SCIOS INC
Form 10-Q
May 15, 2001

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One) |X| QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the quarterly period ended March 31, 2001 OR |_| TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the transition period from _____ to _____ Commission file number: 0-11749

Scios Inc.

(Exact name of Registrant as specified in its charter) Delaware 95-3701481 (State or other jurisdiction of (I.R.S. Employer incorporation or organization) Identification No.) Scios Inc. 820 W. Maude Ave. Sunnyvale, CA 94085 (Address of principal executive offices) (Zip code) (408) 616-8200 (Registrant's telephone number including area code) Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes X No ____ - Number of shares outstanding of the issuer's common stock, par value $.001 per share, as of March 31, 2001: 39,364,224 26

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

SCIOS INC. AND SUBSIDIARY Consolidated Balance Sheets (In thousands, except share data)

ASSETS	March 31, 2001
	(Unaudited)
Current assets:	
Cash and cash equivalents	$ 613
Marketable securities	28,002
Accounts receivable	12,204
Prepaid expenses and other assets	1,503
Total current assets	42,322
Marketable securities, non-current	33,564
Property and equipment, net	8,119
Other assets	2,082

TOTAL ASSETS	$ 86,087
LIABILITIES AND STOCKHOLDERS' EQUITY	
Current liabilities:	
Accounts payable	$ 3,919
Other accrued liabilities	10,236
Deferred contract revenues	16,372
Total current liabilities	30,527
Long-term debt	39,944
Total liabilities	70,471
Stockholders' equity:	
Preferred stock; $.001 par value; 20,000,000 shares authorized; 4,991 shares issued and outstanding	--
Common stock; $.001 par value; 150,000,000 shares authorized; 39,364,224 and 39,166,373 shares issued and outstanding, respectively	39
Additional paid-in capital	430,408
Notes receivable from stockholders	(406)
Deferred compensation, net	(106)
Accumulated other comprehensive income	1,311
Accumulated deficit	(415,630)
Total stockholders' equity	15,616
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 86,087

The accompanying notes are an integral part of these consolidated financial statements. SCIOS INC. AND SUBSIDIARY Consolidated Statements of Operations and Comprehensive Loss (In thousands, except share and per share data)

	Three months ended March 31,	
	2001	
	(Unaudited)	
Revenues:		
Product sales and co-promotion commissions, net of expenses	$ 1,483	$ 1,331
Research & development contracts	1,097	1

Gain on sale of marketing rights	9,363	
	11,943	3
Costs and expenses:		
Research and development	9,480	9
Marketing, general and administration	6,480	3
	15,960	1
Loss from operations	(4,017)	
Other income (expense):		
Investment income	812	1
Interest expense	(849)	
Realized gains (losses) on securities	254	
Other expense	(423)	
	(206)	
Net loss	(4,223)	
Other comprehensive loss:		
Change in unrealized gains (losses) on securities:	116	
Comprehensive loss	$ (4,107)	$ (9,62
Loss per common share, basic and diluted	$ (0.11)	$ (0.25
Weighted average number of common shares outstanding used in the calculation of net loss per share, basic and diluted	39,290,982	3

The accompanying notes are an integral part of these consolidated financial statements.

_____ SCIOS INC. AND SUBSIDIARY Consolidated Statements of Cash Flows (In thousands)

Three months
March 31
2001

	(Unaudite
Cash flows from operating activities:	
Net loss	$ (4,223)
Adjustments to reconcile net loss to net cash used in operating activities:	
Depreciation and amortization	872
Loss on disposal of property and equipment	365
Accrued long-term interest payable	849
Amortization of deferred compensation	311
Changes in assets and liabilities:	
Accounts receivable	(6,987)
Accounts payable	(668)
Other accrued liabilities	(513)
Prepaid expenses and other assets	(856)
Deferred contract revenue	179
Net cash used in operating activities	(10,671)
Cash flows from investing activities:	
Purchases of property and equipment	(446)
Sales/maturities of marketable securities	43,371
Purchases of marketable securities	(36,581)
Net cash provided by investing activities	6,344
Cash flows from financing activities:	
Issuance of common stock and collection of notes receivable from stockholders, net	1,649
Payment of notes payable	--
Net cash provided by (used in) financing activities	1,649
Net decrease in cash and cash equivalents	(2,678)
Cash and cash equivalents, at beginning of period	3,291
Cash and cash equivalents, at end of period	$ 613

The accompanying notes are an integral part of these consolidated financial statements.

SCIOS INC.

AND SUBSIDIARY

Notes to Consolidated Financial Statements (unaudited)

1. Basis of Presentation

The accompanying unaudited consolidated financial statements of Scios have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not contain all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, the accompanying unaudited, condensed consolidated financial statements reflect all adjustments (consisting of normal, recurring adjustments) considered necessary for a fair presentation of Scios' interim financial information. These consolidated financial statements and notes should be read in conjunction with the audited financial statements of Scios included in our Annual Report on Form 10-K for the year ended December, 31, 2000. The results of operations for the three months ended March 31, 2001 are not necessarily indicative of the operating results that may be reported for the fiscal year ending December 31, 2001 or for any other future period.

