufactures and markets OTC, foot care and sun care products. Principal products in this segment include:

*Over-the-Counter (OTC) Products:* CLARITIN non-sedating antihistamines; MIRALAX treatment for occasional constipation; CORICIDIN HBP decongestant-free cold/flu medicine for people with high blood pressure; DRIXORAL cold and allergy, allergy sinus, flu and nasal decongestant tablets; 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***

|                                    | <b>Year Ended December 31,</b> |             |             |
|------------------------------------|--------------------------------|-------------|-------------|
|                                    | <b>2007</b>                    | <b>2006</b> | <b>2005</b> |
|                                    | <b>(Dollars in millions)</b>   |             |             |
| Human Prescription Pharmaceuticals | \$ 10,173                      | \$ 8,561    | \$ 7,564    |
| Animal Health                      | 1,251                          | 910         | 851         |

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|                        |           |           |          |
|------------------------|-----------|-----------|----------|
| Consumer Health Care   | 1,266     | 1,123     | 1,093    |
| Consolidated net sales | \$ 12,690 | \$ 10,594 | \$ 9,508 |

**Table of Contents*****(Loss)/Profit by segment***

|   | <b>Year Ended December 31,</b> |             |             |
|---|--------------------------------|-------------|-------------|
|   | <b>2007(1)</b>                 | <b>2006</b> | <b>2005</b> |
|   | <b>(Dollars in millions)</b>   |             |             |
| Human Prescription Pharmaceuticals  | \$ (1,206)                     | \$ 1,394    | \$ 733      |
| Animal Health   | (582)                          | 120         | 120         |
| Consumer Health Care  | 275                            | 228         | 235         |
| Corporate and other (including net interest income of \$150 million, \$125 million and \$13 million in 2007, 2006 and 2005, respectively) | 298                            | (259)       | (591)       |
| Consolidated (loss)/profit before tax and cumulative effect of a change in accounting principle   | \$ (1,215)                     | \$ 1,483    | \$ 497      |

- (1) In 2007, the Human 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 4, 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 Human 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. 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 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 severance charges as part of integration activities. It is estimated the charges relate to the reportable segments as follows: Human 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 Human 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 Human Prescription Pharmaceuticals segment.

In 2005, Corporate and other includes special charges of \$294 million, including \$28 million of employee termination costs, \$16 million of asset impairment and other charges, and an increase in litigation reserves by \$250 million resulting in a total reserve of approximately \$500 million representing Schering-Plough's then current estimate to resolve the Massachusetts investigation as well as the investigations and the state litigation disclosed under AWP.

Litigation and Investigations, in Note 20, Legal, Environmental and Regulatory Matters, in Item 8, Financial Statements and Supplementary Data. It is estimated that the charges relate to the reportable segments as follows: Human Prescription Pharmaceuticals \$289 million, Consumer Health Care \$2 million, Animal Health \$1 million and Corporate and other \$2 million.

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

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

In May 2000, Schering-Plough and Merck & Co., Inc. (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 to the maximum degree possible by relying 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.

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

- i. as a once-daily monotherapy (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 several 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 4, Equity Income, under Item 8, Financial Statements and Supplemental Data, for additional information regarding the profits and costs sharing and accounting as provided by the agreements.

The allergy/asthma agreements provide for the joint development and marketing by the companies of a once-daily, fixed-combination tablet containing CLARITIN and Singulair. Singulair is Merck's once-daily leukotriene receptor antagonist for the treatment of asthma and seasonal allergic rhinitis. In 2007, a New Drug Application filing for this combination tablet had been accepted by the U.S. Food and Drug Administration (FDA) for standard review.

During 2007, Schering-Plough announced that it had agreed with Merck to commence development of a single-tablet combination of ezetimibe and atorvastatin as a treatment for elevated cholesterol levels.

***Information About the Centocor Licenses***

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 currently in Phase III trials. Schering-Plough has exclusive marketing rights to both products outside of 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 now 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.

**Table of Contents****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 Human 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***

|                        | <b>2007</b>                  | <b>2006</b> | <b>2005</b> |
|------------------------|------------------------------|-------------|-------------|
|                        | <b>(Dollars in millions)</b> |             |             |
| United States          | \$ 4,597                     | \$ 4,192    | \$ 3,589    |
| Europe and Canada      | 5,500                        | 4,403       | 4,040       |
| Latin America          | 1,359                        | 990         | 884         |
| Pacific Area and Asia  | 1,234                        | 1,009       | 995         |
| Consolidated net sales | \$ 12,690                    | \$ 10,594   | \$ 9,508    |

Schering-Plough has subsidiaries in more than 55 countries outside the U.S. 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:

|                               | <b>2007</b>                  |                                    | <b>2006</b>      |                                    | <b>2005</b>      |                                    |
|-------------------------------|------------------------------|------------------------------------|------------------|------------------------------------|------------------|------------------------------------|
|                               | <b>Net Sales</b>             | <b>% of Consolidated Net Sales</b> | <b>Net Sales</b> | <b>% of Consolidated Net Sales</b> | <b>Net Sales</b> | <b>% of Consolidated Net Sales</b> |
|                               | <b>(Dollars in millions)</b> |                                    |                  |                                    |                  |                                    |
| Total International net sales | \$ 8,093                     | 64%                                | \$ 6,402         | 60%                                | \$ 5,919         | 62%                                |
| France                        | 965                          | 8%                                 | 809              | 8%                                 | 771              | 8%                                 |
| Japan                         | 709                          | 6%                                 | 669              | 6%                                 | 687              | 7%                                 |
| Canada                        | 578                          | 5%                                 | 478              | 5%                                 | 418              | 4%                                 |
| Italy                         | 498                          | 4%                                 | 441              | 4%                                 | 457              | 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:

|                      | <b>2007</b>  |                     | <b>2006</b>                  |                     | <b>2005</b>  |                     |
|----------------------|--------------|---------------------|------------------------------|---------------------|--------------|---------------------|
|                      | <b>Net</b>   | <b>% of</b>         | <b>Net</b>                   | <b>% of</b>         | <b>Net</b>   | <b>% of</b>         |
|                      | <b>Sales</b> | <b>Consolidated</b> | <b>Sales</b>                 | <b>Consolidated</b> | <b>Sales</b> | <b>Consolidated</b> |
|                      |              | <b>Net Sales</b>    | <b>Sales</b>                 | <b>Net Sales</b>    | <b>Sales</b> | <b>Net Sales</b>    |
|                      |              |                     | <b>(Dollars in millions)</b> |                     |              |                     |
| McKesson Corporation | \$ 1,526     | 12%                 | \$ 1,159                     | 11%                 | \$ 1,073     | 11%                 |
| Cardinal Health      | 1,196        | 9%                  | 1,019                        | 10%                 | 841          | 9%                  |



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Sales of products comprising 10 percent or more of Schering-Plough's U.S. or international sales for the year ended December 31, 2007, were as follows:

|                      | <b>Amount</b>                | <b>Percentage</b> |
|----------------------|------------------------------|-------------------|
|                      | <b>(Dollars in millions)</b> |                   |
| <b>U.S.</b>          |                              |                   |
| NASONEX              | \$ 667                       | 15%               |
| OTC CLARITIN         | 445                          | 10%               |
| <b>International</b> |                              |                   |
| REMICADE             | \$ 1,648                     | 20%               |

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***

|               | <b>2007</b>                  | <b>2006</b> | <b>2005</b> |
|---------------|------------------------------|-------------|-------------|
|               | <b>(Dollars in millions)</b> |             |             |
| United States | \$ 4,310                     | \$ 2,547    | \$ 2,538    |
| Netherlands   | 7,057                        | 1           | 1           |
| Ireland       | 3,414                        | 488         | 486         |
| Singapore     | 678                          | 824         | 840         |
| Other         | 1,823                        | 804         | 908         |
| Total         | \$ 17,282                    | \$ 4,664    | \$ 4,773    |

Long-lived assets shown by geographic location are primarily intangibles and property. The significant increase in long-lived assets as of December 31, 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.

Company-sponsored research and development expenditures were \$2.9 billion, \$2.2 billion, and \$1.9 billion in 2007, 2006, and 2005, respectively. As a percentage of consolidated net sales, research and development expenditures represented approximately 23 percent, 21 percent and 20 percent in 2007, 2006 and 2005, 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 also has substantial efforts directed toward biotechnology, vaccine development and immunology. Research activities include expenditures for both internal research efforts and research collaborations with various partners.

