

SCIOS INC  
Form 10-Q  
August 14, 2002

**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 June 30, 2002

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  
incorporation or organization)

**95-3701481**  
(I.R.S. Employer  
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

Number of shares outstanding of the issuer's common stock, par value \$.001 per share, as of August 2, 2002: 46,622,390.

## Part I

## Item 1. Financial Statements

**SCIOS INC.**  
**Consolidated Balance Sheets**  
(in thousands, except share data and per share data)

	June 30, 2002	December 31, 2001
	(Unaudited)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 39,212	\$ 58,296
Marketable securities	13,396	7,351
Accounts receivable, net	11,081	6,943
Inventory	2,613	1,158
Prepaid expenses and other assets	5,070	4,214
	<u>71,372</u>	<u>77,962</u>
Total current assets	71,372	77,962
Marketable securities, non-current	48,673	63,669
Property and equipment, net	10,252	10,424
Other assets	758	4,123
	<u>131,055</u>	<u>156,178</u>
Total assets	\$ 131,055	\$ 156,178
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Accounts payable	\$ 7,727	\$ 9,625
Accrued employee compensation	10,697	9,685
Other accrued liabilities	9,531	7,206
Deferred contract revenue	1,102	
Current portion of long-term debt	41,313	33,035
	<u>70,370</u>	<u>59,551</u>
Total current liabilities	70,370	59,551
Deferred contract revenue	3,493	
Long-term debt	15,396	15,479
	<u>89,259</u>	<u>75,030</u>
Total liabilities	89,259	75,030
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; issued and outstanding 46,614,473 and 45,985,167, respectively	47	46
Additional paid-in capital	567,958	561,352
Treasury stock; shares of 40,000 and 30,000, respectively	(644)	(445)
Deferred warrant costs	(4,389)	(6,794)
Deferred compensation	(106)	(106)
Accumulated other comprehensive income	564	999
Accumulated deficit	(521,634)	(473,904)
	<u>41,796</u>	<u>81,148</u>
Total stockholders equity	41,796	81,148
Total liabilities and stockholders equity	\$ 131,055	\$ 156,178

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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 June 30,		Six months ended June 30,	
	2002	2001	2002	2001
	(Unaudited)		(Unaudited)	
<b>Revenues:</b>				
Product sales	\$ 22,510	\$ 2,098	\$ 37,883	\$ 2,098
Research and development contracts and royalties	517	1,484	1,588	2,581
Psychiatric product sales and co-promotion commissions, net of expenses		1,659		3,142
Gain on sale of marketing rights				9,363
	<u>23,027</u>	<u>5,241</u>	<u>39,471</u>	<u>17,184</u>
<b>Costs and expenses:</b>				
Cost of product sales	1,381		2,392	
Research and development	16,808	13,084	31,663	22,564
Selling, general and administration	26,075	10,278	50,789	16,758
	<u>44,264</u>	<u>23,362</u>	<u>84,844</u>	<u>39,322</u>
Loss from operations	<u>(21,237)</u>	<u>(18,121)</u>	<u>(45,373)</u>	<u>(22,138)</u>
<b>Other income (expense):</b>				
Interest income	913	742	1,721	1,554
Interest expense	(2,498)	(754)	(4,442)	(1,603)
Realized gains on securities	370	135	293	389
Other income (expense)	(56)	(275)	71	(698)
	<u>(1,271)</u>	<u>(152)</u>	<u>(2,357)</u>	<u>(358)</u>
Net loss	<u>(22,508)</u>	<u>(18,273)</u>	<u>(47,730)</u>	<u>(22,496)</u>
Other comprehensive loss				
Change in net unrealized gains on securities	(4)	(755)	(435)	(639)
Comprehensive loss	<u>\$ (22,512)</u>	<u>\$ (19,028)</u>	<u>\$ (48,165)</u>	<u>\$ (23,135)</u>
<b>Loss per common share:</b>				
Basic and diluted	\$ (0.48)	\$ (0.46)	\$ (1.03)	\$ (0.57)
Weighted average number of common shares outstanding used in calculation of:				
Basic and diluted	46,436,087	40,087,161	46,246,360	39,653,959

