

SCIOS INC
Form DEFA14A
February 28, 2003

SCHEDULE 14A

(Rule 14a-101)

INFORMATION REQUIRED IN PROXY STATEMENT

SCHEDULE 14A INFORMATION

Proxy Statement Pursuant to Section 14(a) of the
Securities Exchange Act of 1934 (Amendment No.)

Filed by the Registrant

Filed by a Party other than the Registrant

Check the appropriate box:

Preliminary Proxy Statement

Confidential, for Use of the Commission Only
(as permitted by §14a-6(e)(2))

Definitive Proxy Statement

Definitive Additional Materials

Soliciting Material Under Rule 14a-12

SCIOS INC.

(Name of Registrant as Specified in Its Charter)

Edgar Filing: SCIOS INC - Form DEFA14A

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

Payment of Filing Fee (Check the appropriate box):

No Fee Required.

Fee computed on table below per Exchange Act Rules 14a-6(i) (4) and 0-11.

(1) Title of each class of securities to which transaction applies:

(2) Aggregate number of securities to which transaction applies:

(3) Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (set forth the amount on which the filing fee is calculated and state how it was determined):

(4) Proposed maximum aggregate value of transaction:

(5) Total fee paid:

Fee paid previously with preliminary materials:

Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by Registration Statement number, or the Form or Schedule and the date of its filing.

(1) Amount previously paid:

(2) Form, Schedule or Registration Statement No.:

(3) Filing party:

(4) Date filed:

The following is the transcript of a presentation by Richard B. Brewer, our President and Chief Executive Officer, at the BIO CEO & Investor Conference 2003 on February 26, 2003, and the text of one of the slides shown at the presentation.

TRANSCRIPT

MODERATOR:

Scios's CEO is Richard Brewer. He will be presenting of course on his company, located in the Sunnyvale California. Scios first generation oral p38 MAP kinase inhibitor, SCIO-469 continues to be evaluated, in a Phase IIa clinical trial in patients with rheumatoid arthritis. We thank you for coming Mr. Brewer, and we look forward to your presentation.

MR. RICHARD BREWER:

Good morning everybody. In spite of the recent news, I'm going to tell you about all the things that are going on at Scios, and before I do that, I'd like you to just take a second to look at our forward-looking statements, which now includes the language relevant to the Johnson & Johnson merger. And then we'll move on. First of all, because we're still in that period where Scios is still Scios, and we still have to move along with what we're doing, I want to talk you about our successes so far, and I think there are 3 that are primary here. First, with Natrecor, nesiritide, which we launched about 18 months ago. Net sales in our first year were 107 million, in 2002, which makes this probably second only to Reopro in the last 9 IV cardiovascular launches, and I'll show you some data on that in a histogram in just a second, but really it has been one of the most successful IV cardiovascular launches ever, and one of the reasons for that is because congestive heart failure is basically an epidemic in this country, and acute decompensated congestive heart failure is treated quite nicely with the combination of diuretics and Natrecor, or even Natrecor by itself, and as was just mentioned, we are deep into human clinical trials, with our p38 MAP kinase inhibitor program, which has a broad range of potential therapeutic applications, including rheumatoid arthritis. We have 2 products that are moving along right now, in the clinic, 469 as we call it is our first generation, and our second generation product, 323, is also in the clinic and moving along quite rapidly. And finally, the products that our research group just nominated for development, is our TGF beta inhibitor program, and we have a lead molecule that's been nominated and will be moving and actually has moved into the clinic, as of December of 2002.

Now, the fact that Natrecor has done well, allows us to grow our asset base as you might imagine, particularly with regard to the sales and marketing expertise that we have developed in the cardiovascular field. Right now, we have 170 representatives out there, calling on hospitals that account for about 85 percent of all patients, who come into hospitals with acutely decompensated CHF, so we're in the right places with the right people, and these are representatives who are quite experienced in the cardiovascular market, that have done the work for Scios. Our success with Natrecor also allows us to invest more heavily in research and development, to advance Natrecor to its full potential, and I'll be talking about that in just a second. We believe Natrecor has an exciting future outside of the hospital. We also can develop additional effective therapeutics, p38 kinase being one of them. The third opportunity is that all of these revenue growth with Natrecor will benefit patients, because it allows us to identify and develop new drugs, and that's what it's all about here, is helping patients over the long-term, and in turn, helping our shareholders received increased value over time.