While several 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 website at [www.schering-plough.com](http://www.schering-plough.com). Due to the nature of the development and approval process as well as the fact that human

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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 several 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; and an A2a Adenosine receptor antagonist for the treatment of Parkinson's disease. Of these products, two are in Phase III clinical testing phase: thrombin receptor antagonist, and vicriviroc. Significant expenditures would be required to progress these through development, due to the large number of patients necessary for Phase III trials.

Research and development expenses are expected to continue 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 learn of new indications for the product. Another reason is to respond to any safety or effectiveness benefits or risks that may become known as more people use a product for a longer period of time.

## **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 and 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.

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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 U.S. Food and Drug Administration (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 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 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. In recent years, 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.

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

### **Marketing Activities and Competition**

Schering-Plough, through its trained professional sales representatives, introduces and makes known its prescription drugs to physicians, pharmacists, hospitals, managed care organizations and buying groups. Schering-Plough sells prescription drugs to hospitals, certain managed care organizations, wholesale distributors and retail pharmacists. Schering-Plough also introduces and makes known its prescription products through journal advertising, direct mail advertising, the distribution of samples to physicians and through television, radio, Internet, print and other advertising media.

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.

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.

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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 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 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.

Schering-Plough operates primarily in the prescription pharmaceutical marketplace. However, where appropriate, Schering-Plough seeks regulatory approval to switch prescription products to over-the-counter status as a means of extending a product's life cycle. In this way, the OTC marketplace is another means of maximizing the return on investments in discovery and development.

## **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 20, Legal, Environmental and Regulatory Matters, under Item 8, Financial Statements and Supplementary Data.

In the prescription drug 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 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 Food and Drug Administration (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 (EMA). Pharmaceutical products are regulated at both of these levels through various national, mutual recognition or centralized regulatory procedures. The EMA coordinates the evaluation and



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

As all of the major countries have some influence over pricing, even with the CMS in the United States, there is increasing pressure on 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.

## **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 pronounced effect on the consolidated operations of Schering-Plough.

## **Environment**

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

## **Employees**

At December 31, 2007, Schering-Plough employed approximately 55,000 people worldwide.

## **Available Information**

Schering-Plough's 10-Ks, 10-Qs, 8-Ks and amendments to those reports that are filed with or furnished to the SEC are available free of charge on Schering-Plough's website as soon as reasonably practicable after such materials are electronically filed with the SEC. Schering-Plough's internet address is [www.schering-plough.com](http://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 website 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](http://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 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.

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***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. In addition, other key products such as REMICADE, NASONEX, PEGINTRON, TEMODAR, CLARINEX, and AVELOX account for a material portion of revenues. As a result of Schering-Plough's dependence on key products, any events that adversely affects the markets for these products could have a significant impact on results of operations. These events 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.

For example, the profitability of Schering-Plough's cholesterol franchise may be adversely affected by competition from multiple generic cholesterol products. The FDA has held a public meeting to solicit comment on making certain prescription drugs available behind-the-counter without a prescription and continues to study this scenario. Although the FDA did not indicate what drugs might be included this category, if the FDA approved behind-the-counter sales of products that compete with products of Schering-Plough or the Merck/Schering-Plough cholesterol joint venture, such competition could have an adverse result on sales and profitability.

***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 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;

- 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. U.S. patents relating to Schering-Plough's significant products are of material importance to Schering-Plough. Upon the expiration or the successful challenge of Schering-Plough's patents covering a

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

A generic manufacturer may file an Abbreviated New Drug Application seeking approval after the expiration of the applicable data exclusivity and alleging that one or more of the patents listed in the innovator's New Drug Application are invalid, not infringed or unenforceable. This allegation is commonly known as a Paragraph IV certification. The innovator then has the ability to file suit against the generic manufacturer to enforce its patents. Generic manufacturers have used Paragraph IV certifications extensively to challenge patents on a wide array of innovative pharmaceuticals, and it is anticipated that this trend will continue. In recent years, some generic manufacturers have launched generic versions of products before the ultimate resolution of patent litigation (commonly known as "at-risk" product launches). Generic entry may result in the loss of a significant portion of sales or downward pressures on the prices at which Schering-Plough offers formerly patented products. Please refer to "Legal Proceedings" in Schering-Plough's 10-K and 10-Qs 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' patents in the U.S., 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, invalid, and/or unenforceable. Such an adverse determination could lead to a loss of market exclusivity. An adverse result in a patent dispute involving 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 through injunctive relief, 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 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 increased 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.

In addition to legislation concerning price controls, other trends could affect Schering-Plough's business. These trends include legislative or regulatory action relating to pharmaceutical pricing and reimbursement, health care reform initiatives and 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,

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reimbursement of products, prescribers' practices and policies of third party payors may be 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 Medicaid expenses, managed care organizations continue to grow in influence, and Schering-Plough faces increased pricing pressure as managed care organizations 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 therapeutic areas not currently covered by Schering-Plough's existing marketed products portfolio and pipeline projects, including women's health and fertility, anesthesia, and neuroscience, each of which carry unique risks and uncertainties which could have a negative impact on future results of operations.***

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 the regulators as various R&D 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 the 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 be material.

***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. 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 a generic drug before reimbursing for a more effective, branded product that is more expensive; 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 against 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. Attorney's 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.

Congress and certain states have initiated investigations into the timing and disclosure of the ENHANCE clinical trial and related events, as well as the timing of certain stock sales by one executive officer, Carrie Cox.

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.

***There are other legal matters in which adverse outcomes could negatively affect Schering-Plough's 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 could 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 its business.

Please refer to "Legal Proceedings" in Item 3 of this 10-K for descriptions of significant pending litigation.

***Issues concerning the Merck/Schering-Plough Cholesterol Joint Venture's ENHANCE clinical trial 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" — ENHANCE Matter — for background information about the Merck/Schering-Plough cholesterol joint venture's ENHANCE clinical trial and related matters.

These issues concerning the Merck/Schering-Plough cholesterol joint venture's ENHANCE clinical trial could have a material adverse effect on the Merck/Schering-Plough cholesterol joint venture's sales of VYTORIN and ZETIA. There was significant negative media surrounding the release of the top-line results. To date in 2008, IMS data shows that prescriptions for VYTORIN and ZETIA have declined. If sales of such products continue to trend down further or remain at current levels for a prolonged period, Schering-Plough's business, cash flow, results of operations, financial position and prospects could also be materially adversely affected. In addition, unfavorable outcomes resulting from the government investigations or the litigation concerning the sale and promotion of these products could have a material adverse effect on Schering-Plough's financial position, liquidity and results of operations.

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***Schering-Plough is 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 financial position and results of operations.***

Schering-Plough's manufacturing facilities and clinical/research practices 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 financial position, cash flows and results of operations. Failure to comply with regulations, which include pharmacovigilance reporting requirements and standards relating to clinical, laboratory and manufacturing practices, can result in delays in the approval of drugs, seizure or recalls of drugs, suspension or revocation of the authority necessary for the production and sale of drugs, 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;
- uncertainties concerning safety 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. These situations also have raised concerns among some prescribers and patients relating to the safety and efficacy of pharmaceutical products in general, which have negatively affected the sales of such products. In addition, increased scrutiny of the outcomes of clinical trials have lead to increase volatility in market reaction.

In addition, following the wake of recent product withdrawals of other companies and other significant safety issues, health authorities such as the FDA, the European Medicines Agency and the Pharmaceuticals and Medicines Device Agency 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 the prevalence of negative publicity regarding known side effects of any of Schering-Plough's products, it could significantly reduce demand for the product or may require Schering-Plough to remove the product from the market. Further, in the current environment in which all pharmaceutical companies operate, Schering-Plough is at risk for product liability claims for its products.

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

Schering-Plough operates in a highly competitive industry. Schering-Plough competes with a large number of multinational pharmaceutical companies, biotechnology companies and generic pharmaceutical companies. Many of Schering-Plough's competitors have been conducting research and development in areas served both by Schering-Plough's current products and by those products Schering-Plough is in the process of

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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 Human Prescription Pharmaceuticals and Animal Health increased. Acquisitions, such as the recently completed purchase of OBS, further expanded the size, scale and scope of its global operations. Risks inherent in conducting a global business include:

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

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

trade protection measures and import or export licensing requirements;

diminished protection of intellectual property in some countries; and

possible nationalization and expropriation.