2. Computation of Loss Per Share

The following table sets forth the computation of the Scios' basic and diluted loss per share (in thousands, except per share amounts):

	Three months end March 31, 2001
Numerator	
Basic	
Net loss	$ (4,223)
Diluted	
Net loss	$ (4,223)
Denominator	
Basic and diluted	
Weighted average shares	39,290,982
Effect of dilutive securities:	
Employee stock options	--
Weighted average shares and assumed conversions	39,290,982
Basic loss per share	$ (0.11)
Diluted loss per share	$ (0.11)

The potentially dilutive effect of outstanding options to purchase common stock would have been anti-dilutive as to the reported loss per share in both 2001 and 2000, and they were therefore excluded from the diluted loss per share calculation for both periods. Although potentially dilutive, the optional settlement of the Genentech loan through the issuance of preferred stock would have been anti-dilutive in both 2001 and 2000 and was therefore excluded from the calculations. At March 31, 2001, Scios had 5,125,383 outstanding stock options at prices ranging from $3.6875 to $21.38 per share. At March 31, 2000, Scios had 5,368,560 outstanding stock options at prices ranging from $3.6875 to $21.13 per share. 3. Industry and Geographic Segment Information Scios operates in one business segment, using one measurement of profitability for its business. Scios receives revenue from product sales and from licensing and

development of products from partners in the United States, Europe and Asia Pacific. At March 31, 2001, all long-lived assets were located in the United States and all revenues were earned in the United States in the three months ended March 31, 2001 and the three months ended March 31, 2000.

4. Gain on Sale of Marketing Rights

During the last two quarters, Scios solicited and received bids in connection with selling its marketing rights for certain products sold by Scios. The marketing rights were sold to GlaxoSmithKline, or GSK. The marketing rights were originally licensed from GSK under a 1990 licensing agreement. In order to effect the purchase, the licensing agreement was terminated effective March 31, 2001, and we will receive from GSK $4.0 million in 2001, $3.0 million in 2002, and $2.5 million in 2003. We recognized a one-time gain on the sale of $9.4 million which has been classified on the statement of operations under the caption Gain on Sale of Marketing Rights. In addition, we ended the deployment of our Psychiatric Sales Marketing Division sales force and terminated certain full-time support personnel. Severance payments for these personnel amounted to approximately $788,000.

5. Notes Receivable from Officers

At March 31, 2001, we had notes receivable from three officers. The first note is in the amount of $179,466 with interest at 6.30% per annum, due and payable on October 31, 2001. The loan was granted in connection with the payment of income taxes for restricted stock granted to the officer. This loan is collateralized by the vested portion of the officer s stock options and is classified with other current assets on the balance sheet at March 31, 2001.

The second note is in the amount of $280,040 with interest at 5.18% per annum, due and payable on February 28, 2002. The loan was granted in connection with the payment of income taxes for restricted stock granted to the officer. This loan is collateralized by the vested portion of the officer s stock options and is classified with other current assets on the balance sheet at March 31, 2001.

The third note is in the amount of $33,333 with interest at 5.82% per annum. This loan will be forgiven over the next two years based on the continued employment of the officer and is collateralized by the officer s residence. The loan was granted in connection with a housing subsidy for the officer to live in California. This note balance is classified with other assets on the balance sheet at March 31, 2001.

6. Subsequent Events

On May 8, 2001, the stockholders approved an amendment to the 1992 Equity Incentive Plan adding 1.5 million shares of common stock to this plan. In addition, an Employee Stock Purchase Plan was approved by the stockholders with an initial allocation of 375,000 shares of common stock. Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations The following discussion should be read in conjunction with our audited consolidated financial statements, including the related notes, contained in our Annual Report on Form 10-K for the year-ended December 31, 2000. The following discussion also contains forward-looking statements about our plans, objectives and future results. These forward-looking statements are based on our current expectations, and we assume no obligation to update this information. Realization of these plans and results involves risks and uncertainties, and our actual results could differ materially from those discussed here. Factors that could cause or contribute to such differences include those set forth under "Risk Factors" in this report on Form 10-Q.

Overview

We are a biopharmaceutical company developing novel treatments for cardiovascular and inflammatory diseases. Our disease-based technology platform integrates expertise in protein biology with computational and medicinal chemistry to identify novel targets and protein-based small molecule compounds for large markets with unmet medical needs. We have primarily focused on the development of two product candidates-- Natrecor(R)for the treatment of acute Congestive Heart Failure, or acute CHF, and SCIO-469, an oral small molecule inhibitor of p38 kinase, for the treatment of rheumatoid arthritis. We submitted an amendment to our New Drug Application, or NDA, for

