

SCIOS INC
Form 10-Q
May 14, 2003

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2003

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
(State or other jurisdiction of

95-3701481
(I.R.S. Employer

Edgar Filing: SCIOS INC - Form 10-Q

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 No

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes No

Number of shares outstanding of the issuer's common stock, par value \$.01 per share, as of May 14, 2003: 100

Part I**Item 1. Financial Statements****SCIOS INC.****Consolidated Balance Sheets**

(in thousands, except share data)

	March 31, 2003	December 31, 2002
	<u>(Unaudited)</u>	
Assets		
Current assets:		
Cash and cash equivalents	\$ 15,794	\$ 32,174
Marketable securities	15,547	18,504
Restricted marketable securities	8,166	8,435
Accounts receivable, net	17,679	16,395
Inventory	8,092	8,179
Prepaid expenses and other assets	8,202	6,569
	<u>73,480</u>	<u>90,256</u>
Total current assets	73,480	90,256
Marketable securities, non-current	122,314	121,340
Restricted marketable securities, non-current	11,817	15,791
Property and equipment, net	11,662	10,089
Other assets	7,598	7,843
	<u>226,871</u>	<u>245,319</u>
Total assets	\$ 226,871	\$ 245,319
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	\$ 5,894	\$ 11,150
Accrued employee compensation	11,572	20,731
Other accrued liabilities	10,185	11,807
Deferred contract revenue	2,632	1,166
Accrued interest payable	1,031	3,323
Current portion of long-term debt	22,854	25,561
	<u>54,168</u>	<u>73,738</u>
Total current liabilities	54,168	73,738
Deferred contract revenue	1,558	3,116
Long-term debt	159,829	159,624
Other long-term liabilities	3,113	2,245
	<u>218,668</u>	<u>238,723</u>
Total liabilities	218,668	238,723

Edgar Filing: SCIOS INC - Form 10-Q

Stockholders' equity:		
Preferred stock; \$.001 par value; 20,000,000 shares authorized; 4,991 issued and outstanding		
Common stock; \$.001 par value; 150,000,000 shares authorized; 47,710,446 and 47,200,660 shares issued, respectively; 47,448,646 and 46,938,860 shares outstanding, respectively		
	48	47
Additional paid-in capital	583,960	575,935
Treasury stock; shares of 261,800 and 261,800 respectively	(6,014)	(6,014)
Deferred warrant costs	(1,097)	(2,194)
Accumulated other comprehensive income	427	832
Accumulated deficit	(569,121)	(562,010)
	<u> </u>	<u> </u>
Total stockholders' equity	8,203	6,596
	<u> </u>	<u> </u>
Total liabilities and stockholders' equity	\$ 226,871	\$ 245,319
	<u> </u>	<u> </u>

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

SCIOS INC.

Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)

	Three months ended	
	March 31,	
	2003	2002
	(Unaudited)	
Revenues:		
Product sales	\$ 50,368	\$ 15,373
Research and development contracts and royalties	2,236	1,071
	<u>52,604</u>	<u>16,444</u>
Costs and expenses:		
Cost of product sales	2,825	1,011
Research and development	18,949	14,855
Selling, general and administration	29,864	24,714
	<u>51,638</u>	<u>40,580</u>
Gain (loss) from operations	966	(24,136)
Other income (expense):		
Interest income	1,053	808
Interest expense	(9,370)	(1,944)
Realized gains on securities	301	(77)
Other income (expense)	(61)	127
	<u>(8,077)</u>	<u>(1,086)</u>
Net loss	(7,111)	(25,222)
Other comprehensive gain (loss)		
Change in net unrealized gains on securities	(405)	(431)
Comprehensive loss	<u>\$ (7,516)</u>	<u>\$ (25,653)</u>
Net loss per common share:		
Basic and diluted	\$ (0.15)	\$ (0.55)
Weighted average number of common shares outstanding used in calculation of:		
Basic and diluted	47,210,552	46,091,188

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

SCIOS INC.

Consolidated Statements of Cash Flows

(in thousands)

	Three months ended March 31,	
	2003	2002
	(Unaudited)	
Cash flows from operating activities:		
Net loss	\$ (7,111)	\$ (25,222)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,207	1,163
Amortization of debt discount	1,558	311
Amortization of debt issue costs	190	
Accretion of discount on restricted marketable securities	(111)	
(Gain) loss on disposal of marketable securities	(301)	77
Accrued interest payable	7,622	1,634
Loss on disposal of property and equipment		75
Allowance for bad debt		55
Stock options issued to non-employee for services rendered	68	47
Changes in assets and liabilities:		
Accounts receivable	(1,284)	(2,694)
Inventory	87	(38)
Prepaid expenses and other assets	(1,578)	2,623
Accounts payable	(5,256)	(3,790)
Accrued employee compensation	(9,159)	(2,038)
Accrued expenses and other liabilities	(754)	1,922
Deferred contract revenue	(92)	4,873
Net cash used in operating activities	(14,914)	(21,002)
Cash flows from investing activities:		
Purchases of property and equipment	(2,780)	(962)
Sales/maturities of marketable securities	62,547	116,795
Purchases of marketable securities	(60,668)	(113,207)
Sales of restricted marketable securities	4,354	
Net cash provided by investing activities	3,453	2,626
Cash flows from financing activities:		
Issuance of common stock	7,958	1,489
Purchase of treasury stock		(199)
Payment of interest on convertible notes	(4,354)	
Proceeds from commercialization agreement	3,230	3,750
Payment of commercialization agreement	(11,753)	(928)
Net cash provided by (used in) financing activities	(4,919)	4,112
Net decrease in cash and cash equivalents	(16,380)	(14,264)

Edgar Filing: SCIOS INC - Form 10-Q

Cash and cash equivalents at beginning of period	32,174	58,296
Cash and cash equivalents at end of period	<u>\$ 15,794</u>	<u>\$ 44,032</u>
Supplemental cash flow data:		
Cash paid during the period for interest	\$ 16,107	\$ 928
Change in net unrealized gains on securities	\$ (405)	\$ (431)
Discount on commercialization obligation	\$ 1,558	\$ 311
Warrant issued in connection with commercialization agreement	\$ (1,097)	\$ (1,274)

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

SCIOS INC.

