

SCIOS INC
Form 8-K
July 13, 2001
6

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): July 10, 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 July 10, 2001, Scios Inc., announced that it has received a letter from the U.S. Food and Drug Administration stating that the Natrecor® (nesiritide) New Drug Application is approvable. 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 July 10th, 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: July 12th, 2001

EXHIBIT INDEX

No. Exhibit --- ----- 99.1 Press Release dated July 10th, 2001 Exhibit 99.1 ----- Contact: ----- David Gryska, Scios Inc. (408) 616-8325 (investors) Ed Bisno, Edelman Public Relations (212) 704-8212 (investors) Michelle Choi, Edelman Public Relations (212) 704-4580 (media) Scios Receives Natrecor Approvable Letter

SUNNYVALE, CA, July 10, 2001 Scios Inc. (Nasdaq: SCIO) announced today that it has received a letter from the U.S. Food and Drug Administration (FDA) stating that the Natrecor® (nesiritide) New Drug Application (NDA) is approvable. Scios has developed Natrecor as an intravenous treatment for patients with acutely decompensated congestive heart failure (CHF).

The approvable letter is the official communication from the FDA that the agency is prepared to approve the NDA following finalization of Natrecor labeling and completion of a pre-approval inspection. The FDA's Cardiovascular and Renal Drugs Advisory Committee unanimously recommended approval of Natrecor for the treatment of acute CHF on May 25, 2001.

Edgar Filing: SCIOS INC - Form 8-K

We are delighted to receive the approvable letter and are working closely with the FDA to complete the final steps to approval, said Richard B. Brewer, Scios president and chief executive officer. When approved by the FDA, Natrecor will become the first new treatment for acutely decompensated CHF in more than a decade. Natrecor is a recombinant form of B-type natriuretic peptide (BNP), and would become the first natriuretic peptide product available as a therapeutic in the United States. Human BNP is a naturally occurring hormone in the body that aids healthy functioning of the heart. Roughly five million Americans suffer from heart failure, with 550,000 new cases diagnosed each year. There are approximately one million hospitalizations each year in the United States due to acute CHF.

Conference Call

Scios executives will host a conference call and live audio webcast at 2:30 p.m. PDT (5:30 p.m. EDT) on Tuesday, July 10 to discuss Natrecor and its next steps to commercialization. To participate, please call (800) 474-8920 at least 5 minutes prior to start time. To access the live webcast, please log on to www.sciosinc.com approximately fifteen minutes prior to the call to register, download and install any necessary audio software. A replay of the live webcast will be made available on the Scios website shortly after the conclusion of the call through July 18, 2001. A replay of the telephonic conference call will be available by dialing (888) 203-1112, access code 713213. The telephone replay will be available through July 18, 2001. **Scios Inc.**

Scios is a biopharmaceutical company developing novel treatments for cardiovascular and inflammatory disease. 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 for large markets with unmet medical needs.

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 the timing of the final approval of Natrecor, 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 form 10-Q for the quarter ended March 31, 2001.