Natrecor(R)to the U.S. Food and Drug Administration, or FDA, in January 2001, and the FDA's Cardiovascular and Renal Drugs Advisory Committee is expected to review our amended NDA on May 25, 2001. We expect the FDA to respond to our application by July 2001. During January 2001, we completed a Phase Ia clinical trial with single oral doses of SCIO-469 for the treatment of rheumatoid arthritis. The trial showed SCIO-469 to be safe and well tolerated. In February 2001, a Phase Ib clinical trial was initiated with 20 volunteers to evaluate the safety and tolerability of multiple oral doses of SCIO-469. The Phase Ib trial was completed in April 2001 in the 20 volunteers demonstrating the safety and tolerability of multiple oral doses of SCIO-469 over a two-week period. Based on the favorable Phase Ib trial results, we plan to begin a Phase II clinical trial in the second half of 2001. In March 2001, we also initiated the PROACTION (Prospective Randomized Outcomes Study of Acutely Decompensated Congestive Heart Failure Treated Initially in Outpatients with Natrecor(R)) trial, a pilot study designed to compare the clinical effects, safety profile and economic impact of standard therapy plus Natrecor(R) to standard therapy plus placebo. The PROACTION trial has an enrollment target of 250 acute CHF patients. We expect to complete this study in the third quarter of 2001. These patients are being treated in the Emergency Department/Observation Unit of hospitals, where the majority of the one million hospitalizations each year for this indication begin. During the last two quarters, Scios solicited and received bids in connection with selling its marketing rights for certain products sold by Scios. The marketing rights were sold to GlaxoSmithKline, or GSK. The marketing rights were originally licensed from GSK under a 1990 licensing agreement. In order to effect the purchase, the licensing agreement was terminated effective March 31, 2001, and we will receive from GSK $4.0 million in 2001, $3.0 million in 2002, and $2.5 million in 2003. Approximately 40% of our total revenues in 2000 were derived from these psychiatric products. In April 2001, Kaken Pharmaceuticals Co., Ltd. received notice from the Japanese Ministry of Health and Welfare that they have been granted marketing approval for Fiblast(R)Spray as a treatment for dermal ulcers. The active ingredient in Fiblast(R)Spray is recombinant basic Fibroblast Growth Factor, or FGF, which Kaken licensed from us in 1988. Based on this approval, we expect to recognize $15.9 million in revenue during 2001 as FGF is shipped to Kaken in Japan. At March 31, 2001, the $15.9 million is recorded as deferred contract revenue. In May 2001, we entered into a research collaboration with Medtronic, Inc. to study the effects of Natrecor(R)in combination with Medtronic's heart failure devices and implantable infusion systems. In the first of a planned program of pilot clinical studies, the hemodynamic and clinical effects of Natrecor(R), including the effects on spontaneous activity and controlled exercise tolerance, will be evaluated using information collected by Medtronic's Chronicle(R)Implantable Hemodynamic Monitor (IHM) both during and after infusions of Natrecor(R). The pilot feasibility study is expected to begin this quarter at the Karolinska Hospital in Stockholm. The Chronicle IHM is an implanted system designed to measure and record hemodynamic variables over time such as right ventricular systolic and diastolic pressures, estimated pulmonary artery diastolic pressure, heart rate and activity. The Chronicle IHM is not yet approved for marketing in the U.S. or Europe. Investors are encouraged to review our Annual Report on Form 10-K for the year ended December 31, 2000 filed with the SEC on March 30, 2001 for a broader discussion of our business and the opportunities and risks inherent in our business. Copies of the Form 10-K are available from us on request and from the Securities and Exchange Commission's Edgar database found at the SEC's web site at http://www.sec.gov. New Accounting Pronouncement Financial Accounting Standards No. 133. In June 1998, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments and Hedging Activities." SFAS 133 establishes new standards of accounting and reporting for derivative instruments and hedging activities. SFAS 133 requires that all derivatives be recognized at fair value in the statement of financial position and that the corresponding gains or losses be reported either in the statement of operations or as a component of comprehensive income, depending on the type of relationship that exists. Effective January 1, 2001, Scios adopted SFAS 133. We do not currently hold derivative instruments or engage in hedging activities and as such the implementation of SFAS 133 did not have a material effect on our financial position and results of operations.

Results of Operations

Three Months Ended March 31, 2001 and 2000 Revenues Net Product Sales and Co-Promotion Commissions. Net product sales and co-promotion commissions for the three months ended March 31, 2001 were $1.5 million versus $1.3 million for the three months ended March 31, 2000. Scios no longer intends to sell or co-promote psychiatric products after March 31, 2001. Research and Development Contract Revenues. Research and development contract

revenues were $1.1 million for the three months ended March 31, 2001 versus $1.9 million for the three months ended March 31, 2000. The decrease of $0.8 million is primarily due to the end of our research collaboration agreement with DuPont Pharmaceutical Company, effective November 2000. Gain on Sale of Marketing Rights. During the last two quarters, Scios solicited and received bids in connection with selling its marketing rights for certain products sold by Scios. The marketing rights were sold to GSK. The marketing rights were originally licensed from GSK under a 1990 licensing agreement. In order to effect the purchase, the licensing agreement was terminated effective March 31, 2001, and we will receive from GSK $4.0 million in 2001, $3.0 million in 2002, and $2.5 million in 2003. We recognized a one-time gain of $9.4 million related to the sale. Costs and Expenses Research and Development. Research and development expenses were $9.5 million and $9.3 million for the three months ended March 31, 2001 and 2000, respectively. The expenses were mainly attributable to clinical expenses related to Natrecor(R)and research expenses related to our p38 kinase inhibitor program. Marketing, General and Administrative. Marketing, general and administrative expenses were $6.5 million and $3.5 million for the three months ended March 31, 2001 and 2000, respectively. The increase of $3.0 million in expenses for the quarter is largely attributable to the costs associated with building a marketing and sales infrastructure for the anticipated Natrecor(R)product launch. Other Income (Expense) Net other income (expense) were $(0.2) million and $10,000 for the three months ended March 31, 2001 and 2000, respectively. The decrease of $0.2 million in income (expense) was principally due to the $0.6 million decline in investment income due to the lower cash balances from quarter to quarter, which was partially offset by an increase in realized gains on marketable securities of $0.3 million.

Liquidity and Capital Resources

To date, our operations and capital requirements have been financed primarily with the proceeds of public and private sales of common stock and preferred stock, research and development partnerships, collaborative agreements with pharmaceutical firms, product sales and investment income. At March 31, 2001, our combined cash, cash equivalents and marketable securities (both current and non-current) totaled $62.2 million. In anticipation of the launch of Natrecor(R)in the third quarter of 2001, we entered into a sales and marketing agreement with Innovex, a subsidiary of Quintiles Transnational Corp. We believe that this marketing alliance will allow us to quickly commercialize Natrecor(R)in the United States. Under the terms of the three and a half year agreement, PharmaBio Development, Inc., an affiliate of Innovex, has agreed to fund $30.0 million of our costs to launch Natrecor(R)over the first 24 months of Natrecor(R)'s commercialization and to loan us up to $5.0 million. Of the $30.0 million, we anticipate that $10.0 million will be paid to us in 2001 following FDA approval of Natrecor(R). Under the agreement, Innovex will identify, hire, train and deploy a dedicated cardiology and emergency medicine sales force of approximately 180 people to launch and market Natrecor(R). Net cash used in operating activities of $10.7 million in the quarter ended March 31, 2001 was primarily attributable to the loss of $4.2 million and decreases in operating assets and liabilities of $8.9 million, partially offset by non-cash expenses of $2.4 million. Net cash provided by investing activities of $6.3 million in the quarter ended March 31, 2001 consisted of a net increase in sales/maturities of marketable securities of $6.8 million, offset by purchases of property and equipment of $0.5 million. Net cash provided by financing activities of $1.6 million in the quarter ended March 31, 2001 was due to the proceeds from the issuance of common stock and collection of notes receivable from stockholders. We anticipate that our existing cash, cash equivalents and marketable securities and proceeds from existing collaborations, including our agreement with Innovex and PharmaBio, will enable us to maintain our current and planned operations for the next twelve months. In the long-term, and in the event we do not receive FDA approval to market Natrecor(R), we will need to arrange additional financing for the operation of our business, including the commercialization of our products currently under development. We will consider collaborative arrangements and additional public or private financing, including additional equity financings. Factors influencing the availability of additional financings include our progress in product development, investor perception of our prospects and the general conditions of the financial markets.