Notes to Consolidated Financial Statements

(unaudited)

1. Basis of Presentation

The accompanying unaudited consolidated financial statements of Scios have been prepared in accordance with accounting principles generally accepted in the United States of America 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 accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, the accompanying unaudited consolidated financial statements reflect all adjustments (consisting of normal, recurring adjustments) considered necessary for a fair presentation of Scios' interim unaudited consolidated financial information. These unaudited 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, 2002.

The results of operations for the three month period ended March 31, 2003 are not necessarily indicative of the operating results that may be reported for the fiscal year ending December 31, 2003, or for any other future period.

2. Acquisition by Johnson & Johnson

On April 29, 2003, Scios became a wholly owned subsidiary of Johnson & Johnson through the merger of Saturn Merger Sub, Inc., a wholly owned subsidiary of Johnson & Johnson, with and into Scios. In connection with the merger each outstanding share of Scios common stock was converted into the right to receive \$45.00 in cash, and each outstanding share of Scios series B preferred stock was converted into the right to receive \$4,500.00 in cash. In addition, each outstanding stock option issued pursuant to Scios' stock option plans will no longer be exercisable for shares of Scios common stock, but instead will constitute an option to acquire shares of Johnson & Johnson common stock.

3. Computation of Loss Per Share

Basic net loss per share is computed by dividing net loss available to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed using the weighted-average number of common and potentially dilutive common shares outstanding during the period using the treasury stock method. Potentially dilutive common shares include the effect of stock options, the effect of warrants granted to PharmaBio in connection with the sales and marketing agreement with Innovex, the conversion of series B preferred stock issued to repay \$5.0 million of the Genentech loan in 2000 and the conversion of the subordinated convertible notes.

The following items were not included in the calculation of diluted net loss per share for the three months ended March 31, 2003 and 2002, as they were considered antidilutive due to the net loss the Company experienced in these fiscal periods.

Edgar Filing: SCIOS INC - Form 10-Q

	At March 31,	
	2003	2002
Outstanding stock options	8,922,173	8,199,312
Warrants to purchase 700,000 shares of common stock granted to PharmaBio with an exercise price of \$20.00	700,000	700,000
Conversion of series B preferred stock issued to Genentech, 4,991 shares with a conversion rate of 100:1	499,100	499,100
Conversion of convertible notes, principal amount of \$150.0 million at a conversion price of \$39.30 per share	3,816,794	
	<u>13,938,067</u>	<u>9,398,412</u>

As a result of the acquisition of Scios by Johnson & Johnson, the Scios warrants and series B preferred stock are no longer outstanding. In addition, as a result of the acquisition each outstanding stock option issued pursuant to Scios' s stock option plans

is no longer exercisable for shares of Scios common stock, but instead constitutes an option to acquire shares of Johnson & Johnson common stock. In connection with the acquisition, each \$1,000 principal amount of the convertible notes became convertible only into the right to receive \$1,145.04 in cash without interest.

4. Stock-Based Compensation

The Company accounts for stock-based employee compensation using the intrinsic value method under APB 25 and related interpretations and complies with the disclosure provisions of SFAS 123 and SFAS 148. The following table illustrates the effect on net loss and net loss per common share if the Company had applied the fair value recognition provisions of SFAS 123 to stock-based employee compensation:

	Three months ended	
	March 31,	
	2003	2002
<i>(in thousands, except per share amounts)</i>		
Net loss, as reported	\$ (7,111)	\$ (25,222)
Add: Stock-based employee compensation expense included in reported net earnings	68	47
Deduct: Total stock-based employee compensation determined under fair value based method for all awards	(6,162)	(5,623)
Pro forma net loss	\$ (13,205)	\$ (30,798)
Basic and diluted net loss per common share:		
As reported	\$ (0.15)	\$ (0.55)
Pro forma	\$ (0.28)	\$ (0.67)

5. GlaxoSmithKline Agreement

In March 2002, we entered into an agreement with GlaxoSmithKline, to license nesiritide to GlaxoSmithKline in all European markets. Under the terms of the agreement, GlaxoSmithKline will have the rights to sell and distribute the product for which we received an up-front fee of GB£3.5 million and may receive milestone payments of up to an additional GB£11.5 million, in addition to future royalties in the identified countries. The GB£3.5 million (which equaled approximately \$4.9 million), we received in March 2002 was recorded as deferred contract revenue. We are recognizing the \$4.9 million of up-front fees ratably over an estimated period of three years, which approximates the period in which we will incur the costs to assist GlaxoSmithKline in obtaining European approval to sell nesiritide. For the three months ended March 31, 2003, we recognized \$0.1 million of the \$4.9 million as revenue. As of March 31, 2003, we recognized \$0.7 million of the \$4.9 million as revenue. We will be responsible for the manufacture and supply of bulk active pharmaceutical ingredient to GlaxoSmithKline. The companies will work together to continue clinical development of nesiritide in Europe. In September 2002, GlaxoSmithKline submitted a Marketing Authorization Application for nesiritide with the European Agency for the Evaluation of Medicinal Products. GlaxoSmithKline expects to launch nesiritide in Europe in 2004.

