SCHERING PLOUGH CORP
Form 8-K
February 25, 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

February 25, 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

Schering-Plough today issued a press release titled "Schering-Plough Increases Litigation Reserves." The press release is attached to this 8-K as Exhibit 99.1.

Management reviews the status of pending litigation and investigation matters on an on-going basis and from time to time may settle or otherwise resolve them on such terms and conditions as management believes are in the best interests of the Company. The Company is aware that settlements of matters of the types set forth below frequently involve fines and/or penalties that are material to the financial condition and the results of operations of the entity entering into the settlement. There are no assurances that the Company will prevail in any of these matters, that settlements can be reached on acceptable terms or in amounts that do not exceed the amounts reserved, and outcomes cannot be predicted.

The press release dated February 25, 2003, filed with this 8-K relates to the following matters:

In October 1999, the Company received a subpoena from the U.S. Attorney's Office for the Eastern District of Pennsylvania, pursuant to the Health Insurance Portability and Accountability Act of 1996, concerning the Company's contracts with pharmacy benefit managers (PBMs) and managed care organizations to provide disease management services in connection with the marketing of its pharmaceutical products. It appears that the subpoena was one of a number addressed to industry participants as part of an inquiry into, among other things, pharmaceutical marketing practices. The government's inquiry has focused on, among other things, whether the Company's disease management and other marketing programs and arrangements comply with federal health care laws and whether the value of its disease management programs and other marketing programs and arrangements should have been included in the calculation of rebates to the government. The Company has been cooperating with the investigation.

In March 2002, the U.S. Attorney's Office began issuing grand jury subpoenas. The grand jury investigation appears to be focused on one or more transactions with managed care organizations where the government believes the Company offered or provided deeply discounted pharmaceutical products (known as "nominally priced" products which are generally excluded from Medicaid rebate calculations), free or discounted disease management services, and other marketing programs and arrangements that delivered value, in order to place or retain one or more of the Company's major pharmaceutical products on the managed care organization's formulary. The grand jury appears to be investigating, among other things, (i) whether the transactions described above and conduct relating thereto violated federal anti-kickback statutes; and (ii) whether the value of the items and services described above should have been included in the Company's calculation of Medicaid rebates. The outcome of the investigations could include the commencement of civil and/or criminal proceedings involving substantial fines, penalties and injunctive or administrative remedies, including exclusion from government reimbursement programs, and the Company cannot predict whether the investigations will affect its marketing practices or sales.

The Company is responding to an investigation by the U.S. Attorney's Office for the District of Massachusetts, regarding, inter alia, whether the average wholesale price (AWP) set by pharmaceutical companies for certain drugs improperly exceeds the average prices paid by dispensers and, as a consequence, results in unlawful inflation of certain government drug reimbursements that are based on AWP. The Company is cooperating with this investigation. The outcome of this investigation could include the imposition of substantial fines, penalties and injunctive or administrative remedies.

The U.S. Attorney's Office for the District of Massachusetts is also investigating whether the Company sales of a product that was repackaged for sale by a managed care organization should have been included in the Company Medicaid best price calculations. In early November 2002, the Company was served with two additional grand jury subpoenas by the U.S. Attorney for the District of Massachusetts. Among other information, the subpoenas seek a broad range of information concerning the Company sales, marketing and clinical trial practices and programs with respect to INTRON A, REBETRON and TEMODAR; the Company's sales and marketing contacts with managed care

organizations and doctors; and the Company's offering or provision of grants, honorariums or other items or services of value to managed care organizations, physician groups, doctors and educational institutions. The Company understands that this investigation is focused on whether certain sales, marketing and clinical trial practices and conduct related thereto, which in certain instances relate to the use of one or more of the above-mentioned products for indications for which FDA approval had not been obtained -- so-called "off-label" uses -- were in violation of federal laws and regulations with respect to off-label promotional activities. The investigation also appears to focus on whether drug samples, clinical trial grants and other items or services of value were given to providers to incentivize them to prescribe one or more of the above-mentioned products, including for "off-label" uses, in violation of the federal healthcare anti-kickback laws. The Company has implemented certain changes to its sales, marketing and clinical trial practices and is continuing to review those practices to ensure compliance with relevant laws and regulations. The Company is cooperating with these investigations. Future sales of INTRON A, REBETRON and TEMODAR may be adversely affected, but the Company cannot at this time predict the ultimate impact, if any, on such sales. The outcome of these investigations could include the commencement of civil and/or criminal proceedings involving the imposition of substantial fines, penalties and injunctive or administrative remedies, including exclusion from government reimbursement programs.

In February 2003, the Company increased its litigation reserves related to the investigations described above in this 8-K by $150 million. The increased litigation reserves reflects an adjustment to the Company's estimate of its minimum liability relating to those investigations, in compliance with generally accepted accounting principles (GAAP). Under GAAP, companies are required to estimate and recognize a minimum liability when a loss is probable but no better estimate of the loss can be made. Also, under GAAP, the Company is required to recognize this liability in its 2002 results. The Company notes that its total reserves reflect an estimate and that any final settlement or adjudication of any of these matters could possibly be less than or could materially exceed the aggregate liability accrued by the Company and could have a materially adverse effect on the operations or financial condition of the Company. This adjustment is consistent with the Company's policy of reviewing regularly the status of pending actions and investigations and making adjustments as appropriate.

Disclosure Notice: The adjustment of the Company's litigation reserves is based on the Company's current understanding of the investigations and its estimate of possible outcomes, which may change from time to time. Any settlement or adjudication of these investigations could include the commencement of civil and/or criminal proceedings involving the imposition of substantial fines materially in excess of the amounts accrued, penalties and injunctive or administrative remedies resulting from exclusion from government reimbursement programs, and furthermore that such resolution of these matters, individually or in the aggregate, could have a material adverse effect on the Company's results of operations or financial condition. For further details and a discussion of these and other risks and uncertainties, also see the Company's 2001 Annual Report on Form 10-K and subsequent quarterly reports on Form 10-Q and current reports on Form 8-K.

Item 7. Financial Statements and Exhibits

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

99.1 Press Release Dated February 25, 2003, Titled "Schering-Plough Increases Litigation Reserves."

99.2 Product Sales Data

Item 9. Regulation FD Disclosure

Schering-Plough today issued updated product sales data. It 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: February 25, 2003

Exhibit Index

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