Now, Natrecor is our first product. Natrecor is used by physicians because it is effective, clearly proven in our clinical trials, it's safe, it acts very quickly, to relieve the symptoms of acutely decompensated CHF patients, and when these patients come into the emergency department, and 90 percent of them do, they can't breathe very well, their lungs are full of fluid, they're having a hard time breathing, and that's because their heart is not working very well, it's not pumping very well, and they need to be treated very quickly, and in our clinical trials we noted that Natrecor can relieve the congestion in these patients in about 15 minutes. Significantly ahead of the standard care drug. It's very easy to use, that is to say, it requires a bolus infusion, and then it requires simply hooking the patient up to a pump, and that's all that's required, a nurse, or physician, or other health-care professional does not need to stand by the patient, and continue to titrate nitroglycerin for example, a patient needs to be monitored for blood pressure and that's about it, and we have demonstrated that Natrecor is cost-effective in the hospital, because it reduces the number of readmissions after the patient is discharged from the hospital, in the thirty-day period where if a patient comes back to the hospital after being discharged, the hospital doesn't necessarily get paid again, if the patient comes back and if the patient is a Medicare patient.

Heart failure is an epidemic in the United States. Gene Braunwald (phonetic) says there are 2 epidemics. One is congestive failure, and the other one is atrial fibrillation, well we're focused on congestive heart failure at the moment, maybe will tackle afib next, but right now there are 5 million patients in this country who have congestive heart failure. Now I'm not going to talk about all 5 million, because I don't have time today, but I want to talk to you about the relevant audience, and the relevant patient population, that we can address with Natrecor, and we like to think of them as basically primary, secondary and outpatient groupings. The primary patients are those who come into the hospital, usually from the emergency department. They come in very early in the morning, after having been up for 2 nights, sleeping on 4 pillows because they can't lie flat, they can't breathe very well, it's an emergent situation, and they need to be treated very quickly. There are a million of those, we think at the end of the day there are about 750,000 eligible, because not all million patients are going to be eligible, some have very low blood pressure and would not be good candidates for Natrecor. Some can be easily treated with diuretics and sent home. But 750,000 of those patients are eligible, based on various studies that we've done, we think we can, at peak sales, penetrate that market to the tune of about 40 percent, and each patient would get about 1.5 vials, currently they get 2.6 vials per patient, and that's because we're treating the most sick patients right now.

Over time, we will start to see less and less sick patients being treated as the drug diffuses more broadly into the practice of medicine. The secondary patients, these patients already in the hospital, that's why we call them secondary diagnosis patients. They're in the hospital for some other reason, usually it's because of myocardial infarction, or it could be because they have just finished the cabbage procedure, or it could be because they have pneumonia, and they have developed signs and symptoms of acute decompensated CHF. There are more than 2 million of these patients every year, who are in the hospital. Not all are eligible, we think half are, about 1.1 million, and we're currently treating those patients. We think at peak sales we can treat about 20 percent of them, and they will get 2 vials each, because they tend to be sicker than the primary patients.

And then there's the wild-card right here, the outpatient market today. The outpatient market today currently consists of 60,000 patients, who are being treated primarily with Milranone or with Dobutamine. Now, the FDA doesn't like this, physicians who use these drugs don't really like it, but it does help improve the quality of life in patients who are New York Heart Association Class 4, and who are pretty much at the end of their road here. We know that there are about 250,000 patients, who are New York Heart Association Class 4 patients, and based upon all of the studies and expert interviews we've done, we think around 145,000 of these patients are eligible for treatment on an outpatient basis. We believe that 15 percent of those patients at peak sales, can be treated with Natrecor, and each one of these patients in a year's time, will receive 24 vials of Natrecor, so you can see that this could be a potentially very lucrative market opportunity, and this is, we think a conservative number. So, just keep that in mind when you think about the potential for Natrecor, and I'll tell you how we're trying to develop this market right in just a second.