6. Notes Receivable from Officers

Edgar Filing: SCIOS INC - Form 10-Q

At March 31, 2003, we had a note receivable from one officer in the amount of \$90,000 bearing interest at 10.0% per annum. This loan with an original principal amount of \$150,000 will be forgiven in five equal installments ending in January 2006 based on the continued employment of the officer and is collateralized by the officer's residence. As of March 31, 2003, the first and second installments of the loan totaling \$60,000 were forgiven. The loan was granted in connection with a housing subsidy for the officer to live in California.

7. Treasury stock

During September 2001, the Board of Directors authorized the repurchase of up to \$10.0 million of Scios common stock. In October 2002, the Board of Directors authorized an additional \$5.0 million for the repurchase of Scios common stock. The repurchases were made through open-market transactions at the discretion of management as market conditions warrant. At

March 31, 2003, there were 261,800 shares of treasury stock. Treasury stock is stated at cost on our consolidated balance sheet and is considered issued. As a result of the acquisition of Scios by Johnson & Johnson, all treasury stock of Scios was canceled.

8. Inventory

Inventory is stated at the lower of cost or market. Cost is determined using a weighted-average approach, which approximates the first-in, first-out method. Inventory consisted of the following:

	<u>March 31,</u> <u>2003</u>	<u>December 31,</u> <u>2002</u>
<i>(in thousands)</i>		
Finished goods	\$ 1,326	\$ 1,594
Work-in-process	1,873	2,095
Raw materials	4,893	4,490
	<u> </u>	<u> </u>
Total inventories	<u>\$ 8,092</u>	<u>\$ 8,179</u>

9. Long Term Debt

5.5% Convertible Subordinated Notes Due 2009

On August 5, 2002, we completed the sale of \$150.0 million of 5.5% convertible subordinated notes due August 15, 2009 through a private placement to qualified institutional buyers. Interest on the notes is payable semi-annually. The notes are unsecured except for the first six scheduled interest payments due on the notes. We pledged a portfolio of approximately \$24.0 million in U.S. government securities as collateral for the first six scheduled interest payments due on the notes. These marketable securities plus interest earned are included in the consolidated balance sheets as restricted marketable securities (current and non-current). In February 2003, we used the proceeds from the sale of restricted marketable securities to fund the first semiannual interest payment of \$4.4 million. We have the option to redeem all or a portion the notes between August 19, 2005 and August 14, 2009, at declining redemption prices ranging from 103.14% to 100.79% of the original principal amount plus accrued interest. In connection with the acquisition of Scios by Johnson & Johnson, each \$1,000 principal amount of the notes became convertible only into the right to receive \$1,145.04 in cash without interest, and Johnson & Johnson issued its subordinated guarantee of the notes.

Quintiles/PharmaBio Funding

In January 2001, we entered into a commercialization agreement with Innovex, a subsidiary of Quintiles. The corporate venture group of Quintiles, PharmaBio, agreed to fund \$30.0 million of our costs to launch Natrecor over 24 months and to loan us up to \$5.0 million. In addition, we granted PharmaBio a fully vested warrant to purchase 700,000 shares of Scios common stock at \$20.00 per share. In November 2001, Scios and PharmaBio amended the January 2001 agreement. The amendment eliminated the \$5.0 million line of credit, among other things. The warrant to purchase 700,000 shares of Scios common stock was exercisable over seven installments beginning December 2001 through May 2003. In December 2002, we agreed with Innovex to allow for the immediate conversion of the leased Natrecor sales force to Scios employees. In connection with the conversion of the sales force, we agreed to give PharmaBio the ability to immediately exercise the installments of their

Edgar Filing: SCIOS INC - Form 10-Q

warrant that otherwise would have become exercisable through May 2003. In connection with the acquisition of Scios by Johnson & Johnson, the warrant was canceled and is no longer outstanding. As of March 31, 2003, we have received \$26.8 million of the \$30.0 million funding commitment and will receive the remaining \$3.2 million in May 2003. As part of the funding agreement, we will pay PharmaBio a declining royalty, up to a maximum of \$65.0 million, on net sales of Natrecor in the United States and Canada through early 2008.

The accounting treatment of the commercialization payments of \$30.0 million from PharmaBio falls under the guidance of Emerging Issues Task Force 88-18 (EITF 88-18), Sales of Future Revenues. EITF 88-18 addresses the accounting treatment when an enterprise (Scios) receives cash from an investor (PharmaBio) and agrees to pay to the investor for a defined period a specified percentage or amount of the revenue or a measure of income of a particular product line, business segment, trademark, patent, or contractual right. The Emerging Issues Task Force reached a consensus on six independent factors that would require reclassification of the proceeds as debt. As we meet one of the factors whereby we have significant continuing involvement in the generation of the cash flows due to the investor, we have recorded the proceeds from PharmaBio of \$26.8 million as of March 31, 2003, as long-term debt and will reduce the debt principal and accrued interest as the royalty payments are made. Interest on the

debt (net of the discount) will accrue monthly using the effective interest method beginning January 2002 and total interest will be adjusted based on the periodic adjustments made on the overall expected royalty. For the three months ended March 31, 2003 and 2002, interest expense associated with the royalty obligation to PharmaBio was \$5.4 million and \$1.1 million, respectively.

The accounting treatment for the warrant to purchase 700,000 shares of Scios common stock is under APB 14, Accounting for Convertible Debt issued With Stock Purchase Warrants. Under APB 14, the total expected net proceeds received of \$30.0 million were allocated between the debt and the warrant based upon the relative fair value of the two components. The relative fair value of the warrants related to the debt, using the Black-Scholes model, was \$10.2 million. At March 31, 2003, \$9.1 million of the total value of the warrants was recognized as a discount related to the debt based on the portion of the cash funding received from PharmaBio as of March 31, 2003. The remaining balance of \$1.1 million is recorded as deferred warrant costs in the stockholders' equity section. The \$1.1 million in deferred warrant costs will be recorded as discount on debt as the remaining \$3.2 million in funding is received from PharmaBio in May 2003. The total value of the warrants of \$10.2 million will be amortized to interest expense using the effective interest method over the life of the royalty payment stream. For the three months ended March 31, 2003 and 2002, interest expense associated with the amortization of the PharmaBio debt discount was \$1.6 million and \$0.3 million, respectively.

