

SCHERING PLOUGH CORP

Form 8-K

July 21, 2005

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**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): July 21, 2005

**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

ITEM 8.01 OTHER EVENTS.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

SIGNATURE(S)

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EX-99.1: PRESS RELEASE

EX-99.2: SUPPLEMENTAL FINANCIAL DATA

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Many factors could cause actual results to differ from Schering-Plough's forward-looking statements. These factors include inaccurate assumptions and a broad variety of other risks and uncertainties, including some that are known and some that are not. Although it is not possible to predict or identify all such factors, they may include the following:

A significant portion of net sales are made to major pharmaceutical and health care products distributors and major retail claims 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 buying decisions or other factors.

Competitive factors, including technological advances attained by competitors, patents granted to competitors, new products of competitors coming to the market, new indications for competitive products, combined competitive products, and new and existing generic, prescription and/or OTC products that compete with products of Schering-Plough or the Merck/Schering-Plough Cholesterol Partnership, such as competition from OTC statins like the one approved for use in the U.K., or the introduction of generic forms of existing well established cholesterol products. The eventual impact of these situations on the cholesterol reduction market cannot be reasonably predicted.

Increased pricing pressure both in the U.S. and abroad from managed care organizations, institutions and government agencies and programs. In the U.S., among other developments, consolidation among customers may increase pricing pressures and may result in various customers having greater influence over prescription decisions through formulary decisions and other policies.

The potential impact of the Medicare Prescription Drug, Improvement and Modernization Act of 2003; possible other U.S. legislation or regulatory action affecting, among other things, pharmaceutical pricing and reimbursement, including Medicaid and Medicare; involuntary approval of prescription medicines for over-the-counter use; and other health care reform initiatives and drug importation legislation. Legislation or regulations in markets outside the U.S. affecting product pricing, reimbursement or access. Laws and regulations relating to trade, antitrust, monetary and fiscal policies, taxes, price controls and possible nationalization.

Patent positions can be highly uncertain and patent disputes are not unusual. An adverse result in a patent dispute can preclude commercialization of products or negatively impact sales of existing products or result in injunctive relief and payment of financial remedies. Certain foreign governments have indicated that compulsory licenses to patents may be granted in the case of national emergencies.

Uncertainties in the regulatory and approval process in the U.S. and other countries, including delays in the approval of new products and new indications and uncertainties in the FDA approval process; and uncertainties concerning regulatory decisions regarding labeling and other matters.

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Failure to meet current Good Manufacturing Practices established by the FDA and other governmental authorities can result in delays in the approval of products, release of products, seizure or recall of products, suspension or revocation of the authority necessary for the production and sale of products, fines and other civil or criminal sanctions. The resolution of manufacturing issues with the FDA discussed in Schering-Plough's 10-Ks, 10-Qs and 8-Ks are subject to substantial risks and uncertainties. These risks and uncertainties, including the timing, scope and duration of a resolution of the manufacturing issues, will depend on the ability of Schering-Plough to assure the FDA of the quality and reliability of its manufacturing systems and controls, and the extent of remedial and prospective obligations undertaken by Schering-Plough.

Pharmaceutical product development is highly uncertain. Products that appear promising in development may fail to reach market for numerous reasons. They may be found to be ineffective or to have harmful side effects in clinical or pre-clinical testing, they may fail to receive the necessary regulatory approvals, they may turn out not to be economically feasible because of manufacturing costs or other factors or they may be precluded from commercialization by the proprietary rights of others.

Once a product is approved and marketed, clinical trials of marketed products or post-marketing surveillance may raise efficacy or safety concerns. Whether or not scientifically justified, this new information could lead to recalls, withdrawals or adverse labeling of marketed products, which may negatively impact sales. Concerns of prescribers or patients relating to the safety or efficacy of Schering-Plough products, or other companies' products or pharmaceutical products generally, may also negatively impact sales.

Major products such as CLARITIN, CLARINEX, INTRON A, PEG-INTRON, REBETOL Capsules, REMICADE, TEMODAR and NASONEX accounted for a material portion of Schering-Plough's 2004 revenues. If any major product were to become subject to a problem such as loss of patent protection, OTC availability of the Company's product or a competitive product (as has been disclosed for CLARITIN and its current and potential OTC competition), previously unknown side effects; if a new, more effective treatment should be introduced; generic availability of competitive products; or if the product is discontinued for any reason, the impact on revenues could be significant. Also, such information about important new products, such as ZETIA and VYTORIN, or important products in our pipeline, may impact future revenues. Further, sales of VYTORIN may negatively impact sales of ZETIA.

Unfavorable outcomes of government (local and federal, domestic and international) investigations, litigation about product pricing, product liability claims, other litigation and environmental concerns could preclude commercialization of products, negatively affect the profitability of existing products, materially and adversely impact Schering-Plough's financial condition and results of operations, or contain conditions that impact business operations, such as exclusion from government reimbursement programs.

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Economic factors over which Schering-Plough has no control, including changes in inflation, interest rates and foreign currency exchange rates.

Instability, disruption or destruction in a significant geographic region due to the location of manufacturing facilities, distribution facilities or customers 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.

Changes in tax laws including changes related to taxation of foreign earnings.

Changes in accounting and auditing standards promulgated by the American Institute of Certified Public Accountants, the Financial Accounting Standards Board, the SEC, or the Public Company Accounting Oversight Board that would require a significant change to Schering-Plough's accounting practices.

For further details and a discussion of these and other risks and uncertainties, see Schering-Plough's past and future SEC reports and filings.

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ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

The following exhibits are furnished pursuant to Item 2.02:

99.1 Press release dated July 21, 2005 titled Schering-Plough Reports Financial Results for 2005 Second Quarter (furnished pursuant to Item 2.02)

99.2 Supplemental Financial Data (furnished pursuant to Item 2.02)

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SIGNATURE(S)

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/ Douglas J. Gingerella  
Douglas J. Gingerella  
Vice President and Controller

Date: July 21, 2005

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