

SCIOS INC  
Form 10-Q  
November 12, 2002

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**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 September 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

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**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.)

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**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)

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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 November 6, 2002: 46,659,442.

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## PART I

## Item 1. Financial Statements

## SCIOS INC.

**CONSOLIDATED BALANCE SHEETS**  
(in thousands, except share data)

	September 30, 2002	December 31, 2001
	(Unaudited)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 35,017	\$ 58,296
Marketable securities	23,064	7,351
Restricted marketable securities	8,403	
Accounts receivable, net	11,813	6,943
Inventory	3,472	1,158
Prepaid expenses and other assets	6,306	4,214
	<u>88,075</u>	<u>77,962</u>
Total current assets	88,075	77,962
Marketable securities, non-current	114,993	63,669
Restricted marketable securities, non-current	15,700	
Property and equipment, net	10,292	10,424
Other assets	8,354	4,123
	<u>237,414</u>	<u>156,178</u>
Total assets	\$ 237,414	\$ 156,178
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 11,857	\$ 9,625
Accrued employee compensation	11,759	9,685
Other accrued liabilities	12,464	7,206
Deferred contract revenue	1,289	
Accrued interest payable	1,260	3,035
Current portion of long-term debt	17,537	30,000
	<u>56,166</u>	<u>59,551</u>
Total current liabilities	56,166	59,551
Deferred contract revenue	3,237	
Long-term debt	160,738	15,479
	<u>220,141</u>	<u>75,030</u>
Total liabilities	220,141	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; 46,722,127 and 46,015,167 shares issued, respectively; 46,460,327 and 45,985,167 shares outstanding, respectively	47	46
Additional paid-in capital	569,157	561,352
Treasury stock; shares of 261,800 and 30,000, respectively	(6,014)	(445)
Deferred warrant costs	(3,291)	(6,794)
Deferred compensation		(106)
Accumulated other comprehensive income	837	999
Accumulated deficit	(543,463)	(473,904)
	<u>17,273</u>	<u>81,148</u>
Total stockholders equity	17,273	81,148

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Total liabilities and stockholders' equity	<u>\$ 237,414</u>	<u>\$ 156,178</u>
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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 September 30,		Nine months ended September 30,	
	2002	2001	2002	2001
	(Unaudited)		(Unaudited)	
<b>Revenues:</b>				
Product sales	\$ 26,140	\$ 18,330	\$ 64,023	\$ 20,428
Research and development contracts and royalties	1,017	1,284	2,605	3,865
Psychiatric product sales and co-promotion commissions, net of expenses				3,142
Gain on sale of marketing rights				9,363
	<u>27,157</u>	<u>19,614</u>	<u>66,628</u>	<u>36,798</u>
<b>Costs and expenses:</b>				
Cost of product sales	1,410	2,035	3,802	2,035
Research and development	19,292	12,101	50,955	34,665
Selling, general and administration	24,511	18,347	75,300	35,105
	<u>45,213</u>	<u>32,483</u>	<u>130,057</u>	<u>71,805</u>
Loss from operations	<u>(18,056)</u>	<u>(12,869)</u>	<u>(63,429)</u>	<u>(35,007)</u>
<b>Other income (expense):</b>				
Interest income	1,103	1,929	2,824	3,483
Interest expense	(4,912)	(653)	(9,354)	(2,256)
Realized gains on securities	169	205	462	594
Other income (expense)	(133)	221	(62)	(477)
	<u>(3,773)</u>	<u>1,702</u>	<u>(6,130)</u>	<u>1,344</u>
Net loss	<u>(21,829)</u>	<u>(11,167)</u>	<u>(69,559)</u>	<u>(33,663)</u>
<b>Other comprehensive gain (loss)</b>				
Change in net unrealized gains on securities	273	700	(162)	61
Comprehensive loss	<u>\$ (21,556)</u>	<u>\$ (10,467)</u>	<u>\$ (69,721)</u>	<u>\$ (33,602)</u>
<b>Net loss per common share:</b>				
Basic and diluted	\$ (0.47)	\$ (0.25)	\$ (1.50)	\$ (0.81)
<b>Weighted average number of common shares outstanding used in calculation of:</b>				
Basic and diluted	46,556,765	45,383,394	46,353,683	41,563,771

