SCIOS INC
Form 8-K
May 29, 2001
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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): May 25, 2001 SCIOS, INC.

(Exact Name of Registrant as Specified in Charter) Delaware__ 0-11749 95-3701481 ---------- ---------- ---------- (State or Other Jurisdiction of (Commission File Number) (I.R.S. Employer Identification No.) Incorporation) 820 West Maude Avenue, Sunnyvale, CA 94086 ---------- (Address of Principal Executive Offices) (Zip Code) (408) 616-8200_ ---------- (Registrant's telephone number, including area code) N/A ---------- (Former Name or Former Address, if Changed Since Last Report)

Item 5. Other Events.

On May 25, 2001, Scios, Inc. announced that the Cardiovascular and Renal Drugs Advisory Committee to the U.S. Food and Drug Administration unanimously recommended approval of Natrecor® (nesiritide) for the treatment of acute congestive heart failure. For additional information, refer to the press release attached as an exhibit to this Current Report on Form 8-K. The contents of the press release are incorporated by reference herein.

Item 7. Financial Statements, Pro Forma Financial Information and Exhibits. (c) Exhibits The following exhibits are filed as part of this Report: No. Exhibit --- ------- 99.1 Press Release dated May 25, 2001

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.

SCIOS, INC. By: /s/ John H. Newman____ ---------- John H. Newman Senior Vice President, General Counsel and Secretary Date: May 29, 2001

EXHIBIT INDEX

No. Exhibit --- ------- 99.1 Press Release dated May 25, 2001 Exhibit 99.1 ---------- Contact: -------- Wendy Carhart, Scios Inc. (408) 616 8325 Jim Weiss, Weisscomm (415) 203 0328 Michelle Choi, Edelman Public Relations (212) 704 4580 SCIOS ANNOUNCES FDA ADVISORY COMMITTEE UNANIMOUSLY RECOMMENDS APPROVAL OF NATRECOR FOR ACUTE CONGESTIVE HEART FAILURE Drug Could Become First New Acute CHF Treatment in Over a Decade

SUNNYVALE, CA, May 25, 2001 Scios Inc. (Nasdaq: SCIO) announced today that the Cardiovascular and Renal Drugs Advisory Committee to the U.S. Food and Drug Administration (FDA) unanimously recommended approval of Natrecor® (nesiritide) for the treatment of acute

congestive heart failure (CHF) by a vote of 10-0.

If approved by the FDA, Natrecor would be the first new treatment for acute CHF in more than a decade. Natrecor is a recombinant form of B-type natriuretic peptide (BNP), a naturally occurring hormone in the body that aids healthy functioning of the heart. BNP causes arteries and veins to dilate, alleviating symptoms by improving blood movement around the heart without a change in heart rate. Natrecor is administered intravenously in a standard fixed dose regimen, and typically does not require titration (i.e., dose adjustments). Approximately five million Americans suffer from congestive heart failure, and there are approximately one million hospitalizations each year in the United States due to acute CHF.

Natrecor is now one step closer to approval and helping physicians manage acute CHF patients, which are growing in number every year, said Darlene P. Horton, M.D., Scios Vice President of Medical Affairs. We commend the clinical investigators and their teams at leading medical centers around the country who made it possible to expedite high-quality clinical trials evaluating Natrecor. We are very proud of this dedicated development effort.

Based on the outcome of clinical trials involving nearly 1,000 patients treated with Natrecor, Scios submitted an amendment to the New Drug Application (NDA) for Natrecor to the FDA in early 2001. The original NDA was filed with the FDA in April 1998. The FDA subsequently requested additional data on Natrecor, which was included in the amended application filed in January of 2001. Despite a positive Advisory Committee recommendation, the FDA s final decision may differ. We expect the FDA to make its decision in July 2001.

In anticipation of final FDA approval of Natrecor, Scios entered into a commercialization and marketing agreement for Natrecor in the United States with Innovex, the commercialization unit of Quintiles Transnational Corp. (NASDAQ: QTRN).

We are building a 180-person strong sales and marketing force that we believe will be the largest and the most focused in the U.S. acute CHF market, said Richard B. Brewer, Scios President and Chief Executive Officer. We have hired two area business directors who will coordinate and lead the field sales effort with the 18 business managers who will support the sales force. We will be ready to launch the product at the end of July if Natrecor is approved by the FDA.

Clinical Trial Results

Presenters at today s advisory committee meeting reviewed results of several clinical trials, including the pivotal 498-patient VMAC (Vasodilation in the Management of Acute Congestive heart failure) trial. The data demonstrated Natrecor s ability to rapidly improve blood circulation and reduce pulmonary capillary wedge pressure (PCWP), a measure of the pulmonary congestion resulting from acute CHF, in as little as 15 minutes. This effect was sustained for at least 48 hours. Natrecor has also been shown to rapidly alleviate patient symptoms, such as shortness of breath and fatigue. The most common side effects have been headache, reversible hypotension, and abdominal pain.

In addition to Dr. Horton, data was also presented to the Advisory Committee by James B. Young, M.D., Head, Section of Heart Failure and Cardiac Transplant Medicine and Medical Director of the Kaufman Center for Heart Failure at the Cleveland Clinic Foundation, and William Abraham, M.D., Chief, Division of Cardiovascular Medicine and Director, Section of Heart Failure and Cardiac Transplantation, University of Kentucky College of Medicine.

Congestive Heart Failure An Epidemic

A potentially life-threatening disorder that has no cure, heart failure is a chronic pathophysiologic condition in which the heart functions inefficiently and circulation is reduced to the body s organs. In congestive heart failure, fluid accumulates in the tissues, including lung tissue, causing such symptoms as difficulty breathing, swelling of the hands and feet, difficulty sleeping, dry cough, fatigue and rapid weight gain. CHF may result from an acute event (e.g., heart attack) or may develop gradually over time.

During an acute episode of CHF, the heart s inability to adequately circulate blood throughout the body worsens beyond its already compromised state, causing symptoms to become so pronounced that hospital treatment is required to stabilize the patient s condition. A sudden increase in dietary sodium (salt), failure to take chronic oral medications for managing CHF, or the development of a new heart arrhythmia can precipitate an acute attack.

I. CONFERENCE CALL DETAILS

Scios will host a conference call and webcast this afternoon to discuss the results of the meeting at 6:00 p.m. (EDT). The webcast will be available on Scios Web site at www.sciosinc.com. The conference call dial-in will be (800) 314-7867. A replay of both the conference call and webcast will be available through June 1, 2001. The replay dial-in number will be (888) 203-1112, confirmation code 593777.

Scios Inc.

Scios is a biopharmaceutical company developing novel treatments for heart failure and rheumatoid arthritis. The company s disease-based technology platform integrates expertise in protein biology with computational and medicinal chemistry to identify novel targets and rationally design small-molecule compounds to treat cardiovascular and inflammatory diseases, for large markets with unmet medical needs. Additional information on Scios is available on its Web site located at www.sciosinc.com and in the company s various filings with the Securities and Exchange Commission (SEC).

The statements in this press release that are not historical facts are forward-looking statements that involve risks and uncertainties. These include uncertainties associated with anticipating the response of the FDA to the results of the VMAC trial, the timing of regulatory approval of Natrecor, and acceptance by the medical community of Natrecor as a new therapy for acute decompensated CHF, as well as other risks detailed from time to time in the reports filed by Scios with the SEC, including the company s annual report on form 10-K for the year ended December 31, 2000, and subsequent reports filed on form 10-Q for the quarter ended March 31, 2001.