10. Recent Accounting Pronouncements

In November 2002, the Emerging Issues Task Force (EITF) reached a consensus on Issue No. 00-21 (EITF 00-21), Revenue Arrangements with Multiple Deliverables. EITF 00-21 provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF 00-21 will apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. We believe that the adoption of EITF 00-21 will not have a material impact on Scios' financial position or results of operations.

In January 2003, the FASB issued FASB Interpretation No. 46 (FIN 46), Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51. FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective immediately for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provision of FIN 46 must be applied for the first interim or annual period beginning after June 15, 2003. We are currently evaluating the impact, if any, that the adoption of FIN 46 will have on Scios' financial position or results of operations.

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, 2002. 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

Edgar Filing: SCIOS INC - Form 10-Q

We are a biopharmaceutical company that discovers, develops and markets novel treatments for cardiovascular and inflammatory diseases. On August 13, 2001, we launched Natrecor (nesiritide) following FDA approval of Natrecor for the treatment of acutely decompensated congestive heart failure. In addition to Natrecor, we have two focused research and development product programs, p38 kinase and TGF-beta. Our first program is directed to the development of inhibitors of p38 kinase, an enzyme responsible for increased production of various proteins that cause inflammation. SCIO-469, our first compound designed to inhibit this enzyme, is targeted for the treatment of rheumatoid arthritis and is currently in clinical development. SCIO-323, our second-generation inhibitor of p38 kinase, commenced clinical development in December 2002. Our second product program is directed to the development of inhibitors of TGF-beta, a signaling protein that is implicated in a broad range of diseases characterized by unregulated scarring and eventual organ failure. We are currently in preclinical development for compounds designed to inhibit this protein. In July 2002, we announced that the lead indication for these compounds will be chronic obstructive pulmonary disease.

Acquisition by Johnson & Johnson

On April 29, 2003, Scios became a wholly owned subsidiary of Johnson & Johnson through the merger of Saturn Merger Sub, Inc., a wholly owned subsidiary of Johnson & Johnson, with and into Scios. In connection with the merger each outstanding share of Scios common stock was converted into the right to receive \$45.00 in cash, and each outstanding share of Scios series B preferred stock was converted into the right to receive \$4,500.00 in cash. In addition, each outstanding stock option issued pursuant to Scios' stock option plans will no longer be exercisable for shares of Scios common stock, but instead will constitute an option to acquire shares of Johnson & Johnson common stock.

Results of Operations

Three Months Ended March 31, 2003 and 2002

Revenues

Product Sales. Product sales for the three months ended March 31, 2003 were \$50.4 million versus \$15.4 million for the three months ended March 31, 2002. The increase of \$35.0 million was mainly due to increased demand for Natrecor and, to a lesser extent, inventory build-up by our wholesaler customers in anticipation of a price increase in the second quarter of 2003.

Research and Development Contracts and Royalties. Research and development contracts and royalties were \$2.2 million for the three months ended March 31, 2003 and \$1.1 million for the three months ended March 31, 2002. For the three months ended March 31, 2003, research and development contract and royalty revenues primarily consisted of \$1.1 million of royalties from Biosite on sales of diagnostic tests for BNP levels, \$1.0 million of royalties from Kaken on sales of Fiblast Spray in Japan and \$0.1 million of recognized deferred contract revenue related to the GlaxoSmithKline commercialization agreement. For the three months ended March 31, 2002, research and development contract and royalty revenues included \$0.6 million of royalties from Kaken, \$0.1 million from Biosite and \$0.4 million of other royalties.

Costs and Expenses

Cost of Product Sales. Cost of product sales were \$2.8 million for the three months ended March 31, 2003 and \$1.0 million for the three months ended March 31, 2002. The increase was primarily due to increased sales volume of Natrecor. Cost of Natrecor sales consist primarily of third-party product manufacturing and distribution costs, manufacturing overhead and royalties on a cross license agreement with Shionogi.

Research and Development. Research and development expenses were \$18.9 million and \$14.9 million for the three months ended March 31, 2003 and 2002, respectively. The increase of \$4.0 million in research and development expenses was mainly attributable to higher clinical expenses related to Natrecor, higher research and clinical expenses related to our p38 kinase inhibitor program, higher pre-clinical development expenses for our TGF-beta program and increased headcount in research and development.

Edgar Filing: SCIOS INC - Form 10-Q

Selling, General and Administration. Selling, general and administration expenses were \$29.9 million and \$24.7 million for the three months ended March 31, 2003 and 2002, respectively. The increase of \$5.2 million was primarily due to increase in overall selling and marketing expenses associated with sales of Natrecor and the addition of general and administrative staff to support the growth of the company. Sales and marketing expenses include the cost of a 189-person sales force and management team, the addition of a sales operations group, the commissions to the sales force on Natrecor sales, the expenses of promotional and marketing programs, and the ADHERE Registry, a nationwide registry to collect and analyze demographic and treatment data about patients hospitalized due to acutely decompensated heart failure.

