

SCHERING PLOUGH CORP

Form 8-K

October 24, 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): October 24, 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.**

Schering-Plough today issued a press release titled "Schering-Plough Reports 2005 Third Quarter Financial Results" 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.**

**Disclosure Notice for Forward Looking Statements**

This 8-K, including each exhibit, the comments of Schering-Plough officers during our earnings teleconference / webcast on October 24, 2005 at 8:00 am (EDT) and other written reports and oral statements made from time to time by the company may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements do not relate strictly to historical or current facts and are based on current expectations or forecasts of future events. You can identify these forward-looking statements by their use of words such as anticipate, believe, could, estimate, expect, forecast, project, intend, plan, potential, similar words and terms. In particular, forward-looking statements include statements relating to future actions, ability to access the capital markets, prospective products or product approvals, future performance or results of current and anticipated products, sales efforts, development programs, estimates of rebates, discounts and returns, expenses and programs to reduce expenses, the cost of and savings from reductions in work force, the outcome of contingencies such as litigation and investigations, growth strategy and financial results.

Any or all forward-looking statements here or in other publications may turn out to be wrong. There are no guarantees about Schering-Plough's financial and operational performance or the performance of Schering-Plough's stock. Schering-Plough does not assume the obligation to update any forward-looking statement. Many factors could cause actual results to differ 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:

**Cholesterol Franchise** The ability of Schering-Plough to generate profits and significant operating cash flow is directly and predominantly dependent upon the increasing profitability of Schering-Plough's cholesterol franchise. As existing products lose patent protection, generic forms of some of the existing well-established cholesterol management products may be introduced. The Company cannot predict reasonably what effect the introduction of generic forms of cholesterol management products may have on VYTORIN and ZETIA.

**Other Major Products** 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. The impact on revenue could be

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significant if any major product was to become subject to a problem such as the loss of its patent protection, OTC availability of Schering-Plough's product or a competitive product (as has been disclosed for CLARITIN and its current and potential OTC competition) or the discovery of previously unknown side effects; there is increased competition with the introduction of new, more effective treatment or the generic availability of competitive products; or the product is discontinued for any reason.

**Uncertain Pharmaceutical Product Development** 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.

**Uncertain Regulatory and Approval Process** There are 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.

**Post-Market Development** 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's products, or other companies' products or pharmaceutical products generally, may also negatively impact sales.

**Limited Opportunities for Obtaining or Licensing Critical Late-stage Products** It may be challenging for Schering-Plough to acquire or license critical late-stage products because it competes for these opportunities against companies often with far greater financial resources than Schering-Plough.

**Competitive Factors** Competitive developments that impact Schering-Plough include technological advances by, patents granted to, and new products developed by competitors and new and existing generic, prescription and/or OTC products that compete with products of Schering-Plough or the Merck/Schering-Plough Cholesterol Partnership.

**Pricing Pressure** Schering-Plough faces increased pricing pressure in the U.S. and abroad from managed care organizations, institutions and government agencies and programs. In the U.S., consolidation among customers and trends toward managed care and health care costs containment may increase pricing pressures.

**Government Action** U.S. legislative and regulatory action that may impact Schering-Plough include the Medicare Prescription Drug, Improvement and Modernization Act of 2003; possible other legislation or regulatory action affecting, among other things, pharmaceutical pricing and reimbursement, including Medicaid and Medicare; involuntary approval of prescription medicines for OTC use; and other health care reform initiatives and drug importation legislation. Legislation or regulations in markets outside the U.S. that may impact the company include those involving product pricing, reimbursement or access.

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**Legal Proceedings** If there are unfavorable outcomes in government (local and federal, domestic and international) investigations, litigation about product pricing, product liability claims, patent and intellectual property disputes, antitrust matters, other litigation and environmental concerns, this 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.

**Consent Decree** 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.

**Patents** 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.

**Tax Laws** Schering-Plough may be impacted by changes in tax laws, including tax rate changes, new tax laws and revised tax law interpretations in domestic and foreign jurisdictions.

**Fluctuations in Buying Patterns** Net sales and quarterly growth comparisons may be affected by fluctuations in the buying patterns of major distributors, retail chains and other trade buyers, which may result from seasonality, pricing, wholesaler buying decisions or other factors.

**Changes in Accounting and Auditing Standards** Schering-Plough may be affected by accounting and audited 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.

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

**Changes in Business and Political Positions** 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. Additionally, Schering-Plough relies on third party relationships for its key products. Any time that third parties are involved, there may be

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changes to the third parties that are outside the control of Schering-Plough that may impact Schering-Plough's business position.

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 with this 8-K:

99.1 Press release dated October 24, 2005 titled Schering-Plough Reports 2005 Third Quarter Financial Results (furnished pursuant to Item 2.02)

99.2 Supplemental Financial Data (furnished pursuant to Item 2.02)

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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/ Douglas J. Gingerella

Douglas J. Gingerella  
Vice President and Controller

Date: October 24, 2005

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