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

## SCIOS INC.

**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in thousands)

	Nine months ended September 30,	
	2002	2001
	(Unaudited)	
Cash flows from operating activities:		
Net loss	\$ (69,559)	\$ (33,663)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	3,837	2,508
Amortization of debt discount	1,435	
Amortization of debt issue costs	125	
(Gain) Loss on disposal of marketable securities	(462)	594
Accrued interest payable	7,800	2,256
Loss on disposal of property and equipment	119	365
Amortization of deferred compensation	106	311
Allowance for bad debt, returns and discounts	1,746	
Stock option issued to non-employee for services rendered	148	
Changes in assets and liabilities:		
Accounts receivable	(6,616)	(1,223)
Inventory	(2,314)	(428)
Prepaid expenses and other assets	(1,383)	(1,822)
Accounts payable	2,232	2,292
Accrued employee compensation	2,074	1,024
Other accrued liabilities	5,165	343
Deferred contract revenue	4,526	(16,065)
	<u>(51,021)</u>	<u>(43,508)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(3,824)	(2,605)
Sales/maturities of marketable securities	84,512	282,340
Purchases of marketable securities	(151,049)	(286,306)
Purchases of restricted marketable securities	(24,103)	
	<u>(94,464)</u>	<u>(6,571)</u>
Cash flows from financing activities:		
Issuance of common stock	7,668	116,949
Purchase of treasury stock	(5,579)	(445)
Proceeds from convertible notes, net of debt issue costs	144,828	
Proceeds from commercialization agreement	10,310	
Payment of commercialization agreement	(928)	
Payment of note payable and accrued interest	(34,093)	
Payment of note receivable		188
	<u>122,206</u>	<u>116,692</u>
Net increase (decrease) in cash and cash equivalents	(23,279)	66,613
Cash and cash equivalents at beginning of period	58,296	3,291

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Cash and cash equivalents at end of period	\$ 35,017	\$ 69,904
Supplemental cash flow data:		
Cash paid during the period for interest	\$ 5,021	\$
Change in net unrealized gains on securities	\$ 162	\$ (61)
Discount on commercialization obligation	\$ 3,503	\$

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, 2001.

The results of operations for the three and nine month periods ended September 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**

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 and nine months ended September 30, 2002 and September 30, 2001, as they were considered antidilutive due to the net loss the Company experienced in these fiscal periods.

	At September 30,	
	2002	2001
Outstanding stock options	8,062,878	7,310,087
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	
	13,078,772	8,509,187

**3. GlaxoSmithKline Agreement**

In March 2002, we finalized the agreement with Glaxo Group Ltd., an affiliate of GlaxoSmithKline, to license Natrecor to Glaxo Group Ltd., in all European markets. Under the terms of the agreement, Glaxo Group Ltd. 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 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 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 Glaxo Group Ltd. in obtaining European approval to sell Natrecor. As of September 2002,

we recognized \$0.3 million of the \$4.9 million as revenue. We will be responsible for the manufacture and supply of bulk active pharmaceutical ingredient to Glaxo Group Ltd. The companies will work together to continue clinical development of Natrecor in Europe. In September 2002, Glaxo Group Ltd. submitted a Marketing Authorization Application for nesiritide with the European Agency for the Evaluation of Medicinal Products. Glaxo Group Ltd. 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 GlaxoSmithKline. The marketing rights were originally licensed from GlaxoSmithKline under a 1990 licensing agreement. In order to effect the purchase, the licensing agreement was terminated effective March 31, 2001, and we received from GlaxoSmithKline \$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 expense in the quarter ended March 31, 2001.

#### 5. Notes Receivable from Officers

At September 30, 2002, we had a note receivable from one officer in the amount of \$120,000 bearing 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 sheets.

In July 2002, a note receivable from another officer was forgiven based on the continued employment of the officer. The loan amount was \$16,666 with interest at 5.82% per annum and the loan was collateralized by the officer's residence.