Risk Factors

You should carefully consider the risks described below before making an investment decision. Our business, financial condition or results of operations could be harmed by any of these risks. The risks described below are not

the only ones facing our company. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations. This document also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of the risks faced by us, including those described below and elsewhere in this document. Risks Related to Natrecor(R)(nesiritide)

If the U.S. Food and Drug Administration, or FDA, finds that our amended New Drug Application, or NDA, for Natrecor® does not support approval for marketing, the commercialization of Natrecor® may be delayed or prevented.

In April 1999, the FDA issued us a non-approval letter for Natrecor(R). To address the FDA's concerns, we conducted a Phase III clinical trial; and in January 2001, we submitted an amendment to our NDA seeking approval to market Natrecor(R)in the United States. We are initially seeking FDA approval for use of Natrecor(R)as a treatment for acute congestive heart failure, or acute CHF. The FDA may not find our clinical data adequate to support Natrecor(R)as a treatment for acute CHF or any other disease. Moreover, the FDA may require us to commence and complete additional clinical trials to generate additional data to support product approval for the treatment of acute CHF, which may lead to a substantial delay in its approval of Natrecor(R)or prevent Natrecor(R)from being approved for any medical use. If Natrecor(R)does not gain market acceptance, our business will suffer. Even if clinical trials demonstrate the safety and efficacy of Natrecor(R)and the necessary regulatory approvals are obtained, Natrecor(R)may not gain market acceptance among physicians, patients, healthcare payors and the medical community. We will need to educate doctors and other healthcare advisors of the safety and clinical efficacy of Natrecor(R)and its potential advantages over other treatments. The degree of market acceptance of Natrecor(R)will also depend on a number of factors, including: o the degree of clinical efficacy and safety; o cost-effectiveness of Natrecor(R); o its advantage over alternative treatment methods; and o reimbursement policies of government and third-party payors. To the extent market acceptance of Natrecor(R)is limited, our revenues may suffer.

If the FDA determines that our third-party manufacturing facilities are not adequate, either before or after receipt of FDA marketing approval, we may lose the ability to manufacture and sell Natrecor®.

As part of the NDA approval process and periodically thereafter, the FDA is likely to inspect each of the facilities involved in manufacturing Natrecor(R). Natrecor(R)is manufactured for us by Biochemie GmbH, a subsidiary of Novartis, in Austria and is shipped in powder form to Abbott Laboratories in McPherson, Kansas where it is blended, filled and packaged for shipment. Although each facility has previously passed FDA inspections, future inspections may find deficiencies in the facilities or processes that may delay or prevent the manufacture or sale of Natrecor(R). Even if the FDA approves Natrecor(R)for marketing, the FDA will subsequently conduct periodic inspections of these manufacturing facilities and, if deficiencies are identified, we may lose the ability to supply and sell Natrecor(R)for extended periods of time.

We rely on third-party manufacturers, and if they experience any difficulties with their manufacturing processes, we may not obtain sufficient quantities of Natrecor® to assure availability.

We rely on third parties for the manufacture of bulk drug substances and final drug product for clinical and commercial purposes relating to Natrecor(R). Biochemie GmbH is responsible for manufacturing Natrecor(R)in bulk quantities and Abbott Laboratories is responsible for blending, filling and packaging Natrecor(R), and if they encounter problems in these processes, our revenues from future sales of Natrecor(R)could decrease. Natrecor(R)is manufactured using industry accepted recombinant manufacturing techniques, which must be conducted under strict controls and tight timelines. Natrecor(R)is subject to strict quality control testing during all phases of production and prior to its release to the market. Any quality control testing failures could lead to a reduction in the available supply of Natrecor(R). Biochemie depends on outside vendors for the timely supply of raw materials used to produce our products, including Natrecor(R). Once a supplier's materials have been selected for use in Biochemie's manufacturing process, the supplier in effect becomes a sole or limited source of that raw material due to regulatory compliance procedures. We depend on these third parties to perform their obligations effectively and on a timely basis. If these third parties fail to perform as required, our ability to deliver Natrecor(R)on a timely basis would be impaired. In

addition, in the event of a natural disaster, equipment failure, power failure, strike or other difficulty, we may be unable to replace our third party manufacturers in a timely manner and would be unable to manufacture Natrecor(R)to meet market needs. The success of Natrecor(R)is highly dependent on our partner, Innovex L.P., a division of Quintiles Transnational Corp., for marketing, promotion and sales activities. We believe that for Natrecor(R)to be widely adopted, the efforts of an experienced sales force are needed. We have limited experience in managing or operating a marketing organization. Accordingly, we have entered into an exclusive agreement with Innovex to co-promote, sell and distribute Natrecor(R)in the United States. As part of our agreement with Innovex, we intend to build a sales force of approximately 180 people solely dedicated to the sale of Natrecor(R). If Innovex and we fail to devote appropriate resources to promote, sell and distribute Natrecor(R), sales of Natrecor(R)could be reduced. If Innovex breaches or terminates its agreement with us or otherwise fails to conduct its Natrecor(R)-related activities in a timely manner or if there is a dispute about its obligations, we may need to seek another partner. In that event, we cannot assure you that we will be able to obtain another partner on favorable terms, if at all.