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

**SCIOS INC.**  
**Consolidated Statements of Cash Flows**  
(in thousands)

	Six months ended June 30,	
	2002	2001
	(Unaudited)	
Cash flows from operating activities:		
Net loss	\$ (47,730)	\$ (22,496)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	2,450	1,417
Amortization of debt discount	744	
Gain on disposal of marketable securities	(293)	(389)
Accrued interest payable	3,698	1,602
Loss on disposal of property and equipment	119	
Amortization of deferred compensation		311
Allowance for bad debt, returns, and discounts	358	
Stock option issued to non-employee for services rendered	109	
Changes in assets and liabilities:		
Accounts receivable	(4,496)	134
Inventory	(1,455)	
Prepaid expenses and other assets	2,509	(2,997)
Accounts payable	(1,898)	3,913
Accrued employee compensation	1,012	731
Other accrued liabilities	2,325	(3,754)
Deferred contract revenue	4,595	(2,095)
	<u>(37,953)</u>	<u>(23,623)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(2,398)	(678)
Sales/maturities/purchases of marketable securities	8,816	(74,921)
	<u>6,418</u>	<u>(75,599)</u>
Cash flows from financing activities:		
Issuance of common stock	6,498	116,657
Purchase of treasury stock	(199)	
Payment of commercialization agreement	(928)	
Proceeds from commercialization agreement	7,080	
	<u>12,451</u>	<u>116,657</u>
Net increase (decrease) in cash and cash equivalents	(19,084)	17,435
Cash and cash equivalents at beginning of period	58,296	3,291
	<u>\$ 39,212</u>	<u>\$ 20,726</u>
Supplemental cash flow data:		
Cash paid during the period for interest	\$ 928	\$
Change in net unrealized gains (losses) on securities	\$ 435	\$ 639
Discount on commercialization obligation	\$ 2,405	\$

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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 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 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, 2001.

The results of operations for the six months ended June 30, 2002 are not necessarily indicative of the operating results that may be reported for the fiscal year ending December 31, 2002 or for any other future period.

**2. Computation of Loss Per Share**

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 2002 and 2001, and they were therefore excluded from the diluted loss per share calculation for both periods. Although potentially dilutive, the optional repayment of up to the \$20 million of the Genentech loan through the issuance of preferred stock would have been anti-dilutive in both 2002 and 2001 and was therefore excluded from the calculations.

At June 30, 2002, Scios had outstanding stock options to purchase 7,939,045 shares of common stock at exercise prices ranging from \$3.8125 to \$30.61 per share and an outstanding warrant to purchase 700,000 shares of common stock. At June 30, 2001, Scios had outstanding stock options to purchase 5,582,368 shares of common stock at exercise prices ranging from \$3.94 to \$27.60 per share and an outstanding warrant to purchase 700,000 shares of common stock.

### **3. GlaxoSmithKline Agreement**

In March 2002, we finalized the agreement with GlaxoSmithKline, or GSK, to license Natrecor to GSK in all European markets. Under the terms of the agreement, GSK has the rights to sell and distribute the product for which we received an up-front fee GB£3.5 million and may receive milestone payments totaling 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 U.S. Dollars), we received in March 2002 has been 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 GSK in obtaining European approval to sell Natrecor. As of June 2002, we recognized \$0.3 million of the \$4.9 million. We believe this amount will be fully amortized by 2004. We will manufacture and supply the bulk active pharmaceutical ingredients to GSK. Both companies will work together to continue clinical development of Natrecor in Europe. GSK expects to file its application with The European Agency for the Evaluation of Medicinal Product using the extensive clinical data Scios submitted to obtain approval from the U.S. Food and Drug Administration in August 2001. In collaboration with Scios, GSK expects to launch Natrecor in Europe in 2004.

### **4. Gain on Sale of Marketing Rights**

In the first quarter of 2001, the marketing rights for psychiatric product sales 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 received from GSK \$4.0 million in 2001 and \$3.0 million in 2002 and expect to receive \$2.4 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, which was recorded as selling, general and administration in the quarter ended March 31, 2001.

### **5. Notes Receivable from Officers**

At June 30, 2002, we had notes receivable from two officers.

The first note is in the amount of \$16,666 with interest at 5.82% per annum and was collateralized by the officer's residence. This loan was forgiven in July 2002 based on the continued employment of the officer. 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 June 30, 2002.

The second note is in the amount of \$120,000 with interest at 10.0% per annum. This loan 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. The loan was granted



in connection with a housing subsidy for the officer to live in California. This loan is classified as other assets on the balance sheet at June 30, 2002.

#### 6. Treasury stock

Treasury stock of 40,000 shares at June 30, 2002 is stated at cost on our consolidated balance sheet and is considered issued. During September 2001, the Board of Directors authorized the repurchase of up to \$10 million of Scios common stock. The repurchases are made through open-market transactions at the discretion of management as market conditions warrant. As of June 30, 2002, we had repurchased 40,000 shares of our common stock at an average purchase price of \$16.11 per share.

#### 7. 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. As of June 30, 2002, inventories consisted of the following:

	<b>June 30, 2002</b>	<b>December 31, 2001</b>
	<u>          </u>	<u>          </u>
<i>(in thousands)</i>		
Work-in-process	\$ 1,790	\$ 24
Finished goods	823	1,134
	<u>          </u>	<u>          </u>
Total inventories	<u>\$ 2,613</u>	<u>\$ 1,158</u>

#### 8. Subsequent Event

On August 5, 2002, we completed the sale of \$150 million of 5.50% convertible subordinated notes due August 15, 2009 through a private placement to qualified institutional buyers. We also granted the initial purchasers a 30-day option to acquire up to an additional \$25 million in principal amount to cover over-allotments. The notes are convertible at the option of the holders into shares of Scios Inc. common stock initially at a conversion price of \$39.30, representing a conversion premium of 23% over the July 30, 2002 closing price of \$31.95. In connection with the offering, we pledged a portfolio of approximately \$24 million in U.S. government securities as security for the first six scheduled interest payments due on the notes.