#### 6. Treasury stock

Treasury stock of 261,800 shares at September 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 \$10.0 million of Scios common stock. The repurchases are made through open-market transactions at the discretion of management as market conditions warrant. As of September 30, 2002, we had repurchased 261,800 shares of our common stock at an average purchase price of \$22.97 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 September 30, 2002, inventory consisted of the following:

	September 30, 2002	December 31, 2001
	_____	_____
	(in thousands)	
Work-in-process	\$ 2,507	\$ 24
Finished goods	965	1,134
	_____	_____
Total inventories	\$ 3,472	\$ 1,158
	_____	_____

#### 8. 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). Upon a change in control, we may be required, at the option of the note holders, to repurchase all or a



portion of the notes at the principal amount plus accrued interest in cash, Scios common stock, or a combination of cash and Scios common stock. 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. The notes are convertible at the option of the holders into shares of Scios common stock at any time prior to redemption, repurchase or maturity initially at a conversion price of \$39.30.

#### *Genentech Loan*

As part of a collaboration agreement with Genentech, Genentech committed to loan the Company up to \$30.0 million. The \$30.0 million was drawn down in March of 1997, and bears interest at the prime rate (4.75% in 2002). In 1999 the terms of the loan were amended. In the first quarter of 2000, the Company paid down \$2.0 million of the Genentech loan. In the third quarter of 2000, the Company paid down the Genentech loan by \$7.6 million, which consisted of a cash payment of \$2.6 million and 4,991 shares of Scios Series B preferred stock. Each share of Series B preferred stock converts at a rate of 100:1 of common stock at Genentech's option. The Series B preferred stock is convertible after December 30, 2002 and at Genentech's option before January 20, 2003. In the third quarter of 2002, the Company repaid the remaining balance of the Genentech loan plus accrued interest equal to \$34.1 million in cash. At September 30, 2002, there was no outstanding balance or amount available under this agreement.

#### *Quintiles/PharmaBio Funding*

In January 2001, we entered into a commercialization agreement with Quintiles, through its corporate venture group PharmaBio Development 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 is exercisable over seven installments beginning December 2001 through May 2003. As of September 30, 2002, we have received \$20.3 million of the \$30.0 million funding commitment and will receive the remaining \$9.7 million in three payments over the following 8 months. 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 \$20.3 million 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 and nine months ended September 30, 2002, interest expense associated with the royalty obligation to PharmaBio was \$2.4 million and \$4.9 million, respectively. There was no interest expense associated with the royalty obligation to PharmaBio during 2001.

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 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. Of this total fair value, \$6.9 million was recognized as a discount related to the debt based on the portion of the cash funding received from PharmaBio as of September 30, 2002. The remaining balance of \$3.3 million is recorded as deferred warrant costs in the Stockholder's Equity section. The \$3.3 million in deferred warrant costs will be recorded as discount on debt as the remaining \$9.7 million in funding is received from PharmaBio over the next 8 months. 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 and nine months ended September 30, 2002, interest expense associated with the amortization of the PharmaBio debt discount was \$0.7 million and \$1.4 million, respectively. There was no interest expense associated with the amortization of the PharmaBio debt discount during 2001.

#### **9. Lease Commitments**

In August 2002, we entered into operating lease agreements to lease two buildings totaling approximately 190,000 square feet in Fremont, California, for 15 years for our new corporate headquarters. Pursuant to the lease agreement, we will make

escalating monthly rent payments ranging from \$270,000 to \$370,000 from September 2003 to August 2017. As of September 30, 2002, future minimum lease payments under the lease agreements for the years ending December 31, 2002 through December 31, 2006 and thereafter are none, \$1.1 million, \$3.2 million, \$3.2 million, \$3.3 million and \$42.1 million.

#### **10. Recent Accounting Pronouncements**

In August 2001, the Financial Accounting Standards Board ( FASB ) issued Statement of Financial Accounting Standards No. 143 ( SFAS 143 ), Accounting for Asset Retirement Obligations, which is effective for fiscal years beginning after June 15, 2002. SFAS 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. SFAS 143 requires, among other things, that the retirement obligations be recognized when they are incurred and displayed as liabilities on the balance sheet. In addition, the asset's retirement costs are to be capitalized as part of the asset's carrying amount and subsequently allocated to expense over the asset's useful life. We believe that the adoption of SFAS 143 will not have a material effect on Scios' financial position or results of operations.