Other Income (Expense)

Net other expense was \$8.1 million and \$1.1 million for the three months ended March 31, 2003 and 2002, respectively. The increase of \$7.0 million in net other expense was primarily due to an increase of \$7.5 million in interest expense, partially offset by an increase of \$0.2 million in interest income and a \$0.4 million increase in realized gain on sale of marketable securities. The increase in interest expense was mainly due to a \$5.5 million increase in interest expense recognized in connection with the sales and marketing agreement with Innovex and \$2.0 million of interest expense on the \$150.0 million of convertible notes issued in August 2002. The increase in interest expense recognized in connection with the Innovex sale and marketing agreement reflects increased royalty obligation to PharmaBio, an affiliate of Innovex, as a result of higher net product sales of Natrecor in the three months ended March 31, 2003 as compared to net Natrecor sales in the three months ended March 31, 2002. See Note 9 of Notes to Consolidated Financial Statements for details of the funding from PharmaBio. The increase in interest income was the result of higher interest-bearing investment balances associated with higher average cash, cash equivalent and marketable security balances partially offset by lower average interest rates.

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, convertible subordinated notes, research and development partnerships, collaborative agreements with pharmaceutical firms, product sales and investment income. Excluding \$20.0 million of restricted marketable securities, our combined cash, cash equivalents and marketable securities (both current and non-current) totaled \$153.7 million at March 31, 2003.

On August 5, 2002, we completed the sale of \$150.0 million of 5.5% convertible subordinated notes due August 15, 2009 through a private placement to qualified institutional buyers. Interest on the notes is payable semi-annually. The notes are unsecured except for the first six scheduled interest payments due on the notes. We pledged a portfolio of approximately \$24.0 million in U.S. government securities as collateral for the first six scheduled interest payments due on the notes. These marketable securities plus interest earned are included in the consolidated balance sheet as restricted marketable securities. In February 2003, we used the proceeds from the sale of restricted marketable securities to fund the first semiannual interest payment of \$4.4 million. We have the option to redeem all or a portion the notes between August 19, 2005 and August 14, 2009 at declining redemption prices ranging from 103.14% to 100.79% of the original principal amount plus accrued interest. In connection with the acquisition of Scios by Johnson & Johnson, each \$1,000 principal amount of the notes became convertible only into the right to receive \$1,145.04 in cash without interest, and Johnson & Johnson issued its subordinated guarantee of the notes. In August and September of 2002, we used \$34.1 million of the proceeds to pay off outstanding debt and accrued interest due to Genentech. We intend to use the remaining amount for general corporate purposes.

In January 2001, we entered into a sale and marketing alliance with Innovex, a subsidiary of Quintiles, which we later amended in November 2001. As part of the agreement, PharmaBio, an affiliate of Innovex, agreed to fund a total of \$30.0 million of our costs to launch Natrecor at set intervals through May 30, 2003. The agreement also grants us the option to assume control of the Natrecor sales force from Innovex in June 2003, and we informed PharmaBio and Innovex of our intention to assume such control in June 2002. Of the \$30.0 million funding from PharmaBio, we received \$26.8 million through March 31, 2003 and will receive the remaining \$3.2 million in May 2003. As part of the funding agreement, we pay PharmaBio a declining royalty, up to a maximum of \$65.0 million, on net sales of Natrecor in the United States and Canada through early 2008. As of March 31, 2003, we have paid PharmaBio \$12.7 million in royalties. We also granted PharmaBio a fully vested warrant to purchase 700,000 shares of Scios common stock at an exercise price of \$20.00 per share. In December 2002, we agreed with Innovex to allow for the immediate conversion of the leased Natrecor sales force to Scios employees. In connection with the conversion of the sales force, we recognized in December 2002 approximately \$2.4 million in fees that were otherwise due to Innovex through May 2003. We also agreed to give PharmaBio the ability to immediately exercise the installments of their warrant that otherwise would have become exercisable through May 2003. In connection with the acquisition of Scios by Johnson & Johnson, we paid PharmaBio \$17.5 million in May 2003, representing the difference between the acquisition price of Scios of \$45.00 per share and the per share exercise price of the warrant of \$20.00. As of May 14, 2003, the warrant was canceled and is no longer outstanding.

In March 2002, we finalized an agreement with GlaxoSmithKline to license nesiritide to GlaxoSmithKline in all European markets. Under the terms of the agreement, GlaxoSmithKline has the rights to sell and distribute the product for which we received an up-front fee of GB£3.5 million and may receive milestone payments of up to an additional GB£11.5 million. In addition, we will receive royalties on future sales of nesiritide in the identified countries. The GB£3.5 million (which equaled approximately \$4.9 million U.S. dollars) we received in March 2002 has been recorded as deferred contract revenue. We will be responsible for the manufacture and supply of bulk active pharmaceutical ingredient to GlaxoSmithKline. The companies will work together to continue clinical development of nesiritide in Europe. In September 2002, GlaxoSmithKline submitted a Marketing Authorization Application for nesiritide with the European Agency for the Evaluation of Medicinal Products. GlaxoSmithKline expects to launch nesiritide in Europe in 2004.

We lease four facilities in Sunnyvale, California with agreements that expire between 2003 and 2008. In addition, we lease a warehouse in Union City, California that expires in 2005. In August 2002, we entered into two lease agreements, which expire in August 2017, to lease two buildings totaling 190,000 square feet in Fremont, California as our new corporate headquarters. We plan to move our operations in the Sunnyvale facilities to the new Fremont headquarters, and we expect the move to be completed by the end of 2003. We are currently in

Edgar Filing: SCIOS INC - Form 10-Q

discussion with our landlord to lease an additional 100,000 square feet at the Fremont campus site. While most of our current leases expire in December 2003, we have two leases that expire in 2008. We are in the process of evaluating our future needs of these two leases totaling 52,000 square feet. The company also has operating leases covering certain laboratory and computer equipment.

We have a \$7.5 million promissory note with Chiron due on December 31, 2006. The note and related interest will be forgiven if Fiblast is approved by the FDA in the United States before December 31, 2006.

Net cash used in operating activities of \$14.9 million in the three months ended March 31, 2003 was primarily attributable to the net loss of \$7.1 million, a decrease in net operating assets of \$18.0 million, partially offset by accrued interest expense of \$7.6 million, amortization of debt discount of \$1.6 million and depreciation of \$1.2 million.