## 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, 2001. 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 rationally design small molecule compounds for large markets with unmet medical needs. We launched Natrecor<sup>®</sup> following U.S. Food and Drug Administration, or FDA, approval of Natrecor (nesiritide) for the treatment of acute decompensated congestive heart failure, or CHF, on August 13, 2001. In addition to Natrecor, we have two focused product programs. SCIO-469 is our oral, small molecule inhibitor of p38 kinase for the treatment of rheumatoid arthritis, or RA. Our second product program is focused on the development of novel and potent small molecule inhibitors of the receptor for transforming growth factor (TGF)-beta, a cytokine that has been implicated in diseases characterized by chronic scar formation, or fibrosis, and are currently in preclinical development.

### Recent Developments

In January 2002, we initiated the FUSION study, or Management of Patients with CHF After Hospitalization with Follow Up Serial Infusions Of Natrecor, a multi-center, randomized, open-label pilot study that will be conducted at approximately 40 U.S. sites and will enroll 210 patients. Patients will be randomized to receive either their usual long-term cardiac medications, with or without IV inotropes, or serial infusions of Natrecor in addition to their usual long-term cardiac medications, excluding IV inotropes. All treatment groups will have weekly outpatient visits, and Natrecor patients will receive infusions for 4 to 6 hours at each weekly visit. Patients will receive study treatment for 12 weeks, followed by a one-month follow up period. The primary objective of this dose ranging trial is to collect safety and tolerability data on Natrecor with repeated dosing in an outpatient setting. Data from the FUSION study are expected to be available in the first quarter of 2003. As of July 23, 2002, 135 patients had been enrolled in the study.

In February 2002, we began enrollment in a Phase IIa clinical trial evaluating SCIO-469, our novel oral p38 kinase inhibitor, for the treatment of rheumatoid arthritis, or RA. This multi-center, randomized, placebo-controlled clinical study will enroll 120 patients who have active RA and are receiving methotrexate. The main objective of the study is to evaluate the safety and tolerability of up to six escalating doses of SCIO-469 in RA patients. We expect to announce results from this study in the first quarter of 2003. As of July 23, 2002, 42 patients had been enrolled in the study.

In March 2002, we added a new drug candidate to our pipeline that we believe could become the first oral inhibitor of TGF-beta. TGF-beta is a multifunctional cytokine, a signaling protein that is produced in a broad range of diseases characterized by unregulated scarring and eventual organ failure. Research has indicated that excessive activation of TGF-beta is involved in the development of scar tissue formation, which is thought to contribute to the progressive loss of function seen in a variety of conditions. Diseases in which TGF-beta may play a role include CHF, chronic obstructive pulmonary disease, or COPD, liver cirrhosis and kidney disease. Current therapies for these conditions treat symptoms exclusively or are only modestly effective in slowing disease progression. In July 2002, we announced the lead indication of our TGF-beta compounds will be COPD.

In March 2002, we finalized the agreement with GSK to license Natrecor to GSK in all European markets. Under the terms of the agreement, GSK has the rights to sell and distribute the product for which we received an up-front fee GB£3.5 million and may receive milestone payments totaling an additional GB£11.5 million, in addition to future royalties in the identified countries. We will manufacture and supply the bulk active pharmaceutical ingredients to GSK. Both companies will work together to continue clinical development of Natrecor in Europe. GSK expects to file its application with The European Agency for the Evaluation of Medicinal Product using the extensive clinical data Scios submitted to obtain approval from the U.S. Food and Drug Administration in August 2001. In collaboration with GSK, we expect to launch Natrecor in Europe in 2004.

In April 2002, we announced that Natrecor has received an Ambulatory Payment Classification, or APC, pass-through code under the Hospital Outpatient Prospective Payment System from the Centers for Medicare & Medicaid Services. The pass-through payment code for Natrecor allows Medicare reimbursement to both hospitals and physicians for the use of Natrecor in an outpatient setting such as the Emergency Department, Observation Unit or Outpatient Clinic. The reimbursement code became effective April 1, 2002.

In June 2002, we announced that the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has determined that the ADHERE (Acute Decompensated Heart Failure National Registry) Registry meets the criteria for inclusion in the accreditation process and is included on the Joint Commission's list of acceptable systems. The Registry will be beneficial to participating hospitals since it will facilitate the submission of specific performance measures related to acute heart failure treatment to JCAHO.

In July 2002, we announced the results of the PROACTION (Prospective Randomized Outcomes Study of Acutely Decompensated Congestive Heart Failure Treated Initially in Outpatients with Natrecor) trial. In this pilot study, two hundred and thirty seven patients were enrolled and treated in the Emergency Department/Observation Unit, or ED/OU, at 38 U.S. hospitals. The study was designed to compare the clinical effects, safety profile and economic impact of Natrecor plus standard therapy to

placebo plus standard therapy, when administered in the ED/OU. Outcomes were assessed over thirty days. The study confirmed that Natrecor could be used safely in the ED/OU. Although not statistically significant results suggest that early use of Natrecor in the ED/OU may decrease the rate of initial hospital admissions and re-admissions following initial hospital discharge, versus standard care. These improved clinical outcomes may lead to cost reductions that neutralize the cost of Natrecor when compared to standard care alone.