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

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***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 impact anticipated cost savings from synergies, expected accretion to earnings and 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. Although substantial efforts are being made to complete the integration phase 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 anticipated cost savings from synergies, anticipated accretion to earnings from the transaction and 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 businesses, Schering-Plough's global animal health business is now 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 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. 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.

***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 European Medicines Agency 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.

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Manufacturing biologics, especially in large quantities, is sometimes complex and may require the use of innovative technologies to handle living micro-organisms. 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.

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.

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

Schering-Plough operates in multiple jurisdictions and, as such, virtually all sales are denominated in currencies of the local jurisdiction. Additionally, Schering-Plough has entered and will enter into acquisition, licensing, borrowings or other financial transactions that may give rise to currency and interest rate exposure. Since Schering-Plough cannot, with certainty, foresee and mitigate against such adverse fluctuations, fluctuations in currency exchange rates and interest rates could negatively affect Schering-Plough's results of operations and/or 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.

***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 may be cost prohibitive, available on limited terms or unavailable.

***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 its jurisdictions. 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's 1997-2007 tax returns remain open for examination by the IRS. Schering-Plough may be challenged by the IRS and other tax authorities on positions it has taken in its income tax returns. Although 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, due to the complexity of tax contingencies, the ultimate resolution of any tax matters may result in payments greater or less than amounts accrued.



With the acquisition of OBS's Organon (human pharmaceutical) and Intervet (animal health) businesses, the main tax risks are correspondingly centered in the Netherlands, where management, intellectual property, and beneficial rights as well as product liability have been predominantly centered. The tax position for both Organon and Intervet in the Netherlands has been closed through 2005.

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.

**Table of Contents****Item 1B. *Unresolved Staff Comments***

None.

**Item 2. *Properties***

Schering-Plough's corporate and global human pharmaceutical headquarters are located in Kenilworth, New Jersey. The Animal Health global headquarters is located in Boxmeer, 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:

| <b>Location</b>                                | <b>Product Type</b>                               |
|--|---|
| 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.

Schering-Plough is currently in the process of building a U.S. pharmaceutical sciences center in New Jersey. Capital expenditures of approximately \$50 million and \$40 million were made in 2007 and 2006, respectively, related to this center. Additional capital expenditures of approximately \$175 million are expected over the next two years.

**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 the Litigation Charges discussion in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, and Note 3, Special and Acquisition Related Charges and Manufacturing Streamlining, and Note 20, Legal, Environmental and Regulatory Matters, contained in Item 8, Financial Statements and Supplementary Data.

***ENHANCE Matter***

*Background.* The Merck/Schering-Plough cholesterol joint venture markets ZETIA and VYTORIN (a combination of Merck's Zocor (simvastatin) and Schering-Plough's Zetia (ezetimibe)).

The Merck/Schering-Plough cholesterol joint venture's ENHANCE (Effect of Combination Ezetimibe and High-Dose Simvastatin vs. Simvastatin Alone on the Atherosclerotic Process in Patients with Heterozygous Familial Hypercholesterolemia) clinical trial was a surrogate endpoint trial, conducted in 720 patients with

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Heterozygous Familial Hypercholesterolemia, a rare condition that affects approximately 0.2% of the population. The primary endpoint was the mean change in the intima-media thickness measured at three sites in the carotid arteries (the right and left common carotid, internal carotid and carotid bulb) between patients treated with ezetimibe/simvastatin 10/80 mg versus patients treated with simvastatin 80 mg alone over a two-year period. There was no statistically significant difference between the treatment groups for the primary endpoint and for each of the components of the primary endpoint, including the common carotid artery. Key secondary imaging endpoints also showed no statistical difference between treatment groups.

On January 14, 2008, the Merck/Schering-Plough cholesterol joint venture announced the top-line results of the ENHANCE clinical trial. There will be fuller discussions of the results of the ENHANCE clinical trial in medical scientific forums, as is customary. A discussion is scheduled for the American College of Cardiology meeting on March 30, 2008.

Technical difficulties in analyzing sometimes fuzzy ultrasound images had consumed a long time period since the last patient was scanned in April 2006 until December 31, 2007, when data from ultrasound images were first unblinded to scientists of the Merck/Schering-Plough cholesterol joint venture. After analysis of the results the summary findings were released by the joint venture on January 14, 2008. In 2008, there has been media speculation about the length of time needed to analyze the ultrasound images and media confusion about the meaning of the trial results.

Medical experts and health advisory groups have long recognized high LDL cholesterol as a significant cardiovascular risk factor and recommended increasingly aggressive treatment of high cholesterol for certain patients. Lowering LDL cholesterol, along with healthy diet and lifestyle changes, remains the cornerstone of lipid treatment for patients at risk for heart disease.

Clinical studies prior to ENHANCE have demonstrated that VYTORIN lowered patients' LDL cholesterol more than rosuvastatin, atorvastatin and simvastatin at the doses studied and was able to get more patients to their LDL cholesterol goals (as defined by ATP III). The findings from the Merck/Schering-Plough cholesterol joint venture's ENHANCE clinical trial further confirmed VYTORIN's effectiveness, compared to simvastatin, at lowering LDL cholesterol. Specifically, there was a significant difference in low-density lipoprotein, or LDL cholesterol lowering seen between the treatment groups' 58% LDL cholesterol lowering at 24 months on ezetimibe/simvastatin as compared to 41% at 24 months on simvastatin alone.

The ENHANCE surrogate endpoint study was not powered nor designed to assess cardiovascular clinical event outcomes, such as the effectiveness of the drugs at lowering the risk of heart attack and stroke. The Merck/Schering-Plough cholesterol joint venture is currently conducting the IMPROVE-IT trial, a large clinical trial comparing VYTORIN (ezetimibe/simvastatin) and simvastatin in more than 10,000 patients. The results of the IMPROVE-IT trial will compare the effectiveness of VYTORIN to simvastatin alone in reducing heart attacks and/or strokes.

Schering-Plough's stock price declined significantly in early 2008, from \$26.64 (closing price) on December 31, 2007 to a 2008 low of \$19.02 (closing price) on January 25, 2008 to \$21.97 (closing price) on February 28, 2008, the day before this 10-K was filed.

*Investigations.* Through the date of filing this 10-K, Schering-Plough, the joint venture and/or its joint venture partner, Merck & Co., Inc. ( Merck ), have received:

several letters from Congress, including the House Committee on Energy and Commerce, the House Subcommittee on Oversight and Investigations, 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, the companies' sale and promotion of VYTORIN, as well as sales of stock by the

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companies' corporate officers (including one executive of Schering-Plough who was named in one of the letters, Carrie Cox) since April 2006; and

several subpoenas from state officials (such as the State Attorney General or State Department of Justice) in several states, including Connecticut, New York and Oregon, seeking similar information and documents.

Schering-Plough is cooperating with these investigations and working with Merck to respond to the inquiries.

*Litigation.* In addition, since mid-January 2008, Schering-Plough has become aware of or been served with 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 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 of the putative securities class actions and, if warranted, bring any appropriate legal action on behalf of Schering-Plough.

Schering-Plough is cooperating fully in the government investigations and intends to vigorously defend the lawsuits that have been filed relating to the ENHANCE study.

## ***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.

### ***DR. SCHOLL'S FREEZE AWAY***

On July 26, 2004, OraSure Technologies filed an action in the U.S. District Court for the Eastern District of Pennsylvania alleging patent infringement by Schering-Plough Healthcare Products by its sale of DR. SCHOLL'S FREEZE AWAY wart removal product. This matter was settled with no material impact on Schering-Plough's financial statements and a stipulation dismissing the action was filed by the parties on February 15, 2008.

### ***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;

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; and

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.

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***AWP Litigation and Investigations***

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

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

***Securities and Class Action Litigation***

***Federal Securities Litigation***

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

***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 corporate officers (Messrs. LaRosa and Moore) 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

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well as other state statutory and common law causes of action. These suits seek unspecified damages. Discovery is ongoing.

