

SCHERING PLOUGH CORP
Form 8-K
October 22, 2003

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 22, 2003

Date of Report (Date of Earliest Event Reported)

Schering-Plough Corporation

(Exact name of registrant as specified in its charter)

New Jersey

1-6571

22-1918501

(State or other jurisdiction
of incorporation)

(Commission File Number)

(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)

Item 5. Other Events and Regulation FD Disclosure

2003 Third Quarter Earnings Press Release

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Schering-Plough issued a press release titled "Schering-Plough Reports Financial Results for 2003 Third Quarter" on October 22, 2003, 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.

The press release contains many important facts that investors may wish to consider, together with information in Schering-Plough's 2002 10-K, 2003 first and second quarter 10-Qs and 8-Ks filed during 2003. These facts include financial results for the 2003 third quarter, performance of certain key products, the status of the previously announced Action Agenda and Value Enhancement Initiative, an increase in the litigation reserves, a change in the estimated 2003 annual effective tax rate, and information about how to dial-in to, or access the Webcast of, the 2003 third quarter earnings conference call scheduled for October 22, 2003 at 8:30 am.

Earnings Outlook Remains Unchanged

In the August 21, 2003 press release titled "Schering-Plough CEO Fred Hassan Completes First 100 Days, '360 Degree Review'" and in our October 9, 2003, Investor Frequently Asked Questions (FAQs), we provided an earnings outlook for the second half of 2003 and 2004. We said that, due to the downward slopes in sales and market share of key profit-generating products, earnings per share (EPS) in the second half of 2003 are likely to be lower than the level registered in the first half of 2003, and, also, EPS in 2004 are likely to be lower than the EPS level for 2003. (All comparisons exclude any possible charges for unusual items.)

Schering-Plough reiterates that earnings outlook today. Also, as mentioned in the October 9 FAQs, Schering-Plough does not expect to issue revised earnings guidance during 2003, and Schering-Plough continues to believe investors should consider Schering-Plough's prospects after its product portfolio transition, which should become increasingly evident beginning in 2005.

Sales and market share of key products, including those in the allergy and hepatitis C markets, and some information about the future product portfolio, such as the ZETIA/simvastatin combination, are discussed in the press release.

Disclosure Notice

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 conference October 22, 2003 at 8:30 am, and other written and oral statements made from time to time by Schering-Plough 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, prospective products, the status of product approvals, future performance or results of current and anticipated products, sales efforts, development programs, expenses and our programs to reduce expenses, the number of employees accepting Schering-Plough's planned voluntary early retirement program and the cost of and savings from that program, the outcome of contingencies such as litigation and investigations, growth strategy and financial results.

Any or all of our forward-looking statements here or in other publications may turn out to be wrong. Our actual results may vary materially, and there are no guarantees about the performance of Schering-Plough stock. Schering-Plough does not assume the obligation to update any forward-looking statement.

You should carefully consider any forward-looking statement and should understand that 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 or generic prescription or OTC competition as Schering-Plough's products mature and patents expire on products.
- 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.
- Government laws and regulations (and changes in laws and regulations) affecting domestic and international operations including healthcare reform initiatives and Medicare drug benefit and drug importation legislation in the United States at the state and federal level and in other countries, as well as 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.

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- 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 and NASONEX accounted for a material portion of Schering-Plough's 2002 revenues. If any major product were to become subject to a problem such as loss of patent protection, OTC availability (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; or if the product is discontinued for any reason, the impact on revenues could be significant. Further such information about important new products, such as ZETIA, or important products in our pipeline, may impact future revenues.
- Unfavorable outcomes of government 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 geographic region important to us - due to the location of our 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 such as SARS.
- 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 or the Securities and Exchange Commission, 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 Securities and Exchange Commission filings.

Item 7. Financial Statements and Exhibits

(c) Exhibits. The following exhibits are filed with this 8-K:

99.1 Press release titled "Schering-Plough Reports Financial Results for 2003 Third Quarter"

99.2 Supplemental Financial Data

Item 12.

Results of Operations and Financial Condition

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Schering-Plough today issued a press release titled "Schering-Plough Reports Financial Results for 2003 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.

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/Thomas H. Kelly

Thomas H. Kelly

Vice President and Controller

Date: October 22, 2003

Exhibit Index

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