## **Results of Operations**

### ***Three Months Ended June 30, 2002 and 2001***

#### ***Revenues***

*Product Sales.* Product sales for the three months ended June 30, 2002 were \$22.5 million versus \$2.1 million for the three months ended June 30, 2001. The increase was principally due to the sales of Natrecor, which was approved by the FDA and launched by us in August 2001. The product sales in 2001 reflect sales of bulk Fibroblast Growth Factor, or FGF, to Kaken in Japan.

*Research and Development Contracts and Royalties.* Research and development contracts and royalties were \$0.5 million for the three months ended June 30, 2002 and \$1.5 million for the three months ended June 30, 2001. In 2002, research and development contract revenues were primarily from recognition of deferred contract revenue from GSK of \$0.3 million and royalties from Biosite for sales of diagnostic tests for BNP levels of \$0.2 million. As of June 30, 2002, we recognized as earned \$0.3 million of the GSK deferred contract revenue from the initial license fee of \$4.9 million relating to the commercialization agreement we entered into in March 2002 with GSK. In 2001, research and development contract revenues and royalties primarily reflect our Alzheimer's research collaboration agreements with Eli Lilly of \$0.8 million, contractual diligence fee of \$0.5 million from Abbott Laboratories relating to the diagnostic tests for BNP levels, and other research collaboration agreements of \$0.1 million. Effective as of December 31, 2001, the Eli Lilly collaboration was jointly terminated.

*Net Product Sales and Co-Promotion Commissions.* Net psychiatric product sales and co-promotion commissions for the three months ended June 30, 2002 were none versus \$1.7 million for the three months ended June 30, 2001. The decrease of \$1.7 million in 2002 from 2001 was due to the sale of marketing rights for certain psychiatric products to GSK and the termination of the license agreement in March 2001. At the same time, we dissolved our Psychiatric Sales and Marketing Division and the deployment of the PSMD sales force.

#### ***Costs and Expenses***

*Cost of Product Sales.* Cost of product sales were \$1.4 million for the three months ended June 30, 2002 and none for the three months ended June 30, 2001. The expenses in 2002 were due to the cost to manufacture and distribute Natrecor and royalties on a cross license agreement with Shionogi.

*Research and Development.* Research and development expenses were \$16.8 million and \$13.1 million for the three months ended June 30, 2002 and 2001, respectively. The expenses were mainly attributable to clinical expenses related to Natrecor, research and clinical expenses related to our p38 kinase inhibitor program, and pre-clinical development of the TGF-beta program.

*Selling, General and Administration.* Selling, general and administration expenses were \$26.1 million and \$10.3 million for the three months ended June 30, 2002 and 2001, respectively. The increase of \$15.8 million was primarily due to selling and marketing expenses to launch Natrecor and the addition of general and administrative staff to support the increase in overall headcount. These 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 cost associated with ADHERE, the Acute Decompensated HEart failure national Registry, a nationwide registry to collect and analyze demographic and treatment data about patients hospitalized due to acute CHF.

***Other Income (Expense)***

Net other income (expense) were \$(1.3) million and \$(0.2) million for the three months ended June 30, 2002 and 2001, respectively. The increase of \$1.1 million in other income (expense) was principally due to higher interest expense of \$1.7 million, which was partially offset by an increase in interest income of \$0.2 million, and realized gain on securities of \$0.2 million. The increase in interest expense was largely due to the debt with PharmaBio Development, an affiliate of Innovex. The realized gain on securities reflects the gain on the disposal of GenVec stock.

***Six Months Ended June 30, 2002 and 2001***

***Revenues***

*Product Sales.* Product sales for the six months ended June 30, 2002 were \$37.9 million versus \$2.1 million for the six months ended June 30, 2001. The increase was due to the sales of Natrecor, which was approved by the FDA and launched by us in August 2001. The product sales in 2001 reflect sales of bulk FGF to Kaken in Japan.

*Research and Development Contracts and Royalties.* Research and development contracts and royalties were \$1.6 million for the six months ended June 30, 2002 and \$2.6 million for the six months ended June 30, 2001. In 2002, research and development contract revenues were primarily from recognition of deferred contract revenue from the GSK commercialization agreement of \$0.3 million and from royalty payments from sales of Fiblast Spray in Japan by Kaken of \$0.5 million, royalties from Biosite for sales of diagnostic tests for BNP levels of \$0.4

million and other royalty agreements of \$0.4 million. In 2001, research and development contract revenues and royalties primarily reflect our Alzheimer's research collaboration agreements with Eli Lilly of \$1.3 million, contractual diligence fee of \$0.8 million from Abbott Laboratories relating to the diagnostic tests for BNP levels, and other research collaboration agreements of \$0.4 million. Effective as of December 31, 2001, the Eli Lilly collaboration was jointly terminated.