### *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.

### *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 is currently being tried in Newark District court. Schering-Plough's tax reserves were adequate to cover the above-mentioned payments.

### *Pending Administrative Obligations*

In connection with the settlement of an investigation with the U.S. Department of Justice and the U.S. Attorney's Office for the Eastern District of Pennsylvania, Schering-Plough entered into a five-year corporate integrity agreement (CIA). The CIA was amended in August 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.

### *Other Matters*

#### *Products Liability*

Beginning in May of 2007, a number of complaints have been filed in various jurisdictions asserting claims against Organon USA, Inc., Organon Pharmaceuticals USA, Inc., and/or Organon International ( Organon ) arising from Schering-Plough's marketing and sale of NUVARING, a combined hormonal contraceptive vaginal ring. The plaintiffs contend that Organon 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, heart attacks and strokes. The majority of the cases are currently pending in the United States District Court for District of New Jersey. Other cases are pending in Wisconsin, Missouri, New York and Georgia.

#### *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.

**Table of Contents****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 February 29, 2008. 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.

| <b>Name</b>                | <b>Title</b>  | <b>Age</b> |
|----------------------------|---|------------|
| Robert J. Bertolini*       | Executive Vice President and Chief Financial Officer(1)                                     | 46         |
| John M. Carroll            | Vice President, Global Internal Audits(2)   | 47         |
| C. Ron Cheeley*            | Senior Vice President, Global Human Resources(3)  | 57         |
| Carrie S. Cox*             | Executive Vice President and President, Global Pharmaceuticals(4)                           | 50         |
| William J. Creelman        | Vice President, Tax(5)  | 53         |
| Fred Hassan*               | Chairman and Chief Executive Officer(6)   | 62         |
| Steven H. Koehler*         | Vice President and Controller(7)  | 57         |
| Thomas P. Koestler, Ph.D.* | Executive Vice President and President, Schering-Plough Research Institute(8)               | 56         |
| Raul E. Kohan*             | Senior Vice President, Corporate Excellence   | 55         |
| Joseph J. LaRosa           | Vice President, Legal Affairs(9)  | 49         |
| Ian A.T. McInnes           | Senior Vice President and President, Global Supply Chain(10)                                | 55         |
| E. Kevin Moore             | Vice President and Treasurer  | 55         |
| Lori Queisser*             | Senior Vice President, Global Compliance and Business Practices(11)                         | 47         |
| Thomas J. Sabatino, Jr.*   | Executive Vice President and General Counsel(12)  | 49         |
| Karl Salnoske              | Vice President and Chief Information Officer(13)  | 54         |
| Brent Saunders*            | Senior Vice President and President, Consumer Health Care(14)                               | 38         |
| Susan Ellen Wolf           | Corporate Secretary, Associate General Counsel and Vice President, Corporate Governance(15) | 53         |

\* 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 and Assistant Treasurer of Bristol-Myers Squibb from 2000 to 2002.
- (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)

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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.

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- (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) 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.
- (8) Dr. Koestler was named Executive President and President of Schering-Plough Research Institute in September of 2006. Dr. Koestler was Executive Vice President, Global Development of Schering-Plough Research Institute from 2005 to September of 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.
- (9) Mr. LaRosa became Vice President, Legal Affairs in 2004. Mr. LaRosa was Staff Vice President, Secretary and Associate General Counsel from 2001 to 2004.
- (10) 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.
- (11) Ms. Queisser joined Schering-Plough in February of 2007 as Senior Vice President, Global Compliance and Business Practices. Ms. Queisser was Vice President, Chief Compliance Officer from October 2002 to February 2007, and Executive Director and General Auditor from March 2002 to October 2002 of Eli Lilly Company.
- (12) 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.
- (13) 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.
- (14) Mr. Saunders joined Schering-Plough in 2003 as Senior Vice President, Global Compliance and Business Practices. Mr. Saunders was a partner at PricewaterhouseCoopers from 2000 to 2003.
- (15) 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 and Related Stockholder Matters***

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.

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The following table provides information with respect to purchases by Schering-Plough of its common shares during the fourth quarter of 2007.

**ISSUER PURCHASES OF EQUITY SECURITIES**

| <b>Period</b>  | <b>Total Number<br/>of<br/>Shares<br/>Purchased</b> | <b>Average<br/>Price<br/>Paid<br/>per Share</b> | <b>Total Number<br/>of<br/>Shares<br/>Purchased as<br/>Part of Publicly<br/>Announced<br/>Plans or<br/>Programs</b> | <b>Maximum<br/>Number<br/>of Shares that<br/>May<br/>Yet Be<br/>Purchased<br/>Under the<br/>Plans or<br/>Programs</b> |
|--|---|---|---|---|
| October 1, 2007 through October 31, 2007               | 11,863(1)   | \$ 32.06  | N/A   | N/A   |
| November 1, 2007 through November 30, 2007             | 12,799(1)   | 29.12   | N/A   | N/A   |
| December 1, 2007 through December 31, 2007             | 108,624(1)  | 30.80   | N/A   | N/A   |
| <b>Total October 1, 2007 through December 31, 2007</b> | <b>133,286(1)</b>                                   | <b>30.75</b>                                    | <b>N/A</b>  | <b>N/A</b>  |

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

**Performance Graph**

**Comparison of Cumulative Total Return  
For the Five Years Ended December 31, 2007**

|                             | <b>2002</b> | <b>2003</b> | <b>2004</b> | <b>2005</b> | <b>2006</b> | <b>2007</b> |
|-----------------------------|-------------|-------------|-------------|-------------|-------------|-------------|
| Schering-Plough Corporation | 100         | 81          | 98          | 99          | 114         | 129         |
| Composite Peer Group        | 100         | 108         | 100         | 96          | 112         | 118         |
| S&P 500 Index               | 100         | 128         | 142         | 149         | 172         | 182         |

The graph above assumes a \$100 investment on December 31, 2002, 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 & Co., Inc., Pfizer Inc. and Wyeth.





**Table of Contents****Item 6. Selected Financial Data**

|   | 2007(1)   | 2006      | 2005     | 2004     | 2003     |
|---|---|-----------|----------|----------|----------|
|   | (In millions, except per share figures and percentages) |           |          |          |          |
| Operating Results   |   |           |          |          |          |
| Net sales   | \$ 12,690   | \$ 10,594 | \$ 9,508 | \$ 8,272 | \$ 8,334 |
| Equity (income)   | (2,049)   | (1,459)   | (873)    | (347)    | (54)     |
| (Loss)/income before income taxes(2)  | (1,215)   | 1,483     | 497      | (168)    | (46)     |
| Net (loss)/income(2)  | (1,473)   | 1,143     | 269      | (947)    | (92)     |
| Net (loss)/income available to common shareholders(2)                                   | (1,591)   | 1,057     | 183      | (981)    | (92)     |
| Diluted (loss)/earnings per common share(2)   | (1.04)  | 0.71      | 0.12     | (0.67)   | (0.06)   |
| Basic (loss)/earnings per common share(2)   | (1.04)  | 0.71      | 0.12     | (0.67)   | (0.06)   |
| Research and development expenses   | 2,926   | 2,188     | 1,865    | 1,607    | 1,469    |
| Acquired in-process research and development  | 3,754   |           |          |          |          |
| Depreciation and amortization expenses  | 861   | 568       | 486      | 453      | 417      |
| Financial Position and Cash Flows   |   |           |          |          |          |
| Property, net   | \$ 7,016  | \$ 4,365  | \$ 4,487 | \$ 4,593 | \$ 4,527 |
| Total assets  | 29,156  | 16,071    | 15,469   | 15,911   | 15,271   |
| Long-term debt(3)   | 9,019   | 2,414     | 2,399    | 2,392    | 2,410    |
| Shareholders' equity  | 10,385  | 7,908     | 7,387    | 7,556    | 7,337    |
| Capital expenditures  | 618   | 458       | 478      | 489      | 711      |
| Financial Statistics  |   |           |          |          |          |
| Net (loss)/income as a percent of net sales   | (11.6)%   | 10.8%     | 2.8%     | (11.4)%  | (1.1)%   |
| Return on average shareholders' equity  | (16.1)%   | 14.9%     | 3.6%     | (12.7)%  | (1.2)%   |
| Net book value per common share(4)  | \$ 6.07   | \$ 5.10   | \$ 4.77  | \$ 4.91  | \$ 4.99  |
| Other Data  |   |           |          |          |          |
| Cash dividends per common share   | \$ 0.25   | \$ 0.22   | \$ 0.22  | \$ 0.22  | \$ 0.565 |
| Cash dividends paid on common shares  | 382   | 326       | 324      | 324      | 830      |
| Cash dividends on preferred shares  | 99  | 86        | 86       | 30       |          |
| Average shares outstanding used in calculating diluted earnings/(loss) per common share | 1,536   | 1,491     | 1,484    | 1,472    | 1,469    |
| Average shares outstanding used in calculating basic earnings/(loss) per common share   | 1,536   | 1,482     | 1,476    | 1,472    | 1,469    |
| Common shares outstanding at year-end   | 1,621   | 1,487     | 1,479    | 1,474    | 1,471    |

(1) Operating results and other financial information reflects the closing of the OBS acquisition on November 19, 2007, including the impacts of purchase accounting in accordance with SFAS No. 141, Business Combinations.