Now, the commercialization fundamentals first begin with educating physicians. Natrecor is a cardiac hormone. It has never been on the market before, physicians do not know much about it, and our sales force, along with our scientific affairs managers, have had to educate physicians as to what Natrecor is, and how it works in a complex patient management situation. And I mean complex, this is not straightforward. There are cardiologists involved, there are emergency medicine physicians involved, there are intensivists involved, it is very complicated. However from a commercialization point of view, rapid penetration of the inpatient market is our goal, that means rapidly penetrating the primary and secondary diagnoses, and I think we've done a pretty good job of that so far, ending the year at \$106 million in sales. We have seen favorable real world clinic experience from this drug, which we capture in the ADHERE registry. Now, the ADHERE registry, is a registry that we started. It is not a Natrecor registry, it is a disease based registry, so it captures all patients who have acutely decompensated CHF, and who get put into this registry, so we have a tremendous amount of experience with Natrecor and other drugs, and as a matter of fact today we have 35,000 patients who are captured in the ADHERE registry, which I'll talk about a little more later.

So, where do we go from here? Well, first, we need to continue to penetrate the CHF markets, we're just scratching the surface here. This is a huge market opportunity, and we've been on the market for 18 months, and like I say, we're doing well, but we're just scratching the surface. Real world feedback from the ADHERE registry is guiding us and physicians, as to how better to treat their patients, once they come into the emergency department, or, if they don't come into the emergency department, and if they're in the hospital already for some other reason, how best to treat them, because we can provide them reports on how well they're doing every month, and they can use these reports to revise and improve on the ways that they are treating patients in their hospitals. We are investigating clinical questions of interest, through physician sponsored studies and our own, and we expect to expand the label, to include treatment of advanced CHF, and treating patients on an outpatient basis. FUSION is the first study, in our effort to eventually get a label claim, allowing us to expand the treatment of these patients with Natrecor in an outpatient setting.

Now, as I mentioned before, we ended the year at \$106 million in net sales, and that compares to the nicely to these 8 other IV cardiovascular drug launches, as you can see, Reopro is probably ahead of us by several million dollars, but not by much, pretty good showing for the first year. Now our p38 kinase program is moving along nicely, as I mentioned earlier, we are deep into human trials, as a matter of fact, well into Phase II trials with 469, these are large, potentially large market opportunities we're investigating, and it includes rheumatoid arthritis, as well as other potential therapeutic indications.

The important thing to note here, is that we have not focused in on one molecule. These are, as you know small molecules, and these are oral products. We have a family of oral compounds, that inhibit TNF, IL-1 synthesis and COX 2 expression. And the TNF inhibition market is already in the United States, a \$2 billion market, with Remicade and Enbrel doing all the heavy lifting there, and those are wonderful drugs. But as you all know, they have to be injected or infused. The 2 small molecules that are advancing in clinical trials as I told you, 469 is further ahead than 323, but 323 is a completely different type of product, and represents a second generation product for us. And, we have the potential to be first in this completely new class of drugs, and that is our goal, and it requires rapid clinical development worldwide, which is why we have set about to find a partner, which eventually led to the merger with Johnson & Johnson. We cannot given our resources at the moment, capitalize on a worldwide launch of SCIO-469 or 323, and that's why we're looking for a partner early on.

But this is an opportunity that I think is unparalleled in much of biotechnology. We think that taking 2 pills, or one pill and a glass of water, is a lot better than getting shots or getting infusions. Patients in our view, will unquestionably prefer the 2 pills and a glass of water. That means we have the opportunity, assuming that the safety and efficacy profile of our products, is the same or better than what is on the market today, we have the opportunity to convert this market over to the SCIO-469 product relatively quickly, and then to obsolete ourselves, with our 323 product which is now in Phase I. What to expect from us in 2003? Well, first Natrecor net sales are expected to grow to \$180 to \$185 million, possibly higher. You can expect us to continue our clinical programs, to expand the Natrecor label, to include outpatient use, advance the clinical development of p38 on a worldwide basis now, especially, and advance the TGF beta product into the clinic.