*Net Product Sales and Co-Promotion Commissions.* Net psychiatric product sales and co-promotion commissions for the six months ended June 30, 2002 were none versus \$3.1 million for the six months ended June 30, 2001. The decrease of \$3.1 million in 2002 from 2001 was due to the sale of marketing rights for certain psychiatric products to GSK and the termination of the license agreement in March 2001. At the same time, we dissolved our Psychiatric Sales and Marketing Division and the deployment of the PSMD sales force.

*Gain on Sale of Marketing Rights.* The decrease of \$9.4 million in 2002 from 2001 was due to the sale of marketing rights for certain psychiatric products to GSK and the termination of the license agreement in March 2001. Commencing in the fourth quarter of 2000, we solicited and received bids regarding the sale of our exclusive marketing rights for certain GSK psychiatric products sold by us. The marketing rights were eventually sold to GSK. The marketing rights were originally licensed from GSK under a 1990 licensing agreement. In order to effect the sale, the licensing agreement was terminated effective March 31, 2001, and we received from GSK \$4.0 million in 2001 and \$3.0 million in 2002 and expect to receive a final payment of \$2.4 million in 2003. We recognized a gain on the sale of the marketing rights of \$9.4 million related to the sale in the first quarter of 2001.

### *Costs and Expenses*

*Cost of Product Sales.* Cost of product sales were \$2.4 million for the six months ended June 30, 2002 and none for the six months ended June 30, 2001. The expenses were due to the cost to manufacture and distribute Natrecor and royalties on a cross license agreement with Shionogi.

*Research and Development.* Research and development expenses were \$31.7 million and \$22.6 million for the six months ended June 30, 2002 and 2001, respectively. The increase in expenses were mainly attributable to clinical expenses related to Natrecor, research and clinical expenses related to our p38 kinase inhibitor program, and pre-clinical development of the TGF-beta program.

*Selling, General and Administration.* Selling, general and administration expenses were \$50.8 million, and \$16.8 million for the six months ended June 30, 2002 and 2001, respectively. The increase of \$34.0 million was primarily due to selling and marketing expenses to launch Natrecor and the addition of general and administrative staff to support the increase in overall headcount. These 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 cost associated with ADHERE, Acute Decompensated HEart failure national 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 income (expense) were \$(2.4) million and \$(0.4) million for the six months ended June 30, 2002 and 2001, respectively. The increase of \$2.0 million in other income (expense) was principally due to higher interest expense of \$2.8 million, which was partially offset by an increase in interest income of \$0.2 million, and other income and expenses of \$0.8 million. The increase in interest expense was largely due to the debt with PharmaBio Development, an affiliate of Innovex.

**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. At June 30, 2002, our combined cash, cash equivalents and marketable securities (both current and non-current) totaled \$101.3 million.

On August 5, 2002, we completed the sale of \$150 million of 5.50% convertible subordinated notes due August 15, 2009 through a private placement to qualified institutional buyers. We also granted the initial purchasers a 30-day option to acquire up to an additional \$25 million in principal amount to cover over-allotments. The notes are convertible at the option of the holders into shares of Scios Inc. common stock initially at a conversion price of \$39.30, representing a conversion premium of 23% over the July 30, 2002 closing price of \$31.95. In connection with the offering, we pledged a portfolio of approximately \$24 million in U.S. government securities as security for the first six scheduled interest payments due on the notes. We intend to use a portion of the proceeds to repay outstanding indebtedness and the remaining amount for general corporate purposes.

In January 2001, we entered into a sale and marketing alliance with Innovex, a subsidiary of Quintiles Transnational Corp. As part of the original three and one half year agreement, PharmaBio Development, Inc., an affiliate of Innovex, agreed to fund \$30.0 million of our costs to launch Natrecor over the first 24 months of the commercialization of Natrecor and to loan us up to \$5.0 million. In December 2001, Scios, Innovex and PharmaBio amended the January 2001 agreement. The amendment enables Scios, at its option, to assume control of the Natrecor sales force in June 2003, one year ahead of schedule, and eliminated the \$5.0 million line of credit provided by PharmaBio to Scios. In June 2002, we informed PharmaBio and Innovex of our intention to assume control of the sales force in June 2003. Of the \$30.0 million funding from PharmaBio, we received \$17.1 million through June 30, 2002, and will receive the remaining \$12.9 million over the next 11 months. As part of the funding agreement, we pay PharmaBio a declining royalty rate on net sales of Natrecor through early 2008. As of June 30, 2002, we have

paid PharmaBio \$0.9 million in payments. We also granted PharmaBio a fully vested warrant to purchase 700,000 shares of our common stock at an exercise price of \$20.00 per share. These warrants are exercisable beginning December 2001 through May 2003. Subject to certain conditions, PharmaBio may include the shares it acquires upon exercise of the warrant in future registration statements filed by us and may require us to file up to two registration statements to register those shares at PharmaBio's expense.