The failure of PharmaBio Development, Inc., an affiliate of Innovex, to fulfill its obligation to partially fund the commercialization of Natrecor® may affect our ability to successfully market Natrecor®.

PharmaBio has agreed to fund $30.0 million of our costs to launch Natrecor(R)over the first 24 months of Natrecor(R)'s commercialization and to loan us up to $5.0 million. Of the $30.0 million, we anticipate that $10.0 million will be paid to us in 2001 following FDA approval of Natrecor(R). If PharmaBio breaches or terminates its agreement with us or otherwise fails to fulfill its financial obligations under the agreement and we are unable to secure alternative funding, we may lose our ability to successfully market Natrecor(R).

In the area of acute CHF, we face competition from companies with substantial financial, technical and marketing resources, which could limit our future revenues from Natrecor®.

Many therapeutic options are available for patients with acute CHF. Currently used drugs fall into three main categories: vasodilators, inotropes, and diuretics. Natrecor(R)would compete against both vasodilators and inotropes in the acute CHF market. Many of these drugs are available in generic formulation with an associated low cost. In addition, milrinone, an inotrope, is currently promoted by Sanofi-Synthelabo Inc. We may not be able to compete effectively with these long-standing current forms of therapy. In addition, we will price Natrecor(R)above the cost of these existing drugs, which may harm our competitive position relative to these drugs. New drugs in development for the treatment of acute CHF would also compete with Natrecor(R)if approved by the FDA or other regulatory agencies. Tezosentan(R), a non-selective endothelin receptor antagonist, is being developed by Actelion LTD. and is currently being evaluated in Phase III clinical trials as a vasodilator for the treatment of acute CHF. In addition, Abbott had previously submitted an NDA for Simdax(R), a calcium sensitizer described as an inotrope, but withdrew the application in 2000. To our knowledge, Abbott has not announced its intent to refile an NDA for Simdax(R). If any such new drug in development is approved by the FDA or other regulatory agencies, we may not be able to compete effectively with these new forms of therapy. If we fail to gain approval for Natrecor(R)and our other product candidates in international markets, our market opportunities will be limited. We have not yet filed for marketing clearance for the use of Natrecor(R)or any other product candidates in foreign countries, and we may not be able to obtain any international regulatory approvals for Natrecor(R)or any other product we develop. If we fail to obtain those approvals or if such approvals are delayed, the geographic market for Natrecor(R)or our other product candidates would be limited.

We will require a partner to market and commercialize Natrecor® and our other product candidates in international markets.

We plan to partner with other companies for the sale of Natrecor(R)and our other product candidates outside of the United States. We cannot assure you that we will be able to enter into such arrangements on favorable terms or at all. In addition, partnering arrangements could result in lower levels of income to us than if we marketed our products entirely on our own. In the event that we are unable to enter into a partnering arrangement for Natrecor(R)or our other product candidates in international markets, we cannot assure you we will be able to develop an effective international sales force to successfully market and commercialize those products. If we fail to enter into partnering arrangements

for our products and are unable to develop an effective international sales force, our revenues would be limited. If we fail to obtain additional marketing approvals from the FDA for the use of Natrecor(R)for additional therapeutic indications or if after approval such approval is subsequently revoked, our revenues from Natrecor(R) will suffer. In order to expand the medical uses, or therapeutic indications, for which we may market Natrecor(R), we must successfully complete additional clinical trials, which could be lengthy and expensive and will require the allocation of both substantial management and financial resources. Thereafter, we will have to apply separately to the FDA for clearance to market Natrecor(R)for other indications. We cannot assure you that we will be able to successfully complete the required clinical trials or that the FDA will approve Natrecor(R)for any additional indications. In addition, even if Natrecor(R)is approved by the FDA, we cannot exclude the possibility that serious adverse events related to the use of Natrecor(R)might occur in the future, which could either limit its use or cause the FDA to revoke our approval to market Natrecor(R).

Other Risks Related to Scios

We have a history of losses, expect to operate at a loss for the foreseeable future and may never be profitable.

We may not be able to achieve or earn a profit in the future. We began operations in December 1981, and since that time, with the sole exception of 1983, we have not earned a profit on a full-year basis. Our losses have historically resulted primarily from our investments in research and development. As of March 31, 2001, we had an accumulated deficit of approximately $415.6 million. To date, nearly all of our revenues have come from: |X| one-time signing fees from our corporate partners under agreements supporting the research, development and commercialization of our product candidates; |X| one-time payments from our corporate partners when we achieved regulatory or development milestones; |X| research funding from our corporate partners; and |X| our psychiatric sales and marketing division. We expect that our research, development and clinical trial activities and regulatory approvals, together with future general and administrative activities and the costs associated with launching and commercializing our product candidates and launching and commercializing Natrecor(R)in the United States, will result in significant expenses for the foreseeable future.

If we fail to obtain the capital necessary to fund our operations, we may have to delay or scale back some of our programs or grant rights to third parties to develop and market our products.

We will continue to expend substantial resources developing new and existing product candidates, including costs associated with research and development, acquiring new technologies, conducting preclinical studies and clinical trials, obtaining regulatory approvals and manufacturing products. We believe our current working capital and future payments, if any, from our collaboration arrangements will be sufficient to meet our operating and capital requirements for at least the next 12 months. Our need for additional funding depends on a number of factors including: |X| higher costs and slower progress than expected in developing product candidates and obtaining regulatory approvals, particularly for Natrecor(R); |X| acquisition of technologies and other business opportunities that require financial commitments; or |X| lower revenues than expected from the commercialization of our potential products. Additional funding may not be available to us on favorable terms, if at all. We may raise funds through public or private financings, collaborative arrangements or other arrangements. Debt financing, if available, may involve covenants, which could restrict our business activities. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, scale back or eliminate expenditures for some of our development programs or grant rights to develop and market product candidates that we would otherwise prefer to develop and market internally. If we are required to grant such rights, the ultimate value of these product candidates to us may be reduced.