(2)

2007, 2006, 2005, 2004, and 2003 include special and acquisition related charges and manufacturing streamlining costs of \$84, \$248, \$294, \$153, and \$599, respectively. See Note 3, Special and Acquisition Related Charges and Manufacturing Streamlining, for additional information on these charges that were incurred in 2007, 2006, and 2005. The special charges incurred in 2004 included \$119 million of employee termination costs and \$34 million for asset impairment and related charges. Special charges in 2003 included the increases in litigation reserves of \$350 million that resulted from the investigations into Schering-Plough's sales and marketing practices, approximately \$179 million of employee termination costs related to the Voluntary Early Retirement Program announced in August 2003 and \$70 million of asset impairment and other charges.

- (3) The increase in long-term debt during 2007 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 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.

## **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 – human 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***

Earlier this decade, Schering-Plough experienced a number of business, regulatory, and legal challenges. In April 2003, the Board of Directors named Fred Hassan as the new Chairman of the Board and Chief Executive Officer of Schering-Plough Corporation. With support from the Board, he initiated a strategic plan, with the goal of stabilizing, repairing and turning around Schering-Plough in order to build long-term shareholder value. He also installed a new senior executive team. That strategic plan, the Action Agenda, is a six- to eight-year, five-phase plan. Schering-Plough is currently in the fourth phase of the Action Agenda – Build the Base. During the Build the Base phase, Schering-Plough continues to focus on its strategy of value creation across a broad front, and believes the Organon BioSciences N.V. (OBS) acquisition was a major, transformative accomplishment in this regard. The OBS acquisition added further diversification of marketed products, including two new therapeutic areas (Women's Health and Central Nervous System), as well as significant strength in Animal Health products and pipeline. Other accomplishments in 2007 include:

growing the business, for example there was double digit sales growth in all three product groups, Human Pharmaceuticals, Animal Health and Consumer Health Care;

penetrating new markets, including China, Brazil and Russia;

expanding the product portfolio for Schering-Plough's three customer groups – human pharmaceutical, animal health and consumer health care; and

discovering and developing or acquiring new products.

A key component of the Action Agenda is applying science to meet unmet medical needs. Research and development activities focus on mechanisms to treat serious diseases. As a result, 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. Schering-Plough has been successful in advancing its pipeline into several late-stage projects that will require sizable resources to complete. Consistent with this core strategy, Schering-Plough is increasing its investment in research and development. As Schering-Plough continues to develop the later phase growth-drivers of the pipeline (e.g., sugammadex, thrombin receptor antagonist, golimumab, vicriviroc, boceprevir and asenapine), it anticipates higher spending on clinical trial activities. Schering-Plough's

progressing early pipeline includes drug candidates across a wide range of therapeutic areas with more than 20 compounds now approaching or in Phase I development.

As part of the Action Agenda, Schering-Plough continues to work to enhance infrastructure, upgrade processes and systems and strengthen talent both the recruitment of talented individuals and the development of key employees. 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.

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Further, with the integration of the OBS employees into Schering-Plough much new talent has been added. In addition, as part of the integration of OBS, Schering-Plough has also announced that there will be some workforce reduction to eliminate redundancies.

### ***2007 Results   Highlights of Schering-Plough's performance in 2007 are as follows:***

Closed the acquisition of OBS on November 19, 2007 for a purchase price of approximately Euro 11 billion.

Schering-Plough's net sales in 2007 were \$12.7 billion, an increase of \$2.1 billion, or 20 percent, as compared to the 2006 period. 2007 net sales included \$626 million of sales of products acquired as part of the OBS acquisition.

Net loss available to common shareholders in 2007 was \$1.6 billion, as compared to net income available to common shareholders of \$1.1 billion in 2006. Included in the 2007 net loss is approximately \$4.0 billion of charges related to purchase accounting for the OBS acquisition, including a \$3.8 billion acquired in-process research and development charge. Cash flow provided by operating activities was \$2.6 billion in 2007.

Global sales of Schering-Plough's cholesterol franchise products, VYTORIN and ZETIA, made by the cholesterol joint venture with Merck & Company, Inc. (Merck) continued to grow in 2007 and contributed significantly to Schering-Plough's improved operating results and cash flow (see note below about 2008 developments). In addition, increased sales of pharmaceutical products such as REMICADE, TEMODAR and NASONEX also contributed favorably to Schering-Plough's overall operating results and cash flow.

The additional strength that Schering-Plough developed, in 2007 and during the four years since Mr. Hassan and the new management team began the Action Agenda, is key for Schering-Plough in the current environment. The pharmaceutical industry continues to be subject to ever-more critical scrutiny, where events can be mischaracterized and drive amplified reactions. Schering-Plough believes that new scientific data are best presented and discussed at appropriate scientific and medical forums.

### ***Early 2008 Developments Relating to the Cholesterol Franchise***

As explained in more detail in Part I, Item 3, Legal Proceedings, ENHANCE Matter, in early 2008, Schering-Plough encountered such a challenge when results of a Merck/Schering-Plough cholesterol joint venture clinical trial, called ENHANCE, and joint venture products ZETIA and VYTORIN, became the subject of much media scrutiny prior to fuller discussions of the trial results at appropriate medical forums. A discussion is scheduled for the American College of Cardiology meeting on March 30, 2008.

Medical experts and health advisory groups have long recognized high LDL cholesterol (often known as "bad cholesterol") as a significant cardiovascular risk factor and recommended increasingly aggressive treatment of high cholesterol for certain patients. Lowering LDL cholesterol, along with a healthy diet and lifestyle changes, remains the cornerstone of lipid treatment for patients at risk for heart disease. Clinical studies, including ENHANCE, have demonstrated that VYTORIN lowers patients' LDL cholesterol more than rosuvastatin, atorvastatin and simvastatin at the doses studied and was able to get more patients to their LDL cholesterol goals (as defined by ATP III).

While it is too early to tell the impact of the joint venture's ENHANCE trial results on the joint venture's cholesterol business, Schering-Plough's diversified group of products and geographic areas, as well as its highly experienced executive team, gives Schering-Plough additional strength that will be helpful in weathering this situation.

## **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

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owned by others pursuant to licensing and joint venture arrangements. Any time that third parties are involved, there are additional factors relating to the third party and outside the control of Schering-Plough that may create positive or negative impacts on Schering-Plough. VYTORIN, ZETIA and REMICADE are subject to such arrangements and are key to Schering-Plough's current business and financial performance.

In addition, any potential strategic alternatives may be impacted by the change of control provisions in those arrangements, which could result in VYTORIN and ZETIA being acquired by Merck or REMICADE 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) to Schering-Plough's 10-K, and the change of control provision relating to REMICADE is contained in the contract with Centocor, filed as Exhibit 10(v) to Schering-Plough's 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, and on a combined basis, these products continued to grow in terms of sales and market share during 2007 (see note above about 2008 developments). A material change in the sales or market share of Schering-Plough's cholesterol franchise would have a significant impact on Schering-Plough's consolidated results of operations and cash flows. In order to maintain and enhance its infrastructure and business, Schering-Plough must continue to increase profits. This increased profitability is largely dependent upon the performance of Schering-Plough's cholesterol franchise.

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.

