

SCHERING PLOUGH CORP

Form 8-K

January 30, 2006

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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): January 30, 2006**

**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)
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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 2005 Fourth Quarter, Full Year" 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 January 30, 2006 at 8:00 am (EDT), and other written reports and oral statements made from time to time by Schering-Plough (the Company) may contain forward-looking statements within the meaning of the 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, potential, will, and other similar words and terms. In particular, forward-looking statements include statements relating to future actions, 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 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 the Company's financial and operational performance or the performance of the Company's stock. The Company does not assume the obligation to update any forward-looking statement. Many factors could cause actual results to differ from the Company'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:

**Dependence on Key Products** The Company's ability to generate profits and significant operating cash flow is dependent upon the increasing profitability of the Company's cholesterol franchise. In addition, products such as CLARINEX, PEG-INTRON, REBETOL, REMICADE, TEMODAR and NASONEX accounted for a material portion of the Company's 2005 revenues. As a result of the Company's dependence on key products, any events that adversely impact the markets for these products could have a significant impact on revenues. These events include loss of patent protection, OTC availability of the Company's product or a competitive product, the discovery of previously unknown side effects, increased competition from the introduction of a new, more effective treatment, and discontinuation of the product for any reason. The profitability of the Company's cholesterol franchise may be adversely impacted by the introduction of generic forms of two competing cholesterol products that will go off patent in 2006.

**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

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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, the re-review of products which are already marketed, uncertainties concerning safety labeling changes, and greater scrutiny on advertising and promotion.

**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 the Company'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 the Company to acquire or license critical late-stage products because it competes for these opportunities against companies often with far greater financial resources than the Company.

**Competitive Factors** Competitive developments that impact the Company 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** The Company faces increased pricing pressure in the U.S. and abroad from managed care organizations, institutions and government agencies and programs. In the U.S., increased pricing pressure could result from legislative or regulatory action relating to pharmaceutical pricing and reimbursement, including health care reform initiatives and drug importation legislation, consolidation among customers, and trends toward managed care and health care costs containment. In the international 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 impact the company.

**Regulatory Compliance** Regulatory compliance, and the cost of compliance failures, can materially impact the Company's financial position 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

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recalls of drugs, suspension or revocation of the authority necessary for the production and sale of drugs, fines and other civil or criminal sanctions. While the Company has completed the action steps under the FDA consent decree, the Company remains subject to its provisions until it is lifted by the FDA, which will depend on the ability of the Company 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 the Company.

**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.

**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** The Company 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** The Company 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 the Company'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 the Company's business and political position if there is instability, disruption or destruction in a significant geographic region regardless of cause, including war,

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terrorism, riot, civil insurrection or social unrest; and natural or man-made disasters, including famine, flood, fire, earthquake, storm or disease. Additionally, the Company relies on third party relationships for its key products. Any time that third parties are involved, there may be changes to the third parties that are outside the control of the Company that may impact the Company's business position.

For further details and a discussion of these and other risks and uncertainties, see Schering-Plough's past and future SEC 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 January 30, 2006 titled Schering-Plough Reports Financial Results for 2005 Fourth Quarter, Full Year (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: January 30, 2006

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The following exhibits are furnished with this 8-K:

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99.2 Supplemental Financial Data (furnished pursuant to Item 2.02)