Our operating results are subject to fluctuations that may cause our stock price to decline.

Our revenues and expenses have fluctuated significantly in the past. This fluctuation has in turn caused our operating results to vary significantly from quarter to quarter and year to year. We expect the fluctuations in our revenues and expenses to continue, and thus, our operating results should also continue to vary significantly. These fluctuations may

be due to a variety of factors including: |X| the timing and realization of milestone and other payments from our corporate partners; |X| the timing and amount of expenses relating to our research and development, product development and manufacturing activities; and

|X| the extent and timing of costs related to our activities to obtain patents on our inventions and to extend, enforce and/or defend our patents and other rights to our intellectual property.

Because of these fluctuations, it is possible that our operating results for a particular quarter or quarters will not meet the expectations of public market analysts and investors, causing the market price of our common stock to decline. We believe that period-to-period comparisons of our operating results are not a good indication of our future performance, and you should not rely on those comparisons to predict our future operating or share price performance.

We depend on our key personnel and we must continue to attract and retain key employees and consultants.

We depend on our key scientific and management personnel. Our ability to pursue the development of our current and future product candidates depends largely on retaining the services of our existing personnel and hiring additional qualified scientific personnel to perform research and development. We also rely on personnel with expertise in clinical testing, government regulation, manufacturing and marketing. Attracting and retaining qualified personnel will be critical to our success. We may not be able to attract and retain personnel on acceptable terms given the competition for such personnel among biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions. Failure to retain our key scientific and management personnel or to attract additional highly-qualified personnel could delay the development of our product candidates and harm our business.

Other than Natrecor®, our product candidates are at early stages of development, and if we are unable to develop and commercialize these product candidates successfully, we will not generate revenues from these products.

To date, none of our product candidates has been commercialized. Other than Natrecor(R), all of our product candidates are in early stages of development. We face the risk of failure normally found in developing biotechnology products based on new technologies. Successfully developing, manufacturing, introducing and marketing our early-stage product candidates will require several years and substantial additional capital. Our operations depend on compliance with complex FDA and comparable international regulations. If we fail to obtain approvals on a timely basis or to achieve continued compliance, the commercialization of our products could be delayed. We cannot assure you that we will receive the regulatory approvals necessary to commercialize our product candidates, which could cause our business to fail. Our product candidates are subject to extensive and rigorous government regulation by the FDA and comparable agencies in other countries. The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution of biopharmaceutical products. If our potential products are marketed abroad, they will also be subject to extensive regulation by foreign governments. None of our lead product candidates has been approved for sale in the United States or any foreign market. In addition, we have only limited experience in filing and pursuing applications necessary to gain regulatory approvals, which may impede our ability to obtain such approvals.

The results of preclinical studies and clinical trials of our products may not be favorable.

In order to obtain regulatory approval for the commercial sale of any of our product candidates, we must conduct both preclinical studies and human clinical trials. These studies and trials must demonstrate that the product is safe and effective for the clinical use for which we are seeking approval. We are currently planning to conduct Phase II clinical trials of our lead p38 kinase inhibitor small molecule compound. The results of these or other clinical trials that we may conduct in the future may not be successful. Adverse results from our current or any future trials would harm our business. We also face the risk that we will not be permitted to undertake or continue clinical trials for any of our product candidates in the future. Even if we are able to conduct such trials, we may not be able to satisfactorily demonstrate that the products are safe and effective and thus qualify for the regulatory approvals needed to market and sell them. Results from preclinical studies and early clinical trials are often not accurate indicators of results of later-

stage clinical trials that involve larger human populations.

Our products use novel alternative technologies and therapeutic approaches, which have not been widely studied.

Many of our product development efforts focus on novel alternative therapeutic approaches and new technologies that have not been widely studied. These approaches and technologies may not be successful. We are applying these approaches and technologies in our attempt to discover new treatments for conditions that are also the subject of research and development efforts of many other companies.

Rapid changes in technology and industry standards could render our potential products unmarketable.

We are engaged in a field characterized by extensive research efforts and rapid technological development. New drug discoveries and developments in our field and other drug discovery technologies are accelerating. Our competitors may develop technologies and products that are more effective than any we develop or that render our technology and potential products obsolete or noncompetitive. In addition, our potential products could become unmarketable if new industry standards emerge. To be successful, we will need to enhance our product candidates and design, develop and market new product candidates that keep pace with new technological and industry developments.

Many other companies are targeting the same diseases and conditions as we are. Competitive products from other companies could significantly reduce the market acceptance of our products.