Net cash provided by investing activities of \$3.5 million in the three months ended March 31, 2003 was mainly due to sales/maturities of marketable securities of \$62.5 million and the sales of restricted marketable securities of \$4.4 million, partially offset by purchases of marketable securities of \$60.7 million and purchases of property and equipment of \$2.8 million.

Net cash used in financing activities of \$4.9 million in the three months ended March 31, 2003 was due to the payments to PharmaBio under the commercialization agreement of \$11.8 million and the first interest payment on the convertible notes of \$4.4 million, partially offset by proceeds from the issuance of common stock of \$8.0 million through the exercise of employee stock options under our option plans and the funding from PharmaBio related to the Innovex commercialization agreement of \$3.3 million.

To finance our current and planned operations, we have used proceeds from existing collaborations, our agreement with PharmaBio, our marketing agreement with GlaxoSmithKline and revenues from sales of Natrecor.

Contractual Obligations and Significant Commercial Commitments. The following summarizes our approximate current contractual obligations as of March 31, 2003:

	Amounts Due by Period				Total
	(in thousands)				
	Less than 1 year	1-3 years	4-5 years	After 5 years	
Operating Lease Obligations	\$ 3,991	\$ 8,270	\$ 8,864	\$ 38,177	\$ 59,302
Long-Term Debt Obligations (1)	36,727	40,343	29,896	162,375	269,341
Manufacturing Purchase Obligations (2)	14,598	13,806	7,692	7,693	43,789
Total	\$ 55,316	\$ 62,419	\$ 46,452	\$ 208,245	\$ 372,432

(1) Long-term debt obligations include:

- a. 5.5% convertible subordinated notes with an aggregate principal amount outstanding of \$150.0 million due in 2009. Accrued interest is \$8.3 million due in one year, \$16.5 million due in one to three years and \$16.5 million due in four to five years. Principal amount and accrued interest due after five years is \$162.4 million. In connection with the acquisition of Scios by Johnson & Johnson, each \$1,000 principal amount of the notes became convertible only into the right to receive \$1,145.04 in cash without interest, and Johnson & Johnson issued its subordinated guarantee of the notes.

Edgar Filing: SCIOS INC - Form 10-Q

- b. Royalty obligation of up to \$52.3 million to PharmaBio, an affiliate of Innovex, in connection with the Innovex sales and marketing agreement. Royalty obligation due to PharmaBio is \$28.5 million in less than one year and \$23.8 million in one to three years.
 - c. Note payable and accrued interest of \$13.4 million due to Chiron in 2006.
- (2) Manufacturing purchase obligations include the minimum purchase commitments to BioChemie and the purchase obligation to Abbott Laboratories at March 31, 2003.

Recent Accounting Pronouncements

In November 2002, the Emerging Issues Task Force (EITF) reached a consensus on Issue No. 00-21 (EITF 00-21), Revenue Arrangements with Multiple Deliverables. EITF 00-21 provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF 00-21 will apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. We believe that the adoption of EITF 00-21 will not have a material impact on Scios' financial position or results of operations.

In January 2003, the FASB issued FASB Interpretation No. 46 (FIN 46), Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51. FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective immediately for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created

or acquired prior to February 1, 2003, the provision of FIN 46 must be applied for the first interim or annual period beginning after June 15, 2003. We are currently evaluating the impact, if any, that the adoption of FIN 46 will have on Scios' financial position or results of operations.

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.

If Natrecor does not continue to gain market acceptance, our business will suffer.

Natrecor may not continue to gain market acceptance among physicians, patients, healthcare payers and the medical community. We will need to educate doctors and other healthcare professionals about the safety and clinical efficacy of Natrecor and its potential advantages over other treatments. The degree of market acceptance of Natrecor will also depend on a number of factors, including:

the degree of clinical efficacy and safety;

cost-effectiveness of Natrecor;

its advantage over alternative treatment methods;

reimbursement policies of government and third party payers; and

future approval of competitive drugs, which work better or are safer.

Sales of Natrecor represented approximately 96% of our revenues for the three months ended March 31, 2003. Natrecor is the only product that we are currently marketing and our other product candidates are only in early stages of development. If market acceptance of Natrecor is limited, our revenues will suffer and we may not generate sufficient funds to meet our operating and capital requirements.

If the FDA determines that our third-party manufacturing facilities are not adequate, we may lose the ability to manufacture and sell Natrecor.

Periodically, the FDA is likely to inspect each of the facilities involved in manufacturing Natrecor. Natrecor bulk active pharmaceutical ingredient is manufactured for us by BioChemie GmbH, a subsidiary of Novartis, in Austria and is shipped 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 result in findings of deficiencies in the facilities or processes that may delay or prevent the manufacture or sale of Natrecor. If

Edgar Filing: SCIOS INC - Form 10-Q

deficiencies are identified, we may lose the ability to supply and sell Natrecor 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 Natrecor bulk drug substance and final drug product for clinical and commercial use. BioChemie is responsible for manufacturing the bulk active pharmaceutical ingredient of Natrecor and Abbott Laboratories is responsible for blending, filling and packaging Natrecor, and if they encounter problems in these processes, our revenues from future sales of Natrecor could decrease. In addition, we understand that Abbott is in late stage clinical trials for Simdax, which if approved, would compete with Natrecor for the treatment of acute congestive heart failure. Natrecor is manufactured using industry-accepted recombinant manufacturing techniques, which uses genetically engineered bacteria to produce a desired protein product. Although the use of genetically engineered bacteria has been approved for production of many other medicines, it must be conducted under strict controls and tight timelines. Natrecor 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. BioChemie depends on outside vendors for the timely supply of raw materials used to produce Natrecor. In the event BioChemie needs to change or add an outside vendor, a regulatory filing may be necessary. The filing and

approval process for the new vendor may take substantial time. 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 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 to meet market needs.