In April of 2002, the FASB issued Statement of Financial Accounting Standards No. 145 ( SFAS 145 ), Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No.13, and Technical Corrections, which is effective for fiscal years beginning after May 15, 2002. Under SFAS 145, gains and losses from the extinguishments of debt should be classified as extraordinary items only if they meet the criteria of Accounting Principles Board Opinion No. 30. SFAS 145 also addresses financial accounting and reporting for capital leases that are modified in such a way as to give rise to a new agreement classified as an operating lease. We believe that the adoption of SFAS 145 will not have a material effect on Scios' financial position or results of operations.

In June of 2002, the FASB issued Statement of Financial Accounting Standards No. 146 ( SFAS 146 ), Accounting for Costs Associated with Exit or Disposal Activities, which is effective for exit or disposal activities initiated after December 31, 2002. SFAS 146 nullifies Emerging Issues Task Force Issue No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring). Under SFAS 146, a liability is required to be recognized for a cost associated with an exit or disposal activity when the liability is incurred. SFAS 146 applies to costs associated with an exit activity that does not involve an entity newly acquired in a business combination or with a retirement or disposal activity covered by FASB Statements No.143 and 144. We believe that the adoption of SFAS 146 will not have a material effect on Scios' financial position or results of the operations.

#### **11. Subsequent Event**

In October 2002, the Board of Directors authorized an additional \$5.0 million for the repurchase of Scios common stock.

#### **Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*The following discussion should be read in conjunction with our audited consolidated financial statements, including the related notes, contained in our Annual Report on Form 10-K for the year-ended December 31, 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 that discovers, develops and markets novel treatments for cardiovascular and inflammatory diseases. On August 13, 2001, we launched Natrecor following approval from the Food and Drug Administration, or FDA, of Natrecor for the treatment of acutely decompensated congestive heart failure. In addition to Natrecor, we have two focused 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. 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.

#### **Recent Developments**

As of September 30, 2002, we have completed the enrollment of 210 patients for the FUSION study, or Management of Patients with Congestive Heart Failure After Hospitalization with Follow Up Serial Infusions Of Natrecor, a multi-center, randomized, open-label pilot study that is being conducted at approximately 40 U.S. sites. The FUSION study was initiated in January 2002. Patients are randomized to receive either their usual long-term cardiac medications, with or without intravenous inotropes, or serial infusions of Natrecor in addition to their usual long-term cardiac medications, excluding intravenous inotropes. All treatment groups have weekly outpatient visits, and Natrecor patients receive infusions for four to six hours at each weekly visit. Patients 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 second quarter of 2003.

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. This multi-center, randomized, placebo-controlled clinical study will enroll 120 patients who have active rheumatoid arthritis 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 rheumatoid arthritis patients. We expect to announce results from this study in the second quarter of 2003. Following the independent safety review of the first treatment group, we began to enroll patients in the second treatment group to evaluate the next two doses in the trial. As of October 24, 2002, we are nearing completion of enrollment in the second treatment group.

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 congestive heart failure, chronic obstructive pulmonary disease, 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 chronic obstructive pulmonary disease.

In March 2002, we finalized the agreement with Glaxo Group Ltd., an affiliate of GlaxoSmithKline, to license Natrecor to Glaxo Group Ltd. in all European markets. Under the terms of the agreement, Glaxo Group Ltd. 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, we will receive royalties on future sales of Natrecor in the identified countries. The GB£3.5 million (which equaled approximately \$4.9 million) 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 Glaxo Group Ltd. Both companies will work together to continue clinical development of Natrecor in Europe. In September 2002, Glaxo Group Ltd. submitted a Marketing Authorization Application for nesiritide with the European Agency for the Evaluation of Medicinal Products. Glaxo Group Ltd. expects 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 October 2002, we announced that the Centers for Medicare & Medicaid Services have granted a permanent code under the Healthcare Common Procedure Coding System, or HCPCS, to Natrecor, which allows Medicare reimbursement of Natrecor for use in the physician office setting. This reimbursement code will be effective on January 1, 2003.