The markets in which we compete are well-established and intensely competitive. We may be unable to compete successfully against our current and future competitors. Our failure to compete successfully may result in pricing reductions, reduced gross margins and failure to achieve market acceptance for our potential products. Our competitors include pharmaceutical companies, biotechnology companies, chemical companies, academic and research institutions and government agencies. For example, many pharmaceutical and biotechnology companies have initiated research programs similar to ours. Many of these organizations have substantially more experience and more capital, research and development, regulatory, manufacturing, sales, marketing, human and other resources than we do. As a result, they may: |X| develop products that are safer or more effective than our product candidates; |X| obtain FDA and other regulatory approvals or reach the market with their products; |X| more rapidly than we can, reducing the potential sales of our product candidates; |X| devote greater resources to market or sell their products; |X| adapt more quickly to new technologies and scientific advances; |X| initiate or withstand substantial price competition more successfully than we can; |X| have greater success in recruiting skilled scientific workers from the limited pool of available talent; |X| more effectively negotiate third-party licensing and collaboration arrangements; and |X| take advantage of acquisition or other opportunities more readily than we can. In addition, our product candidates, if approved and commercialized, will compete against well-established existing therapeutic products that are currently reimbursed by government health administration authorities, private health insurers and health maintenance organizations. We face and will continue to face intense competition from other companies for collaborative arrangements with pharmaceutical and biotechnology companies, for relationships with academic and research institutions and for licenses to proprietary technology. In addition, we anticipate that we will face increased competition in the future as new companies enter our markets and as scientific developments continue to expand the understanding of various diseases. While we will seek to expand our technological capabilities to remain competitive, research and development by others may render our technology or product candidates obsolete or noncompetitive or result in treatments or cures superior to any therapy developed by us. If we are unable to protect our intellectual property rights adequately, the value of our potential products could be diminished. Our success is dependent in part on obtaining, maintaining and enforcing our patents and other proprietary rights. Patent law relating to the scope of claims in the biotechnology field in which we operate is still evolving and surrounded by a great deal of uncertainty. Accordingly, we cannot assure you that our pending patent applications will result in issued patents. Because certain U.S. patent applications may be maintained in secrecy until a patent issues, we cannot assure you that others have not filed patent applications for technology covered by our pending applications or that we were the first to invent the technology. Other companies, universities and research institutions have or may obtain patents and patent applications

that could limit our ability to use, manufacture, market or sell our product candidates or impair our competitive position. As a result, we may have to obtain licenses from other parties before we could continue using, manufacturing, marketing or selling our potential products. Any such licenses may not be available on commercially acceptable terms, if at all. If we do not obtain required licenses, we may not be able to market our potential products at all or we may encounter significant delays in product development while we redesign potentially infringing products or methods. In addition, although we own a number of patents, including issued patents and patent applications relating to Natrecor(R)and certain of our p38 kinase inhibitors, the issuance of a patent is not conclusive as to its validity or enforceability, and third parties may challenge the validity or enforceability of our patents. We cannot assure you how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court or in other proceedings. It is possible that a competitor may successfully challenge our patents or that challenges will result in limitations of their coverage. In addition, the cost of litigation to uphold the validity of patents can be substantial. If we are unsuccessful in such litigation, third parties may be able to use our patented technologies without paying licensing fees or royalties to us. Moreover, competitors may infringe our patents or successfully avoid them through design innovation. To prevent infringement or unauthorized use, we may need to file infringement claims, which are expensive and time- consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or may refuse to stop the other party from using the technology at issue on the grounds that its technology is not covered by our patents. Policing unauthorized use of our intellectual property is difficult, and we cannot assure you that we will be able to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. In addition to our patented technology, we also rely on unpatented technology, trade secrets and confidential information. We may not be able to effectively protect our rights to this technology or information. Other parties may independently develop substantially equivalent information and techniques or otherwise gain access to or disclose our technology. We require each of our employees, consultants and corporate partners to execute a confidentiality agreement at the commencement of an employment, consulting or collaborative relationship with us. However, these agreements may not provide effective protection of our technology or information or, in the event of unauthorized use or disclosure, they may not provide adequate remedies. If we fail to negotiate or maintain successful arrangements with third parties, our development and marketing activities may be delayed or reduced. We have entered into, and we expect to enter into in the future, arrangements with third parties to perform research, development, regulatory compliance, manufacturing or marketing activities relating to some or all of our product candidates. If we fail to secure or maintain successful collaborative arrangements, our development and marketing activities may be delayed or reduced. We may be unable to negotiate favorable collaborative arrangements that, if necessary, modify our existing arrangements on acceptable terms. Most of our agreements can be terminated under certain conditions by our partners. In addition, our partners may separately pursue competing products, therapeutic approaches or technologies to develop treatments for the diseases targeted by us or our efforts. Even if our partners continue their contributions to the collaborative arrangements, they may nevertheless determine not to actively pursue the development or commercialization of any resulting products. Also, our partners may fail to perform their obligations under the collaborative arrangements or may be slow in performing their obligations. In these circumstances, our ability to develop and market potential products could be severely limited.

Risks Related to our Industry

We face uncertainties over reimbursement and healthcare reform. In both domestic and foreign markets, future sales of our potential products, if any, will depend in part on the availability of reimbursement from third-party payors such as government health administration authorities, private health insurers and other organizations. Third-party payors are increasingly challenging the price and cost- effectiveness of medical products and services. Significant uncertainty exists as to the reimbursement status of newly-approved health care products. Even if we were to obtain regulatory approval, our product candidates may not be considered cost-effective and adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investments in product development. Legislation and regulations affecting the pricing of pharmaceuticals may change before any of our product candidates is approved for marketing. Adoption of such legislation and regulations could further limit reimbursement for medical products and services. If the government and third-party payors fail to provide adequate

coverage and reimbursement rates for our potential products, the market acceptance of our products may be adversely affected. We may be required to defend lawsuits or pay damages in connection with the alleged or actual harm caused by our product candidates. We face an inherent business risk of exposure to product liability claims in the event that the use of our product candidates is alleged to have resulted in harm to others. This risk exists in clinical trials as well as in commercial distribution. In addition, the pharmaceutical and biotechnology industries in general have been subject to significant medical malpractice litigation. We may incur significant liability if product liability or malpractice lawsuits against us are successful. Although we maintain product liability insurance, we cannot be sure that this coverage is adequate or that it will continue to be available to us on acceptable terms. We use hazardous materials in our business, and any claims relating to improper handling storage or disposal of these materials could harm our business. Our research and development activities involve the controlled use of hazardous materials, chemicals, biological agents and radioactive compounds. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by such laws and regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any resulting damages, and any such liability could exceed our resources. We may be required to incur significant costs to comply with these laws in the future. Failure to comply with these laws could result in fines and the revocation of permits, which could prevent us from conducting our business.