In December 2001, we entered into a binding summary of terms with Glaxo Group Ltd., an affiliate of GlaxoSmithKline, or GSK, in which we licensed Natrecor to GSK in all European markets. In March 2002, we finalized the agreement with GSK to license Natrecor to GSK in all European markets. Under the terms of the agreement, GSK has the rights to sell and distribute the product for which we received an up-front fee GB£3.5 million and may receive milestone payments totaling 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 U.S. Dollars), we received in March 2002 has been recorded as deferred contract revenue. We will manufacture and supply the bulk active pharmaceutical ingredients to GSK. Both companies will work together to continue clinical development of Natrecor in Europe. GSK expects to file its application with The European Agency for the Evaluation of Medicinal Product using the extensive clinical data Scios submitted to obtain approval from the U.S. Food and Drug Administration in August 2001. In collaboration with Scios, GSK expects to launch Natrecor in Europe in 2004.

We lease five facilities in Sunnyvale, California with agreements that expire between 2003 and 2008. In addition, we lease a warehouse in Mountain View, California that expires in 2003. We are in the process of finalizing a new lease for the new corporate site to consolidate our operations and expect to move into these new facilities in 2003. 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, which includes sub-leasing or continued occupancy by us. The company has also entered into operating leases covering certain laboratory and computer equipment.

As of June 30, 2002 we had \$33.8 million due to Genentech of which \$20.0 million can be repaid in the Company's Series B preferred stock at anytime through December 31, 2002. In addition, if the Company should decide to convert the loan to preferred stock, a portion of the loan that is not convertible will become due and payable before December 31, 2002. The amount of the loan that is due before the maturity date is based on a formula that considers the amount of loan converted to stock and the outstanding loan balance. We intend to use the proceeds from the convertible subordinated notes to repay this loan.

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 in the United States before December 31, 2006.



Net cash used in operating activities of \$37.9 million in the six months ended June 30, 2002 was primarily attributable to the net loss of \$47.7 million, partially offset by increases in net operating assets and liabilities of \$2.6 million and increases in non-cash expenses of \$7.2 million.

Net cash provided by investing activities of \$6.4 million in the six months ended June 30, 2002 consisted of a net increase in sales/maturities of marketable securities of \$8.8 million, partially offset by purchases of property and equipment of \$2.4 million.

Net cash provided by financing activities of \$12.5 million in the six months ended June 30, 2002 was due to the proceeds from the PharmaBio commercialization agreement of \$7.1 million and the issuance of common stock of \$6.5 million, partially offset by the payments to PharmaBio under the commercialization agreement of \$0.9 million and purchases of treasury stock of \$0.2 million.

We expect our existing cash, cash equivalents and marketable securities, proceeds from the private offering of \$150 million of convertible subordinated notes, proceeds from existing collaborations, our agreement with PharmaBio, and our marketing agreement with GSK and revenues from sales of Natrecor will enable us to maintain our current and planned operations for at least the next twelve months. In the event we need 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 financing. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects and the general condition of the financial markets. We cannot assure you that we will be successful in obtaining collaborative agreements, or in receiving milestone and/or royalty payments under those agreements, that our existing cash and marketable securities resources will be adequate or that additional financing will be available when needed or that, if available, this financing will be obtained on terms favorable to us or our stockholders. Insufficient funds may require us to delay, scale back or eliminate some or all of our research or development programs or to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders may result.

*Contractual Obligations and Significant Commercial Commitments.* The following summarizes our approximated current contractual obligations for the years ended December 31, 2002 through December 31, 2006 and thereafter:

	<b>Facilities Leases</b>	<b>Equipment Operating Leases</b>	<b>Interest on Convertible Subordinated Notes</b>
<i>(in thousands)</i>			
2002	\$ 965	\$ 99	\$ 3,368
2003	2,069	105	8,250
2004	917		8,250
2005	948		8,250
2006	979		8,250
Thereafter	1,879		21,563
<b>Total</b>	<b>\$ 8,722</b>	<b>\$ 303</b>	<b>\$ 57,931</b>

## **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**

***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 advisors of 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 for ongoing and future clinical trials;

lack of additional cost-effectiveness of Natrecor;

availability of alternative treatments; and

change in reimbursement policies of government and third party payers.

To the extent market acceptance of Natrecor is limited, our revenues may suffer.

***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 is manufactured for us by BioChemie GmbH, a subsidiary of Novartis, in Austria and is shipped bulk active pharmaceutical ingredient 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. If 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 bulk drug substance and final drug product for clinical and commercial purposes relating to Natrecor. BioChemie GmbH is responsible for manufacturing Natrecor in bulk quantities 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. Natrecor is manufactured using industry-accepted recombinant manufacturing techniques, which 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. 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 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, or bulk API, used in Natrecor, or in the process used by Abbott to manufacture 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 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 in 2002 to the process for manufacturing the bulk API may require us to obtain prior approval from the FDA to sell Natrecor incorporating the bulk API manufactured after those changes were made.

*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. Competing drugs fall into three main categories: vasodilators, inotropes and diuretics. Natrecor competes against both vasodilators and inotropes in the acute CHF 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 CHF would also compete with Natrecor if approved by the FDA or other regulatory agencies. Veletri (tezosentan), a non-selective endothelin receptor antagonist, is being developed by Actelion Ltd. and we believe it is currently being evaluated in Phase II clinical trials for the treatment of acute CHF.