## **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 currently in Phase III trials. Schering-Plough has exclusive marketing rights to both products outside of 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 now 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



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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. For the rights to this device, Schering-Plough made an upfront payment of \$21 million, which is included in research and development expenses for the year ended December 31, 2007.

## **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 OBS manufacturing operations acquired during 2007, 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. From time to time, actions are taken to enhance Schering-Plough's overall manufacturing efficiency. For example, during 2006, Schering-Plough closed a manufacturing plant in Puerto Rico and in 2007 began the process of closing a small manufacturing facility in the Asia Pacific region. Schering-Plough continues to review the carrying value of manufacturing assets for indications of impairment. Future events and decisions may lead to additional 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 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 increasing 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.

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### **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.

Commencing from the acquisition date, OBS assets acquired and liabilities assumed, as well as the results of OBS 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, based on a preliminary valuation, resulted in the following non-cash charges in 2007:

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

Amortization of inventory adjusted to fair value, of which approximately \$1.1 billion will be charged to Cost of Sales (\$258 million in 2007) approximately over a one year period from the acquisition date.

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 (\$65 million in 2007).

Incremental depreciation relating to the adjustment in fair value on property, plant and equipment of \$885 million that will be depreciated primarily to Cost of Sales over the lives of the applicable property (\$3 million in 2007).

The \$3.8 billion acquired IPR&D charge was associated with research projects in the women's health, central nervous system and anesthesia therapeutic areas of human health as well as research projects in animal health. The amount was determined by using discounted cash flow projections of identified research projects for which technological feasibility had not been established and for which there was no alternative future use. The discount rates used ranged from 14 percent to 18 percent. The projected launch dates following FDA or other regulatory approval are years 2008 through 2013, at which time Schering-Plough expects these projects to begin to generate cash flows. All of the research and development projects considered in the valuation are subject to the normal risks and uncertainties associated with demonstrating the safety and efficacy required to obtain FDA or other regulatory approvals.

### **DISCUSSION OF OPERATING RESULTS**

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

#### ***Net Sales***

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

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programs, placed restrictions on physician prescription levels and patient reimbursements, emphasized greater use of generic drugs and enacted across-the-board price cuts as methods to control costs.

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

Consolidated net sales in 2006 were \$10.6 billion, an increase of \$1.1 billion or 11 percent compared to 2005. The increase primarily reflected the growth in sale volumes of REMICADE, NASONEX, PEGINTRON and TEMODAR. This increase also reflected an unfavorable impact of 1 percent from foreign exchange.

Net sales for the years ended December 31, 2007, 2006, and 2005 were as follows:

|   | 2007                  | 2006             | 2005            | % Increase<br>(Decrease) |            |
|---|-----------------------|------------------|-----------------|--------------------------|------------|
|   | (Dollars in millions) |                  |                 | 2007/2006                | 2006/2005  |
| <b>HUMAN PRESCRIPTION<br/>PHARMACEUTICALS</b> | <b>\$ 10,173</b>      | <b>\$ 8,561</b>  | <b>\$ 7,564</b> | <b>19%</b>               | <b>13%</b> |
| REMICADE                                      | 1,648                 | 1,240            | 942             | 33                       | 32         |
| NASONEX                                       | 1,092                 | 944              | 737             | 16                       | 28         |
| PEGINTRON                                     | 911                   | 837              | 751             | 9                        | 11         |
| TEMODAR                                       | 861                   | 703              | 588             | 22                       | 20         |
| CLARINEX/AERIUS                               | 799                   | 722              | 646             | 11                       | 12         |
| CLARITIN Rx                                   | 391                   | 356              | 371             | 10                       | (4)        |
| AVELOX  | 384                   | 304              | 228             | 26                       | 34         |
| INTEGRILIN                                    | 332                   | 329              | 315             | 1                        | 5          |
| REBETOL                                       | 277                   | 311              | 331             | (11)                     | (6)        |
| CAELYX  | 257                   | 206              | 181             | 25                       | 13         |
| INTRON A                                      | 233                   | 237              | 287             | (2)                      | (17)       |
| SUBUTEX/SUBOXONE                              | 220                   | 203              | 197             | 8                        | 3          |
| ASMANEX                                       | 162                   | 103              | 11              | 57                       | N/M        |
| Other Pharmaceutical                          | 2,606                 | 2,066            | 1,979           | 26                       | 44         |
| <b>ANIMAL HEALTH</b>                          | <b>1,251</b>          | <b>910</b>       | <b>851</b>      | <b>37</b>                | <b>7</b>   |
| <b>CONSUMER HEALTH CARE</b>                   | <b>1,266</b>          | <b>1,123</b>     | <b>1,093</b>    | <b>13</b>                | <b>3</b>   |
| OTC   | 682                   | 558              | 556             | 22                       | N/M        |
| Foot Care                                     | 345                   | 343              | 333             | 1                        | 3          |
| Sun Care                                      | 239                   | 222              | 204             | 8                        | 9          |
| <b>CONSOLIDATED NET SALES</b>                 | <b>\$ 12,690</b>      | <b>\$ 10,594</b> | <b>\$ 9,508</b> | <b>20%</b>               | <b>11%</b> |

N/M Not a meaningful percentage.

Sales of Human Prescription Pharmaceuticals in 2007 totaled \$10.2 billion, a \$1.6 billion or 19% increase compared to 2006. Included in 2007 are \$409 million of net sales related to Organon, the human health business of OBS. Sales of Human Prescription Pharmaceuticals in 2006 totaled \$8.6 billion, a \$1.0 billion or 13% increase compared to 2005.

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 33 percent to \$1.6 billion in 2007 as compared to 2006 driven by continued market growth, expanded use across indications and a favorable impact from foreign

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exchange. Global net sales increased 32 percent in 2006 to \$1.2 billion as compared to 2005, due to greater demand, expanded indications and continued market growth. Competitive products for the indications referred to above have been introduced during 2006 and 2007.

Global net sales of NASONEX Nasal Spray, a once-daily corticosteroid nasal spray for allergies, rose 16 percent to \$1.1 billion in 2007 as compared to 2006 due to increased sales across all geographic regions, and 28 percent to \$944 million in 2006 as compared to 2005, as the product captured greater U.S. and international market share in 2006. Competitive products have been introduced in 2007.

Global net sales of PEGINTRON Powder for Injection, a pegylated interferon product for treating hepatitis C, 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 increased 11 percent to \$837 million in 2006 as compared to 2005 reflecting higher sales volume in Japan and the U.S. In Japan, sales in 2005 benefited from a significant number of patients who were waiting for approval of PEGINTRON before beginning treatment.

Global net sales of TEMODAR Capsules, a treatment for certain types of brain tumors, 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. Global net sales increased 20 percent to \$703 million in 2006 as compared to 2005 due to the increased utilization for new indications.

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 2007 increased 11 percent to \$799 million as compared to 2006 primarily due to higher sales in international markets. Global net sales in 2006 increased 12 percent to \$722 million as compared to 2005 due to increased demand in Europe and Latin America as well as increased sales in the U.S. despite slightly declining market share.

International net sales of prescription CLARITIN increased 10 percent to \$391 million in 2007 as compared to 2006 reflecting growth in Latin America, Asia Pacific and Japan. Sales in 2006 decreased 4 percent to \$356 million as compared to 2005.

Net sales of AVELOX, a fluoroquinolone antibiotic for the treatment of certain respiratory and skin infections, sold primarily in the U.S. by Schering-Plough as a result of its license agreement with Bayer, increased 26 percent to \$384 million in 2007 as compared to 2006 primarily as a result of increased market share. Net sales in 2006 increased 34 percent to \$304 million in 2006 as compared to \$228 million in 2005 due to share growth and new indications.

Global net sales of INTEGRILIN Injection, a glycoprotein platelet aggregation inhibitor for the treatment of patients with acute coronary syndrome, which is sold primarily in the U.S. by Schering-Plough, increased 1 percent to \$332 million in 2007 as compared to 2006. During 2006, sales increased 5 percent to \$329 million as compared to 2005.

Global 2007 net sales of REBETOL Capsules, for use in combination with PEGINTRON or INTRON A for treating hepatitis C, decreased 11 percent to \$277 million as compared to 2006 due to lower patient enrollment in Japan and increased generic competition. Global net sales in 2006 decreased 6 percent to \$311 million as compared to 2005 due to lower sales in Europe and increased competition. In Japan, sales in 2005 benefited from the significant number of patients who were waiting for approval of PEGINTRON before beginning hepatitis C treatment.