In June 2002, we announced that the Joint Commission on Accreditation of Healthcare Organizations, or JCAHO, has determined that the Acute Decompensated Heart Failure National Registry, or ADHERE Registry, meets the criteria for inclusion in the accreditation process and is included on the Joint Commission's list of acceptable systems. The ADHERE 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 Prospective Randomized Outcomes Study of Acutely Decompensated Congestive Heart Failure Treated Initially in Outpatients with Natrecor, or PROACTION, trial. In this pilot study, two hundred and thirty seven patients were enrolled and treated in the Emergency Department/Observation Unit 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 Emergency Department/Observation Unit. Outcomes were assessed over thirty days. The study confirmed that Natrecor could be used safely in the Emergency Department/Observation Unit. Although not statistically significant, results suggest that early use of Natrecor in the Emergency Department/Observation Unit 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.

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**Results of Operations****Three Months Ended September 30, 2002 and 2001****Revenues**

*Product Sales.* Product sales for the three months ended September 30, 2002 were \$26.1 million versus \$18.3 million for the three months ended September 30, 2001. The increase was due to a \$21.6 million increase in sales of Natrecor from \$4.5 million for the three months ended September 30, 2001 to \$26.1 million during the comparable period in 2002, partially offset by a \$13.8 million decrease due to the non-recurring sales of bulk Fibroblast Growth Factor, or FGF, to Kaken in Japan following the product approval of Fiblast Spray in Japan, for the three months ended September 30, 2001.

*Research and Development Contracts and Royalties.* Research and development contracts and royalties were \$1.0 million for the three months ended September 30, 2002 and \$1.3 million for the three months ended September 30, 2001. For the three months ended September 2002, research and development contract and royalty revenues primarily consisted of \$0.6 million of royalties from Biosite on sales of diagnostic tests for BNP levels and \$0.4 million of royalties from Kaken on sales of Fiblast Spray in Japan. Research and development contract and royalty revenues for the comparable period in 2001 primarily consisted of \$0.8 million related to the Alzheimer's research collaboration agreements with Eli Lilly, \$0.3 million of royalties from Guilford Pharmaceuticals on sales of Guilford's Gliadel wafer and \$0.2 million of royalties from Kaken on sales of Fiblast Spray in Japan. Effective as of December 31, 2001, the Eli Lilly collaboration was jointly terminated.

**Costs and Expenses**

*Cost of Product Sales.* Cost of product sales were \$1.4 million for the three months ended September 30, 2002 and \$2.0 million for the three months ended September 30, 2001. The decrease in cost of product sales was due to a \$1.4 million decrease in royalty payments to Biotechnology Research Partners, Ltd. associated with the sale of bulk FGF to Kaken in Japan in 2001, which was partially offset by a \$0.9 million increase related to increased sales volume of Natrecor. Cost of Natrecor sales consist primarily of third-party product manufacturing and distribution costs, manufacturing overheads and royalties on a cross license agreement with Shionogi.

*Research and Development.* Research and development expenses were \$19.3 million and \$12.1 million for the three months ended September 30, 2002 and 2001, respectively. The increase of \$7.2 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.

*Selling, General and Administration.* Selling, general and administration expenses were \$24.5 million and \$18.3 million for the three months ended September 30, 2002 and 2001, respectively. The increase of \$6.2 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 income (expense) was \$(3.8) million and \$1.7 million for the three months ended September 30, 2002 and 2001, respectively. The decrease of \$5.5 million in net other income (expense) was principally due to an increase of \$4.3 million in interest expense and a decrease of \$0.8 million in interest income. The increase in interest expense was mainly due to \$3.1 million of interest expense recognized on the funding of \$20.3 million received from PharmaBio Development, an affiliate of Innovex, between December 2001 and September 2002, in connection with the sales and marketing agreement with Innovex, and \$1.4 million of interest expense on the \$150.0 million of convertible notes issued in August 2002. See Note 8 of Notes to Consolidated Financial Statements for details of the funding from PharmaBio. The decrease in interest income was the result of lower interest-bearing investment balances associated with lower average cash, cash equivalent and marketable security balances and lower average interest rates.

**Nine Months Ended September 30, 2002 and 2001****Revenues**

**Product Sales.** Product sales for the nine months ended September 30, 2002 were \$64.0 million versus \$20.4 million for the nine months ended September 30, 2001. The increase was due to a \$59.5 million increase in sales of Natrecor from \$4.5 million for the nine months ended September 30, 2001 to \$64.0 million during the comparable period in 2002, which was partially offset by a \$15.9 million decrease due to the non-recurring sales of bulk FGF to Kaken in Japan following the product approval of Fiblast Spray in Japan during the nine months ended September 30, 2001.