In addition, Abbott had previously submitted an NDA for Simdax (levosimendan), a calcium sensitizer described as an inotrope, but withdrew the application in 2000. However, we understand that Abbott is currently in Phase III development of this product. 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 and our other product candidates in international markets, our market opportunities will be limited.***

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

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

We plan to partner with other companies for the sale of Natrecor and our other product candidates outside of the United States. In March 2002, we entered into an agreement with GSK in all European markets. Under the terms of the agreement, GSK has the rights to sell and distribute Natrecor for which we have received an up-front fee and may receive milestone payments, in addition to future royalties on sales of Natrecor in the identified countries. Accordingly, our revenue from sales of Natrecor in Europe will be highly dependent on GSK's ability to effectively market and sell Natrecor. We will manufacture and supply the bulk active pharmaceutical ingredient to GSK.

GSK expects to file its application with The European Agency for the Evaluation of Medicinal Product using the extensive clinical data we submitted to obtain approval from the FDA in August 2001. If GSK receives the necessary approvals, GSK expects to launch Natrecor 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 Natrecor 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 Natrecor in major European countries. The health outcomes trial could affect the price at which Natrecor will be sold. We cannot assure you that a preferred price for Natrecor will be obtained and that market acceptance of Natrecor will be achieved.

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

We plan to partner Natrecor in international markets other than European markets. 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 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 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.

**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 June 30, 2002, we had an accumulated deficit of approximately \$521.6 million.

To date, nearly all of our revenues have come from:

sales of Natrecor beginning in August 2001;

one-time sales of bulk FGF product and royalties from Fiblast Spray sales by Kaken in Japan;

one-time signing fees from our corporate partners under agreements supporting the research, development and commercialization of our product candidates;

one-time payments from our corporate partners when we achieved regulatory or development milestones;

research funding from our corporate partners; and

our psychiatric sales and marketing division, the operations of which we dissolved on March 31, 2001.

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 commercializing Natrecor in the United States will result in significant expenses for the foreseeable future.

***If we fail to obtain additional 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 that our current working capital, revenues from Natrecor sales 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:

costs and rate of progress expected in developing product candidates and obtaining regulatory approvals;

costs of obtaining regulatory approvals for Natrecor in markets other than the United States and for additional indications in the United States;

acquisition of technologies and other business opportunities that require financial commitments; or

revenues from the commercialization of Natrecor and any other potential products.

***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:

our success in selling Natrecor;

the timing and realization of milestone and other payments from our corporate partners;

the timing and amount of expenses relating to our research and development, product development and manufacturing activities; and

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, 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.

***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 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. 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.

***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:

- 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.

***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 Natreacor 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 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, 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. 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 payers 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.

***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 subjects 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:

prohibit holders of less than ten percent of our outstanding capital stock from calling special meetings of stockholders;

prohibit stockholder action by written consent, thereby requiring stockholder actions to be taken at a meeting of our stockholders; and

establish advance notice requirements for nominations for election to the board of directors or for proposing matters that 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 June 30, 2002, an aggregate of 71,053 shares of preferred stock had been designated for issuance as Series A or Series B preferred stock by the board of directors and 4,991 shares of Series B preferred stock were issued and outstanding. Issuance of other shares of preferred stock could also be used as an anti-takeover device.

***Our substantial indebtedness could harm our financial condition and prevent us from fulfilling our obligations under the notes.***

With the completion in August 2002 of our private offering of \$150 million of convertible subordinated notes due 2009, we will have a significant amount of indebtedness, which could have important consequences to us. For example, it could:

- increase our vulnerability to general adverse economic and industry conditions;
- require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, thereby reducing the availability of our cash flow to fund working capital, capital expenditures and other general corporate purposes;
- limit our flexibility in reacting to changes in our business and the industry in which we operate;
- place us at a competitive disadvantage compared with our competitors that have less debt; and
- limit, among other things, our ability to raise or borrow additional funds.

The indenture governing the notes does not limit our ability to incur additional indebtedness in the future. If new indebtedness is incurred, the related risks that we now face could intensify. Our ability to make required payments on the notes and to satisfy any other debt obligations will depend upon our future operating performance and our ability to obtain additional debt or equity financing.

***Our ability to repurchase the convertible subordinated notes due 2009 upon a change in control is limited and the failure to do so would cause an event of default under the indenture governing the notes.***

Upon the occurrence of a change in control, we will be required to offer to repurchase the notes for cash or common stock, or a combination thereof. If a change in control occurs, we may not have sufficient funds to repurchase all notes tendered by the holders of the notes in cash. The terms of any future credit facilities or other agreements relating to indebtedness may prohibit such purchases. If a change in control occurs at a time when we are prohibited from purchasing notes with cash, we could (if permitted) purchase the notes with common stock, seek the consent of our lenders to purchase the notes with cash, or attempt to refinance the borrowings that contain

such prohibitions. If we do not obtain such a consent or repay such borrowings, we would remain prohibited from purchasing notes in cash, and if we cannot or do not repurchase the notes with shares of our common stock, an event of default would occur on the notes. The occurrence of an event of default under the notes could lead to the acceleration of all amounts outstanding under the notes, and may also trigger cross-default provisions resulting in the acceleration of our other indebtedness. These events in turn could harm our share price as well as our ability to continue our operations.