From time to time changes will be made in the process used by BioChemie to manufacture the bulk active pharmaceutical ingredient used in Natrecor or in the process used by Abbott to blend, fill and package the final drug product. Depending on the extent of these changes, we may need to obtain prior approval from the FDA to sell Natrecor that was manufactured or blended using the changed processes, and if such approval is denied or delayed, our ability to deliver Natrecor could be impaired. We believe that changes made by BioChemie in 2003 to the process for manufacturing the bulk active pharmaceutical ingredient may require us to obtain prior approval from the FDA to sell Natrecor incorporating the bulk active pharmaceutical ingredient manufactured after those changes were made.

In the area of acute congestive heart failure, 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 congestive heart failure. Competing drugs fall into three main categories: vasodilators, inotropes and diuretics. Natrecor competes against both vasodilators and inotropes in the acute congestive heart failure market. Many of these drugs are available in generic formulation with an associated low cost. We may not be able to compete effectively with these long-standing current forms of therapy. In addition, Natrecor costs more than many of these existing drugs, which may harm our competitive position relative to these drugs.

New drugs in development for the treatment of acute congestive heart failure would also compete with Natrecor if approved by the FDA or other regulatory agencies. Tezosentan, a drug which targets both receptors of endothelin, a naturally occurring hormone thought to be damaging to the heart during congestive heart failure, is being developed by Actelion Ltd. Actelion has completed Phase II clinical trials with Tezosentan for the treatment of acute congestive heart failure and has recently announced its intent to begin Phase III trials in the first quarter of 2003. Based on the results of the Phase II clinical trials, Actelion announced in September 2002 that it intends to proceed with a Phase III trial with Tezosentan to evaluate mortality and morbidity benefits.

In addition, we understand that Abbott is in Phase III development of Simdax, which is thought to work by increasing the sensitivity of the heart to calcium and thereby stimulate its ability to contract during congestive heart failure. 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.

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.

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:

develop products that are safer or more effective than our product candidates;

obtain FDA and other regulatory approvals or reach the market with their products more rapidly than we can, reducing the potential sales of our product candidates;

devote greater resources to market or sell their products;

adapt more quickly to new technologies and scientific advances;

initiate or withstand substantial price competition more successfully than we can;

have greater success in recruiting skilled scientific workers from the limited pool of available talent;

more effectively negotiate third-party licensing and collaboration arrangements; and

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.

We are aware of several pharmaceutical and biotechnology companies that are actively developing or have commercialized products addressing the same disease indication as our p38 kinase inhibitor. In addition, competition will result from the most often prescribed drugs to treat rheumatoid arthritis, including the non-steroidal antiinflammatory drugs such as ibuprofen and the COX-2 inhibitors such as Pharmacia's Celebrex and Merck's Vioxx.

In addition, we are aware of pharmaceutical and biotechnology companies that are specifically developing p38 kinase inhibitors for treating rheumatoid arthritis, including Boehringer Ingelheim and Vertex Pharmaceuticals. In 2001, Vertex Pharmaceuticals suspended the development of its lead oral p38 kinase inhibitor compound indicated for rheumatoid arthritis, but initiated clinical trials with two back-up compounds during 2002. Phase I trials for their lead back-up p38 kinase inhibitor are expected to be completed in 2003. Boehringer Ingelheim is currently in Phase II trials with their lead p38 kinase inhibitor in Europe for the treatment of rheumatoid arthritis.

If we fail to gain approval for Natrecor in international markets, our market opportunities will be limited.

We have not yet obtained marketing authorization for the use of Natrecor in foreign countries, and we may not be able to obtain any international regulatory approvals for Natrecor. If we fail to obtain those approvals or if such approvals are delayed, the geographic market for Natrecor would be limited.

The success of nesiritide in European markets is highly dependent on obtaining European approval and our licensing agreement with GlaxoSmithKline for marketing, promotion and sales activities.

In March 2002, we entered into an agreement with GlaxoSmithKline in all European markets. Under the terms of the agreement, GlaxoSmithKline has the rights to sell and distribute nesiritide for which we have received an up-front fee and may receive milestone payments,

Edgar Filing: SCIOS INC - Form 10-Q

in addition to future royalties on net sales of nesiritide in the identified European markets. Accordingly, our revenue from sales of nesiritide in Europe will be highly dependent on GlaxoSmithKline's ability to effectively market and sell nesiritide. We will be responsible for the manufacture and supply of bulk active pharmaceutical ingredient to GlaxoSmithKline.

In September 2002, GlaxoSmithKline submitted a Marketing Authorization Application for nesiritide with the European Agency for the Evaluation of Medicinal Products. If GlaxoSmithKline receives the necessary approvals, GlaxoSmithKline expects to launch nesiritide in Europe in 2004. However, while the clinical data used to support the FDA submission are expected to be adequate for European approval, further clinical trials may be necessary and adverse results from such additional trials could result in a failure to receive European approval. Even if additional trials are successful, a requirement to conduct further clinical trials would delay the launch of nesiritide in Europe, which may result in lower than anticipated revenues.

The companies intend to conduct a health outcomes trial, commencing in 2003, which the companies hope to use to enhance market acceptance of nesiritide in major European countries. The health outcomes trial could affect the price at which nesiritide will be sold. We cannot assure you that a preferred price for nesiritide will be obtained and that market acceptance of nesiritide will be achieved.

If we fail to obtain additional marketing approvals from the FDA for the use of Natrecor for additional therapeutic indications or if approval is revoked, our revenues from Natrecor will suffer.

