

SCHERING PLOUGH CORP

Form 8-K

October 22, 2007

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 8-K
CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 22, 2007

SCHERING PLOUGH CORPORATION

(Exact Name of Registrant as Specified in its Charter)

New Jersey
(State or Other Jurisdiction of
Incorporation)

1-6571
(Commission File Number)

22-1918501
(IRS Employer
Identification Number)

2000 Galloping Hill Road
Kenilworth, NJ 07033
(Address of Principal Executive Office)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION.

Schering-Plough today issued a press release titled "Schering-Plough Reports Financial Results for Third Quarter of 2007" and provided additional supplemental financial data. The press release is furnished as Exhibit 99.1 to this 8-K. The supplemental financial data is furnished as Exhibit 99.2 to this 8-K.

ITEM 8.01 OTHER EVENTS

Risk Factors

Below are updated risk factors relating to Schering-Plough and its business. Schering-Plough's future operating results and cash flows may differ materially from the actual results 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 8-K, including each exhibit, the comments of Schering-Plough officers during the earnings teleconference/webcast on October 22, 2007, beginning at 8 a.m. (EDT), and other written reports and oral statements made from time to time by Schering-Plough.

Key Schering-Plough products generate a significant amount of Schering-Plough's profits and cash flows, and any events that adversely affect the market 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 is largely dependent 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 affect 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, 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 the introduction of multiple generic forms in December 2006 of two competing cholesterol products that lost patent protection earlier in 2006. In addition, on October 4, 2007, the FDA announced a public meeting to solicit comment on making certain prescription drugs available behind-the-counter without a prescription. Although the FDA did not indicate what drugs might be included in 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 as generic statins, 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 development and marketing of new products, and uncertainties in the regulatory and approval process may result in the failure of products to reach the market.

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. Upon the expiration or the successful challenge of Schering-Plough's patents covering a product, competitors may introduce lower-priced generic versions of that product, which may include Schering-Plough's well-established products. 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). Such generic competition could result in the loss of a significant portion of sales or downward pressures on the prices at which Schering-Plough offers formerly patented products, particularly in the U.S. Patents and patent applications relating to Schering-Plough's significant products are of material importance to Schering-Plough.

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., as well as the discussion of 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 loss of market exclusivity and render such patents invalid. An adverse result in a patent dispute involving patents held by a third party may preclude the commercialization of Schering-Plough's products, force Schering-Plough to

obtain licenses in order to continue manufacturing or marketing the affected products, which licenses may not be available on commercially reasonable terms, negatively affect sales of existing products or result in injunctive relief and payment of financial remedies.

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. 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 or not infringed. 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. 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. 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 Part II, Item 1, Legal Proceedings in Schering-Plough's second quarter 10-Q, 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 is resulting 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 that could affect Schering-Plough's business include legislative or regulatory action relating to pharmaceutical pricing and reimbursement, health care reform initiatives and drug importation legislation, involuntary approval of medicines for OTC use, consolidation among customers and trends toward managed care and health care costs containment. Increasingly, market approval or reimbursement of products may be impacted by health technology assessments, which seek to condition approval or reimbursement on an assessment of the impact of health technologies on the healthcare system.

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.

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 who may penalize doctors who prescribe outside approved formularies which may not include branded products when a generic is available; and pharmacists who receive a higher profit when they dispense a generic drug over a branded drug. These issues are more pressing because 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 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.

Regardless of the merits or outcomes of any investigations, 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 in Schering-Plough's 2006 10-K and Part II, Item 1 in Schering-Plough's second quarter 10-Q for descriptions of significant pending litigation.

Schering-Plough is subject to governmental regulations, and the failure to comply with, as well as the costs of compliance of, 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.

For example, in May 2002, Schering-Plough agreed with the FDA to the entry of a Consent Decree to resolve issues related to compliance with current Good Manufacturing Practices at certain of Schering-Plough's facilities in New Jersey and Puerto Rico. The Consent Decree work placed significant additional controls on production and release of products from these sites, which increased costs and slowed production and led to a reduction in the number of products produced at the sites. Further, Schering-Plough's research and development operations were negatively impacted by the Consent Decree because these operations share common facilities with the manufacturing operations.

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

Developments following regulatory approval may decrease demand for 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, 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 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.

Schering-Plough operates in more than 120 countries, and the majority of Schering-Plough's profit and cash flow is generated from international operations. Acquisitions, such as the recently announced purchase of Organon BioSciences, would further expand 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.

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. Schering-Plough has entered into two foreign currency options to partially mitigate the currency exchange rate risk on the Euro purchase price of the Organon BioSciences acquisition. 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 1997-2006 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.

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.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits

99.1 Press release dated October 22, 2007 titled Schering-Plough Reports Financial Results for Third Quarter of 2007

99.2 Supplemental Financial Data

SIGNATURES

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

Schering-Plough Corporation

By: /s/ Steven H. Koehler
Steven H. Koehler
Vice President and Controller
Date: October 22, 2007

Exhibit Index

Exhibit Number	Description
99.1	Press release dated October 22, 2007 titled Schering-Plough Reports Financial Results for Third Quarter of 2007
99.2	Supplemental Financial Data