Just a quick word about the merger of Scios and Johnson & Johnson. We announced this on February 10th 2003, this is a cash deal, \$45 cash per share of the Scios stock. This merger is expected to close in the second quarter of this year. The Scios name, identity and management will be retained, and this is typical of how Johnson & Johnson does things, and as a matter of fact, I believe Joe Scolari will be providing a talk today, at the luncheon hour, and one of his talks will be how to work together, and I think this will be reflective of how Johnson & Johnson likes to do things, it's something that we also enjoy. Johnson & Johnson provides resources to identify develop and commercialize products for unmet medical needs, and they're going to provide us with a host of opportunities, that we currently do not have, and that we're looking forward to. Ladies and gentlemen, thank you very much for your attention, and I will see you later on I guess, at our panel session. Thank you.

TEXT OF SLIDE

Proposed Merger of Scios and
Johnson & Johnson

Announced February 10, 2003
\$45 cash per share of Scios stock
Expect to close in Q2, 2003
Scios name, identity and management retained
J&J provides resources to identify, develop and commercialize products for unmet medical needs

Investors and stockholders are urged to read when it becomes available the proxy statement that Scios will file with the SEC as it will contain important information about the merger. Investors and stockholders will have access to free copies of the proxy statement (when available) and other documents filed with the SEC by Scios through the SEC website at www.sec.gov, or by directing a request to: Investor Relations, Scios Inc., phone (877) 847-7246.

Scios and its directors, executive officers, certain members of management and employees, may be deemed to be participants, under the rules of the SEC, in the solicitation of proxies in connection with the proposed merger, and information regarding these persons is set forth in Scios annual report on Form 10-K for the fiscal year ended December 31, 2001 and proxy statement for its 2002 annual meeting of stockholders filed with the SEC on March 21, 2002. Additional information will be set forth in the proxy statement when it is filed with the SEC.

###

ADDITIONAL INFORMATION

This filing contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, which may include statements concerning the proposed merger with Johnson & Johnson and strategic plans, expectations, and objectives for future operations. We generally identify such forward-looking statements using words like estimate, believe, intend, expect, may, should, plan, project, contemplate, anticipate or similar statements. Statements that are not historical facts are forward-looking statements based on current assumptions that involve risks and uncertainties. These risks and uncertainties may include the sales penetration and success of Natrecor, the success of clinical trials of Natrecor and our pipeline products, the failure to complete the proposed merger in a timely manner, the inability to obtain Scios shareholder or regulatory approvals or to satisfy other conditions to the merger, actions of governmental entities, and costs related to the merger, as well as other risks detailed from time to time in the reports filed by Scios with the SEC, including the Company's quarterly reports and annual report on Form 10-K. Actual results, performance or achievements of Scios may differ significantly from those described in these forward-looking statements. Scios disclaims any intention or obligation to update or revise any financial projections or forward-looking statements, whether as a result of new information, future events or otherwise.

In connection with the proposed merger, Scios will file a proxy statement with the Securities and Exchange Commission (SEC). INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THE PROXY STATEMENT WHEN IT BECOMES AVAILABLE AS IT WILL CONTAIN IMPORTANT INFORMATION ABOUT THE MERGER AND RELATED MATTERS. INVESTORS AND SECURITY HOLDERS WILL HAVE ACCESS TO FREE COPIES OF THE PROXY STATEMENT (WHEN AVAILABLE) AND OTHER DOCUMENTS FILED WITH THE SEC BY SCIOS THROUGH THE SEC WEB SITE AT WWW.SEC.GOV. THE PROXY STATEMENT AND RELATED MATERIALS MAY ALSO BE OBTAINED FOR FREE (WHEN AVAILABLE) FROM SCIOS BY DIRECTING THEIR REQUEST TO: INVESTOR RELATIONS, SCIOS INC., 820 WEST MAUDE AVENUE, SUNNYVALE, CA 94085; PHONE (877) 847-7246.

Scios and its directors, executive officers, certain members of management and employees, may be deemed to be participants in the solicitation of proxies in connection with the proposed merger. Information regarding the persons who may, under the rules of the SEC, be considered to be participants in the solicitation of Scios' stockholders in connection with the proposed merger is set forth in Scios' annual report on Form 10-K for the fiscal year ended December 31, 2001 filed with the SEC on March 15, 2002 and proxy statement for its 2002 annual meeting of stockholders filed with the SEC on March 21, 2002. Additional information will be set forth in the proxy statement when it is filed with the SEC.