### **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. 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 decrease during the quarter ended June 30, 2002 of 10%, the fair value of our total investment portfolio as of June 30, 2002 would have potentially incurred a loss of \$144,000.

As of June 30, 2002, we had cash and cash equivalents of \$39.2 million and marketable securities of \$62.1 million. Overall average duration to maturity for all cash and marketable securities is 0.7 years with 72% of the portfolio under one year and the remaining 28% between one and two years. The average interest rate earned on the portfolio was 3.3%. At June 30, 2002, the portfolio was broken down by the following investment categories: corporate securities 19%, government securities 37%, mortgages 2%, money market 26% and asset back securities 16%.

Our long-term debt includes \$150,000,000 of 5.5% Convertible Subordinated Notes due 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. The notes are convertible into shares of our common stock at any time prior to maturity, unless previously redeemed or repurchased, subject to adjustment in certain events. The market value of the notes will fluctuate with movements in the value of our common stock.

Our long-term debt with Genentech (\$33.8 million at June 30, 2002) has a variable interest rate equal to the prime interest rate. Any increase in the prime interest rate will increase our interest expense on the debt.

Our exposure to foreign currency fluctuations is currently limited to our supply contract for Natrecor, which is denominated in the Euro; the GSK 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.

## **PART II. OTHER INFORMATION**

### **Item 2. Change in Securities and Use of Proceeds**

On August 5, 2002, we completed the sale of \$150 million of 5.50% convertible subordinated notes due August 15, 2009 through a private placement to qualified institutional buyers pursuant to Rule 144A. We also granted the initial purchasers a 30-day option to acquire up to an additional \$25 million in principal amount to cover over-allotments. The notes will be convertible at the option of the holders into shares of Scios Inc. common stock initially at a conversion price of \$39.30 at any time, representing a conversion premium of 23% over the July 30, 2002 closing price of \$31.95. In connection with the offering, we pledged a portfolio of approximately \$24 million in U.S. government securities as security for the first six scheduled interest payments due on the notes. We intend to use a portion of the proceeds to repay outstanding indebtedness and the remaining amount for general corporate purposes. JP Morgan, Lehman Brothers, SG Cowen, Adams, Harkness & Hill, Needham & Company, and Prudential Securities acted as initial purchasers of the notes.

**Item 4. Submission of Matters to a Vote of Security Holders**

Our Annual Meeting of Stockholders was held on May 7, 2002.

- (a) The following individuals were elected directors of Scios, each to serve until the Annual Meeting of Stockholders in 2003:

Name	Total Vote For Each Director	Total Vote Withheld From Each Director
Samuel H. Armacost	34,151,233	6,759,896
Richard B. Brewer	40,758,581	152,548
Randal J. Kirk	40,433,215	477,914
Donald B. Rice, Ph.D.	40,598,913	312,216
Charles A. Sanders, M.D.	40,732,487	178,642
Solomon H. Snyder, M.D.	40,756,721	154,408
Burton E. Sobel, M.D.	40,575,166	335,963
Eugene L. Step	40,576,822	334,307

On May 15, 2002, Mr. Kirk resigned from our Board of Directors for personal reasons.

- (b) The following matters were submitted and each was approved by our stockholders, with votes cast as indicated:

To ratify the selection of PricewaterhouseCoopers LLP as our independent accountant for fiscal 2002:

Votes cast for:	40,108,287
Votes cast against:	765,315
Abstentions:	37,527

**Item 6. Exhibits and reports on Form 8-K**

- (a) Exhibits

- 4.3 For a discussion of certain registration rights in favor of PharmaBio, an affiliate of Innovex, see the Warrant Agreement filed with Exhibit 10.51 on our Annual Report on Form 10-K for the year ended December 31, 2001.
- 10.54 BNP Agreement between Scios Inc. and BioChemie Gesellschaft GmbH, dated November 17, 1995, as amended on April 30, 1996, September 30, 1997 and September 1, 1998 (portions of the exhibit have been omitted pursuant to a request for confidential treatment).

- (b) Reports on Form 8-K

Report on Form 8-K Filed on July 26, 2002. On July 25, 2002, Scios Inc. announced its financial results for the second quarter and six months ended June 30, 2002.

Report on Form 8-K Filed on August 6, 2002. On August 5, 2002, Scios Inc. closed a private offering of \$150 million aggregate principal amount of its 5.50% Convertible Subordinated Notes due 2009.



**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.

August 14, 2002

By:

/s/ RICHARD B. BREWER

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Richard B. Brewer, President and CEO

August 14, 2002

By:

/s/ DAVID W. GRYSKA

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David W. Gryska, Senior Vice President and CFO