Our stock price continues to experience large fluctuations, and you could lose some or all of your investment.

The market price of our stock has been and is likely to continue to be highly volatile. These price fluctuations have been rapid and severe. The market price of our common stock may fluctuate significantly in response to the following factors, most of which are beyond our control: |X| variations in our quarterly operating results; |X| changes in securities analysts 'estimates of our financial performance; |X| changes in market valuations of similar companies; |X| announcements by us or our competitors of significant contracts; |X| acquisitions, strategic partnerships, joint ventures or capital commitments; |X| additions or departures of key personnel; |X| future sales of common stock; |X| announcements by us or our competitors of technological innovations of new therapeutic products, clinical trial results and developments in patent or other proprietary rights; |X| announcements regarding government regulations, public concern as to the safety of drugs developed by us or others or changes in reimbursement policies; and

|X| fluctuations in stock market price and volume, which are particularly common among securities of biopharmaceutical companies.

We are at risk of securities class action litigation. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology companies have experienced greater than average stock price volatility in recent years. Several years ago, we were the subject of a securities class action lawsuit, which was eventually dismissed with a determination that the plaintiffs had no basis for their claim. If we face such litigation in the future, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

We have implemented provisions in our charter documents that may ultimately delay, discourage or prevent a change in our management or control of us.

Our certificate of incorporation and bylaws contain provisions that could make it more difficult for our stockholders to replace or remove our directors or to effect any other corporate action. These provisions include those which: |X| prohibit holders of less than ten percent of our outstanding capital stock from calling special meetings of stockholders; |X| prohibit stockholder action by written consent, thereby requiring stockholder actions to be taken at a meeting of our stockholders; and

|X| establish advance notice requirements for nominations for election to the board of directors or for proposing matters than can be acted upon by stockholders at stockholder meetings.

Moreover, our certificate of incorporation does not provide for cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates. Some of the above provisions may also have possible anti-takeover effects, which may make an acquisition of us by a third party more difficult, even if such an acquisition could be beneficial to our stockholders. In addition, our certificate of incorporation also authorizes us to issue up to 20,000,000 shares of preferred stock in one or more different series with terms to be determined by our board of directors at time of issuance. As of March 31, 2001, an aggregate of 71,053 shares of preferred stock had been reserved for issuance by the board of directors and 4,991 preferred shares were issued and outstanding. Issuance of other shares of preferred stock could also be used as an anti-takeover device.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

We are exposed to a variety of risks, including changes in interest rates affecting the return on our investments and foreign currency fluctuations. In the normal course of our business, we employ established policies and procedures to manage our exposure to fluctuations in interest rates and foreign currency values. Our exposure to market rate risk for changes in interest rates relates primarily to our investment portfolio. We attempt to place our investments with high quality issuers and, by policy, limit the amount of credit exposure to any one issuer and do not use derivative financial instruments in our investment portfolio. We maintain an investment portfolio of various issuers, types and maturities, which consist of both fixed and variable rate financial instruments. These securities are classified as available-for-sale, and consequently, are recorded on the balance sheet at fair value with unrealized gains or losses reported as a separate component in stockholders' equity, net of applicable taxes. At any time, sharp changes in interest rates can affect the value of our investment portfolio and its interest earnings. Currently, we do not hedge these interest rate exposures. However, through our money manager, we maintain management control systems to monitor interest rate risk. The risk management control systems use analytical techniques as well as other procedures to review interest rate risk. Assuming a hypothetical interest rate increase of 10%, the fair value of our total investment portfolio as of March 31, 2001 would have potentially incurred a loss of $263,000. Our exposure to foreign currency fluctuations is currently limited to our supply contract for Natrecor(R), which is denominated in German Marks. Changes in the exchange rate between German Marks and the U.S. dollar could adversely affect our manufacturing costs. All of our other contracts are denominated in U.S. dollars. Exposure to foreign currency exchange rate risk may change over time as our business evolves and our products are introduced into international markets. Currently, we do not hedge against any foreign currencies and, as a result, could incur unanticipated gains or losses.

PART II. OTHER INFORMATION

Item 4. Submission of Matters to a Vote of Security Holders Our Annual Meeting of Stockholders was held on May 8, 2001.

(a) The following individuals were elected directors of Scios, each to serve until the Annual Meeting of Stockholders in 2002:

Name		Total Vote For Each Director	Total Vote With From Each Direc
Samuel H. Armacost		35,072,131	1
Richard B. Brewer	35,064,818	1,380,473	
Randal J. Kirk		34,955,102	1
Donald B. Rice, Ph.D.		35,070,778	1
Charles A. Sanders, M.D.	35,042,005	1,403,286	
Solomon H. Snyder, M.D.	35,073,989	1,371,302	
Burton E. Sobel, M.D.		35,071,225	1
Eugene L. Step	35,064,182	1,381,109	

(b) The following matters were submitted and each was approved by our stockholders, indicated:

o To approve an amendment to our 1992 Equity Incentive Plan:

Votes cast for:	31
Votes cast against:	4
Abstentions:	

o To approve adoption of our 2001 Employee Stock Purchase Plan:

Votes cast for:	3
Votes cast against:	
Abstentions:	

="Times New Roman, Times, Serif" SIZE=2>o To ratify the selection of PricewaterhouseCoopers LLP as our independent accountant for fiscal 2001:

Votes cast for:	3
Votes cast against:	
Abstentions:	

Item 6. Exhibits and Reports on Form 8-K (a) Exhibits None (b) Reports on Form 8-K None 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, thereunto duly authorized. SCIOS INC. May 15, 2001 By: /s/ Richard B. Brewer ---------- Richard B. Brewer, President and CEO May 15, 2001 By: /s/ David W. Gryska ---------- David W. Gryska, Senior Vice President and CFO 2