International net sales of CAELYX, for the treatment of ovarian cancer, metastatic breast cancer and Kaposi's sarcoma, increased 25 percent to \$257 million in 2007 as compared to 2006 primarily due to increased sales in Latin

America and a favorable impact from foreign exchange. Sales in 2006 increased 13 percent to \$206 million as compared to 2005 primarily due to an expanding market for this product.

Global net sales of INTRON A Injection, for chronic hepatitis B and C and other antiviral and anticancer indications, decreased 2 percent to \$233 million in 2007 as compared to 2006, and 17 percent in 2006 to



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\$237 million as compared to 2005. The decrease in both 2007 and 2006 were 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 8 percent to \$220 million in 2007 as compared to 2006 as a result of a benefit from foreign exchange. Sales increased 3 percent to \$203 million in 2006 as compared to 2005 due to increased market share. In October 2006, SUBOXONE was approved by the EU, including the 25 member states as well as Iceland and Norway, for the treatment of opioid dependence.

Global net sales of ASMANEX, an orally inhaled steroid for asthma, were up 57 percent to \$162 million in 2007 as compared to 2006 primarily due to market share growth in the U.S. Sales increased to \$103 million in 2006 as compared to 2005 due to the ASMANEX launch commencing in late 2005.

Other pharmaceutical net sales include all net sales of Organon from the date of the acquisition through December 31, 2007 and a large number of lower sales volume human prescription pharmaceutical products. Net sales of Organon were \$409 million in 2007 and included \$57 million for FOLLISTIM/PUREGON, a fertility treatment, and \$45 million for NUVARING, a contraception product. Also included in other pharmaceutical sales are several lower volume products which are often 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. Included in other pharmaceutical sales is sales of Schering-Plough's albuterol products. In 2005, the FDA issued a Final Rule that requires all CFC albuterol products, including Schering-Plough's PROVENTIL CFC, be removed from the market no later than December 31, 2008. Schering-Plough's transition to albuterol HFA (PROVENTIL HFA) is complete. Schering-Plough no longer manufactures the CFC product and all remaining CFC inventories have been sold during 2007. Schering-Plough is uncertain as to the ultimate impact on Schering-Plough's overall future sales of PROVENTIL HFA, due to the complexities and multiple external factors influencing this transition, including competing albuterol HFA products.

Global net sales of Animal Health products increased 37 percent to \$1.3 billion in 2007 as compared to 2006. Included in global Animal Health net sales are \$217 million related to Intervet, the animal health business of OBS, for the period subsequent to the acquisition. Global net sales in 2007 also benefited from solid growth in all geographic areas, led by the cattle and companion animal product lines, coupled with a positive impact from foreign currency exchange rates. Global net sales increased 7 percent in 2006 to \$910 million as compared to 2005, reflecting strong growth of core brands across most geographic and species areas led by higher sales of companion animal products. The Animal Health segment's sales growth rate is impacted by intense competition and the frequent introduction of generic products.

Global net sales of Consumer Health Care products, which include OTC, foot care and sun care products, increased 13 percent or \$143 million as compared to 2006. The increase in 2007 was primarily due to the 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, and higher sales of OTC CLARITIN. Global net sales in 2006 increased 3 percent or \$30 million as compared to 2005 reflecting an increase in sales of sun care products and DR. SCHOLL'S and other foot care products. Sales of OTC CLARITIN increased 18 percent to \$462 million in 2007 as compared to 2006 due to sales growth across all product forms. OTC CLARITIN sales decreased 1 percent in 2006 as compared to 2005 as a result of the restrictions on the retail sale of OTC products containing pseudoephedrine (PSE). In addition, OTC CLARITIN continues to face competition from private labels and branded loratadine, and a competing prescription antihistamine was launched for OTC sale in early 2008. Net sales of sun care products increased \$17 million or 8 percent in 2007 as compared to 2006 due to COPPERTONE CONTINUOUS SPRAY line extensions, and \$18 million or 9 percent in 2006 as compared to 2005, primarily due to the success of new COPPERTONE CONTINUOUS SPRAY products launched in 2005. Future sales in the Consumer Health Care segment are difficult to predict because the consumer health care

market is highly competitive, with heavy advertising to consumers and frequent competitive product introductions.

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A summary of costs, expenses and equity income for the years ended December 31, 2007, 2006 and 2005 is as follows:

|  | 2007                  | 2006     | 2005     | % Increase<br>(Decrease) |           |
|--|-----------------------|----------|----------|--------------------------|-----------|
|  | (Dollars in millions) |          |          | 2007/2006                | 2006/2005 |
| Gross margin   | 65.3%                 | 65.1%    | 64.8%    | 0.2%                     | 0.3%      |
| Selling, general and administrative (SG&A)           | \$ 5,468              | \$ 4,718 | \$ 4,374 | 15.9%                    | 7.9%      |
| Research and development (R&D)                       | 2,926                 | 2,188    | 1,865    | 33.7%                    | 17.3%     |
| Acquired in-process research and development (IPR&D) | 3,754                 |          |          | N/M                      | N/M       |
| Other (income)/expense, net                          | (683)                 | (135)    | 5        | N/M                      | N/M       |
| Special and acquisition-related charges              | 84                    | 102      | 294      | N/M                      | N/M       |
| Equity income  | (2,049)               | (1,459)  | (873)    | 40.4%                    | N/M       |

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 65.3 percent in 2007 as compared to 65.1 percent in 2006. Gross margin in 2007 was unfavorably impacted by \$326 million of purchase accounting adjustments included in cost of sales. These purchase accounting adjustments were a result of the amortization of fair values of certain 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.

Despite negative impacts on cost of sales from the costs resulting from Schering-Plough's actions to streamline its manufacturing operations during 2006, gross margin increased to 65.1 percent in 2006 from 64.8 percent in 2005. This improvement in gross margin was primarily due to increased sales of higher margin products and process improvements within Schering-Plough's supply chain, including cost savings from the manufacturing streamlining activities completed during 2006. In 2006, cost of sales included charges totaling \$146 million associated with Schering-Plough's actions to streamline its manufacturing operations, offset by savings of approximately \$30 million as a result of these actions. See Note 3, Special and Acquisition Related Charges and Manufacturing Streamlining, under Item 8, Financial Statements and Supplemental Data, for additional information.

***Selling, general and administrative***

Selling, general and administrative expenses (SG&A) increased 16 percent to \$5.5 billion in 2007 as compared to 2006. Included in SG&A in 2007 were \$227 million from OBS. In addition, the increase in SG&A reflects higher promotion spending, ongoing investments in emerging markets and an unfavorable impact from foreign exchange.

SG&A increased 8 percent to \$4.7 billion in 2006 as compared to 2005, reflecting ongoing investments in emerging markets and field support for product launches as well as higher promotional spending.

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### *Research and development*

Research and development (R&D) spending increased 34 percent to \$2.9 billion in 2007 as compared to the 2006 period. Included in R&D in 2007 were \$111 million from OBS. Also included in R&D were upfront payments of \$197 million mainly related to certain licensing transactions. The increase in R&D spending versus 2006 also reflects higher spending for clinical trials and related activities and investments to build greater breadth and capacity to support the continued expansion of Schering-Plough's pipeline. In 2006, R&D spending increased 17 percent to \$2.2 billion as compared to the 2005 period. The 2006 increase was due to higher costs associated with clinical trials as well as building greater breadth and capacity to support Schering-Plough's progressing pipeline. Generally, changes in R&D spending reflect the timing of Schering-Plough's funding of both internal research efforts and research collaborations with various partners to discover and develop a steady flow of innovative products.

To maximize Schering-Plough's 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. In 2007, certain aspects of the Global Clinical Harmonization Program have been implemented.

### *Acquired in-process research and development*

The acquired in-process research and development charge of \$3.8 billion in 2007 was a result of the OBS acquisition and represents the immediate expense recognition of the fair value of acquired research projects for which technological feasibility has not been established and for which there is no alternative future use.

