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SCHERING PLOUGH CORP

Form 8-K

October 21, 2004

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

OCTOBER 21, 2004  
Date of Report (Date of Earliest Event Reported)

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 offices, including Zip Code)

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

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))

ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION.

Schering-Plough today issued a press release titled "Schering-Plough Reports Financial Results for 2004 Third Quarter" and provided additional supplemental financial data. The press release is attached to this 8-K as Exhibit 99.1. The supplemental financial data is attached to this 8-K as Exhibit 99.2.

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### ITEM 7.01 REGULATION FD DISCLOSURE.

Schering-Plough issued a press release titled "Schering-Plough Reports Financial Results for 2004 Third Quarter" on October 21, 2004, and the press release is attached to this 8-K as Exhibit 99.1. Schering-Plough also issued related supplemental data, which is attached to this 8-K as Exhibit 99.2.

#### Disclosure Notice for Forward Looking Statements

#### Cautionary Factors That May Affect Future Results (Cautionary Statements Under the Private Securities Litigation Reform Act of 1995)

This 8-K, including each exhibit, the comments of Schering-Plough officers during our earnings teleconference/webcast on October 21, 2004 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 Securities Litigation Reform Act of 1995. Forward-looking statements relate to expectations or forecasts of future events. They use words such as "anticipate," "believe," "could," "estimate," "expect," "forecast," "project," "intend," "plan," "potential," "will," and other words and terms of similar meaning in connection with a discussion of potential future events, circumstances or future operating or financial performance. You can also identify forward-looking statements by the fact that they do not relate strictly to historical or current facts.

In particular, forward-looking statements include statements relating to future actions, ability to access the capital markets, prospective products, the status of product approvals, future performance or results of current and anticipated products, sales efforts, development programs, 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. Actual results may vary materially, and there are no guarantees about Schering-Plough's financial and operational performance or the performance of Schering-Plough 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:

- A significant portion of net sales are made to major pharmaceutical and health care products distributors and major retail chains in the United States. 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, and generic, prescription and/or OTC products that compete with products of Schering-Plough or the Merck/Schering-Plough Pharmaceuticals joint venture (such as competition from OTC statins, like the one approved for use in the U.K. for which impact in the cholesterol reduction market is not yet

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known).

- Increased pricing pressure both in the United States and abroad from managed care organizations, institutions and government agencies and programs. In the United States, 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.
- Uncertainties of the FDA approval process and the regulatory approval and review processes in other countries, including, without limitation, delays in approval of new products.
- Failure to meet 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.
- Difficulties in product development. 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.
- Efficacy or safety concerns with respect to marketed products, whether or not scientifically justified, leading to recalls, withdrawals or declining sales.
- Major products such as CLARITIN, CLARINEX, INTRON A, PEG-INTRON, REBETOL Capsules, REMICADE and NASONEX accounted for a material portion of Schering-Plough's 2003 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

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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, the launch 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.
- 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 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.

### ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

The following exhibits are filed with this 8-K:

- 99.1 Press release titled "Schering-Plough Reports Financial Results for 2004 Third Quarter"
- 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/ Douglas J. Gingerella

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Douglas J. Gingerella  
Vice President and Controller

Date: October 21, 2004

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### Exhibit Index

The following exhibits are filed with this 8-K:

- 99.1 Press release titled "Schering-Plough Reports Financial Results for 2004 Third Quarter"
- 99.2 Supplemental Financial Data