In order to expand the medical uses, or therapeutic indications, for which we may market Natrecor, 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 approval to market Natrecor 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 for any additional indications. In addition, even if Natrecor is approved by the FDA for additional clinical indications, we cannot exclude the possibility that serious adverse events related to the use of Natrecor might occur in the future, which could either limit its use or cause the FDA to revoke our approval to market Natrecor.

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

While we are not dependent upon any one key employee, the loss of a significant number of scientific, clinical research or management personnel could harm our business. 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, sales 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 personnel or to attract additional highly qualified personnel could delay the development of our product candidates and harm our business. In addition, other than with Richard Brewer, our President and Chief Executive Officer, we do not have employment agreements with any of our key employees, and we do not have key person insurance policies with any of our key employees.

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.

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, including SCIO-469, SCIO-323 and our inhibitors of TGF-beta, will require at least 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. 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. In the first quarter of 2002, we began Phase IIa clinical trials of our lead p38 kinase inhibitor small molecule compound, SCIO-469. 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.

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.

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 and certain of our p38 kinase and TGF-beta 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 we have targeted. 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.

We face uncertainties over reimbursement and healthcare reform.

In both domestic and foreign markets, sales of Natrecor and future sales of our potential products, if any, will depend in part on the availability of reimbursement from third-party payers such as government health administration authorities, private health insurers and other organizations. Third-party payers 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. Natrecor and our product candidates may ultimately 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. Adoption of such legislation and regulations could further limit reimbursement for medical products and services. If the government and third-party payers fail to provide adequate coverage and reimbursement rates for Natrecor and 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 products and product candidates.

We face an inherent business risk of exposure to product liability claims in the event that the use of our products and 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.

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 relate primarily to our investment portfolio and our long-term debt. 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. Marketable 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 decrease during the quarter ended March 31, 2003 of 10%, the fair value of our total investment portfolio as of March 31, 2003 would have potentially incurred a loss of approximately \$170,000.

We pledged a portfolio of approximately \$24.0 million in U.S. government securities as collateral for the first six scheduled interest payments due on the convertible subordinated notes. The first installment of interest payment of \$4.4 million was made in February 2003. The remaining marketable securities are classified as held-to-maturity and are recorded on the balance sheet at amortized cost.

As of March 31, 2003, we had cash and cash equivalents of \$15.8 million, marketable securities of \$137.9 million and restricted marketable securities of \$20.0 million. Overall average duration to maturity for all cash and marketable securities is 0.9 years with 32% of the portfolio under one year and the remaining 68% between one and five years. The average interest rate earned on the portfolio was 2.3%. At March 31, 2003, the portfolio was broken down by the following investment categories: corporate securities 18%, government securities 43%, mortgages 5%, money market 14% and asset-backed securities 20%.

Our long-term debt includes \$150,000,000 of 5.5% convertible subordinated notes due in August 2009. Interest on the notes is fixed and payable semi-annually on February 15 and August 15 each year, with the first payment due February 15, 2003. Each \$1,000 principal amount of the notes is convertible into the right to receive \$1,145.04 in cash without interest, unless previously redeemed or repurchased.

Our exposure to foreign currency fluctuations is currently limited to our supply contract for bulk active pharmaceutical ingredient in Natrecor, which is denominated in the Euro; the GlaxoSmithKline agreement, which is denominated in the British Pound; and the royalty income from sales of Fiblast spray by Kaken, which is denominated in the Japanese Yen. Changes in the exchange rate between the Euro and the U.S. dollar could adversely affect our manufacturing costs. Changes in the exchange rate between the British Pound and U.S. dollar could adversely affect our milestone and future royalty payments. Changes in the exchange rate between the Japanese Yen and U.S. dollar could adversely affect our future royalty payments. 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.

Item 4. Controls and Procedures

Edgar Filing: SCIOS INC - Form 10-Q

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Within 90 days prior to the date of this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective.

There have been no significant changes in our internal controls or in other factors that could significantly affect our internal controls subsequent to the date we completed our evaluation.

PART II. OTHER INFORMATION

Item 6. Exhibits and reports on Form 8-K

(a) Exhibits

None.

(b) Reports on Form 8-K

Report on Form 8-K filed on February 7, 2003. On February 7, 2003, Scios announced that it was engaged in discussions with a number of life sciences companies concerning potential strategic transactions, which included partnering arrangements for the Scios p38 kinase inhibitor program and mergers.

Report on Form 8-K filed on February 11, 2003. On February 10, 2003, Scios and Johnson & Johnson announced that they had entered into a definitive agreement under which Johnson & Johnson will acquire Scios in a cash for stock exchange with a purchase price of \$45.00 for each outstanding Scios share.

Report on Form 8-K filed on February 13, 2003. On February 13, 2003, Scios Inc. announced its financial results for the fourth quarter and year ended December 31, 2002.

Report on Form 8-K filed on April 3, 2003. On April 3, 2003, Johnson & Johnson and Scios Inc. jointly announced that the U.S. Federal Trade Commission has granted early termination of the waiting period under Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, for the acquisition of Scios, Inc. by Johnson & Johnson.

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 14, 2003

By:

/s/ RICHARD B. BREWER

Richard B. Brewer, President and CEO

May 14, 2003

By:

/s/ DAVID W. GRYSKA

David W. Gryska, Senior Vice President and CFO

Certifications

I, Richard B. Brewer, President and Chief Executive Officer of Scios Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Scios Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and
 - c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
 - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

Edgar Filing: SCIOS INC - Form 10-Q

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 14, 2003

/s/ RICHARD B. BREWER

Richard B. Brewer

President and Chief Executive Officer

Certifications

I, David W. Gryska, Senior Vice President and Chief Financial Officer of Scios Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Scios Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and
 - c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
 - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

Edgar Filing: SCIOS INC - Form 10-Q

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 14, 2003

/s/ DAVID W. GRYSKA

David W. Gryska

Senior Vice President and Chief Financial Officer