### *Other (income)/expense, net*

Schering-Plough had other income, net, of \$683 million in 2007 compared to \$135 million of other income, net, in 2006 and other expense, net, of \$5 million in 2005. Other income, net, in 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 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*

#### **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 severance charges 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. In total, these actions resulted in the elimination of over 1,000 positions. Schering-Plough expects these actions to yield an annualized cost savings of approximately \$100 million.

*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:

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

**2005 special charge activities**

Special charges incurred in 2005 are as follows:

|                                    | <b>2005<br/>(Dollars in Millions)</b> |
|------------------------------------|---------------------------------------|
| Litigation charges                 | \$ 250                                |
| Employee termination costs         | 28                                    |
| Asset impairment and other charges | 16                                    |
|                                    | <b>\$ 294</b>                         |

*Litigation Charges:* In 2005, litigation reserves were increased by \$250 million. This increase resulted in a total reserve of \$500 million for the Massachusetts Investigation, as well as the investigations and the state litigation disclosed under AWP Litigation and Investigations in Note 20, Legal, Environmental and Regulatory Matters, representing Schering-Plough's then current estimate to resolve this matter. On August 29, 2006, Schering-Plough announced it had reached an agreement with the U.S. Attorney's Office for the District of Massachusetts and the U.S. Department of Justice to settle the Massachusetts Investigation for an aggregate amount of \$435 million plus interest. This settlement amount relates only to the Massachusetts Investigation. The AWP investigations and

litigation are ongoing. During 2007, Schering-Plough made payments totaling \$435 million related to this settlement.

*Employee termination costs:* Employee termination costs in 2005 consisted of \$7 million associated with a Voluntary Early Retirement Program (VERP) in the U.S. during 2003 and \$21 million of other employee termination costs.

*Asset impairment and other charges:* For the year ended December 31, 2005, Schering-Plough recognized asset impairment and other charges of \$16 million related primarily to the consolidation of Schering-Plough's U.S. biotechnology organizations.

*Equity income*

Sales of the Merck/Schering-Plough cholesterol joint venture totaled \$5.2 billion, \$3.9 billion, and \$2.4 billion in 2007, 2006, and 2005, respectively. The sales growth in 2007 was due primarily to higher market share and market growth in the U.S. and continued expansion into international markets. The sales growth in 2006 was due primarily to an increase in market share.



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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 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 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.

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. Under certain conditions, as specified in the joint venture agreements with Merck, Schering-Plough could be entitled to receive reimbursements of its future research and development expenses of up to \$105 million. Additional information regarding the joint venture with Merck is also included in Note 4, Equity Income, under Item 8, Financial Statements and Supplementary Data.

Equity income from the Merck/Schering-Plough joint venture totaled \$2.0 billion, \$1.5 billion, and \$873 million in 2007, 2006, and 2005, respectively. The increase in 2007 equity income as compared to 2006 reflected higher market share in the U.S. and international sales growth. The increase in 2006 equity income as compared to 2005 reflected continued strong sales of VYTORIN and ZETIA.

During 2005, Schering-Plough recognized milestones from Merck of \$20 million related to certain European approvals of VYTORIN (ezetimibe/simvastatin) in 2005.

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 \$258 million, \$362 million, and \$228 million in 2007, 2006, and 2005, respectively. The 2007 tax provision included tax benefits of \$89 million related to the amortization of fair values of certain assets acquired as part of the OBS acquisition. The 2006 income tax provision primarily relates to foreign taxes. The 2005 tax provision includes a benefit of \$46 million related to an IRS Notice issued in August 2005, which resulted in a reduction of the previously accrued tax liability attributable to repatriations under the American Jobs Creation Act of 2004 (AJCA). The tax provisions in 2007, 2006 and 2005 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, 2007, 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 \$1.7 billion on its tax return for the year ended December 31, 2007. This U.S. NOL carryforward could be materially reduced after examination of Schering-Plough's income tax returns by the Internal Revenue Service (IRS).

In 2007, Schering-Plough generated approximately \$980 million in U.S. losses including the impact of purchase accounting, however, due to differences between financial and tax reporting, Schering-Plough expects to report a minimal increase in its NOL on its 2007 U.S. tax return.

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

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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 20, Legal, Environmental and Regulatory Matters, under Item 8, Financial Statements and Supplemental Data, for additional information). At January 1, and December 31, 2007, the total amount of unrecognized tax benefits was \$924 million and \$859 million, respectively, which includes reductions to deferred tax assets carrying a full valuation allowance, potential refund claims and tax liabilities. At January 1, and December 31, 2007, approximately \$645 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 by up to \$615 million. This decrease would be primarily attributable to a decision in the tax matter currently being litigated in Newark District Court, possible final resolution of Schering-Plough's 1997-2002 examination at IRS 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/or 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 related to tax positions as a component of income tax expense in the Statement of Consolidated Operations. The total amount of accrued interest related to tax positions at January 1, and December 31, 2007 was \$193 million and \$197 million, respectively, and is included in other accrued liabilities.

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. Schering-Plough remains open with the IRS for the 1997-2007 tax years. For most of its other significant tax jurisdictions (both U.S. state and foreign), Schering-Plough's income tax returns are open for examination for the period 2000 through 2007.

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

Schering-Plough had a net (loss)/income available to common shareholders of \$(1.6) billion, \$1.1 billion and \$183 million for 2007, 2006 and 2005, respectively. Net loss available to common shareholders for 2007 included approximately \$4.0 billion of charges related to purchase accounting for the OBS acquisition, including a \$3.8 billion acquired in-process research and development charge. Net loss available to common shareholders for 2007 included the deduction of preferred stock dividends of \$118 million related to the 2004 and 2007 Preferred Stock. Net income available to common shareholders for 2006 and 2005 included the deduction of preferred stock dividends of \$86 million, in each period, related to the 2004 Preferred Stock. Net (loss)/income available to common shareholders for 2007, 2006, and 2005 also included special and acquisition related charges and manufacturing streamlining costs of approximately \$84 million, \$248 million, and \$294 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,          |          |        |
|-------------------------------------|-----------------------|----------|--------|
|                                     | 2007                  | 2006     | 2005   |
|                                     | (Dollars in millions) |          |        |
| Cash flow from operating activities | \$ 2,630              | \$ 2,161 | \$ 882 |
| Cash flow from investing activities | (13,156)              | (2,908)  | (454)  |
| Cash flow from financing activities | 10,089                | (1,361)  | (633)  |

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*Operating Activities*

In 2007, operating activities provided \$2.6 billion of cash, compared with net cash provided by operations of \$2.2 billion in 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 \$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 have been classified as operating cash flows in the Statement of Consolidated Cash Flows.

In 2006, net cash provided by operating activities was \$2.2 billion, an increase of \$1.3 billion as compared to 2005. The increase primarily resulted from higher net income and the timing of operating cash payments and receipts. In 2005, operating activities generated \$882 million of cash including payments of approximately \$375 million to tax authorities for tax liabilities related to the repatriation of foreign earnings under the AJCA; and tax payments of \$239 million related to the settlement of certain tax contingencies for the tax years 1993 through 1996.

*Investing Activities*

Net cash used for investing activities during 2007 was \$13.2 billion, primarily consisting of \$15.8 billion of net cash used to purchase OBS. In addition, source of cash for investing activities 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. Net cash used for investing activities during 2005 was \$454 million, primarily related to \$478 million of capital expenditures and the purchase of intangible assets of \$51 million, partially offset by proceeds from sales of property and equipment of \$43 million and the net reduction in short-term investments of \$33 million.

*Financing Activities*

Net cash provided by financing activities was \$10.1 billion for 2007, compared to cash used of \$1.4 billion for the same period in 2006. Net cash provided by financing activities in 2007 included net proceeds on the issuance of common and mandatory convertible 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 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 and 2005 was \$1.4 billion and \$633 million, respectively. Uses of cash for financing activities in 2006 and 2005 include the payment of dividends on common and preferred shares of \$412 million and \$410 million, respectively; the repayment of \$1.0 billion of bank debt and short-term commercial paper borrowings in 2006; and \$1.2 billion of short-term commercial paper borrowings in 2005. Uses of cash for financing activities in 2005 was partially offset by proceeds of \$900 million from bank debt incurred by a foreign subsidiary related to funding of a portion of the repatriations under the AJCA during 2005. This bank debt was fully repaid in 2006.