**Research and Development Contracts and Royalties.** Research and development contracts and royalties were \$2.6 million for the nine months ended September 30, 2002 and \$3.9 million for the nine months ended September 30, 2001. For the nine months ended September 30, 2002, research and development contract and royalty revenues primarily consisted of \$1.0 million of royalties from Biosite on sales of diagnostic tests for BNP levels, \$0.9 million of royalties from Kaken on sales of Fiblast Spray in Japan, \$0.3 million of recognized deferred contract revenue related to the Glaxo Group Ltd. commercialization agreement and \$0.4 million of other royalty agreements. For the nine months ended September 30, 2001, research and development contract revenues and royalties primarily reflect our Alzheimer's research collaboration agreements with Eli Lilly of \$2.2 million, a contractual diligence fee of \$0.8 million from Abbott Laboratories relating to the diagnostic tests for BNP levels, royalties of \$0.4 million from Guilford Pharmaceuticals on sales of Guilford's Gliadel wafer, royalties of \$0.2 million from Kaken on sales of Fiblast Spray in Japan, and other royalty agreements of \$0.3 million. Effective as of December 31, 2001, the Eli Lilly collaboration was jointly terminated.

**Net Psychiatric Product Sales and Co-Promotion Commissions.** Net psychiatric product sales and co-promotion commissions for the nine months ended September 30, 2002 were none versus \$3.1 million for the nine months ended September 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 GlaxoSmithKline and the termination of the license agreement in March 2001. At the same time, we dissolved our Psychiatric Sales and Marketing Division, or PSMD, 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 GlaxoSmithKline 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 GlaxoSmithKline psychiatric products sold by us. The marketing rights were eventually sold to GlaxoSmithKline. The marketing rights were originally licensed from GlaxoSmithKline under a 1990 licensing agreement. In order to effect the sale, the licensing agreement was terminated effective March 31, 2001, and we received from GlaxoSmithKline \$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 \$3.8 million for the nine months ended September 30, 2002 and \$2.0 million for the nine months ended September 30, 2001. The increase in costs of sales was mainly due to increased sales volume of Natrecor, which was partially offset by a \$1.4 million decrease in royalty payments to Biotechnology Research Partners, Ltd. associated with the sale of bulk FGF to Kaken in Japan in 2001. Cost of Natrecor sales consist primarily of third-party product manufacturing and distribution costs, manufacturing overheads and royalties on a cross license agreement with Shionogi.

**Research and Development.** Research and development expenses were \$51.0 million and \$34.7 million for the nine months ended September 30, 2002 and 2001, respectively. The increase in research and development expenses were 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.

**Selling, General and Administration.** Selling, general and administration expenses were \$75.3 million and \$35.1 million for the nine months ended September 30, 2002 and 2001, respectively. The increase of \$40.2 million was primarily due to increase in overall selling and marketing expenses associated with higher sales of Natrecor and 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 income (expense) was \$(6.1) million and \$1.3 million for the nine months ended September 30, 2002 and 2001, respectively. The decrease of \$7.4 million in net other income (expense) was principally due to higher interest expense of \$7.1 million and lower interest income of \$0.7 million. The increase in interest expense was mainly due to \$6.4 million of interest expense recognized on the funding of \$20.3 million received from PharmaBio Development, an affiliate of Innovex, between

December 2001 and September 2002, in connection with the sales and marketing agreement with Innovex, and \$1.4 million of interest expense on the \$150.0 million of convertible notes issued in August 2002. See Note 8 of Notes to Consolidated Financial Statements for details of the funding from PharmaBio. The decrease in interest income was the result of lower interest-bearing investment balances associated with lower average cash, cash equivalent and marketable security balances and 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 \$24.1 million of restricted marketable securities, our combined cash, cash equivalents and marketable securities (both current and non-current) totaled \$173.1 million at September 30, 2002.

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. Upon a change in control, we may be required, at the option of the note holders, to repurchase all or a portion of the notes at the principal amount plus accrued interest in cash, Scios common stock, or a combination of cash and Scios common stock. 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. The notes are convertible at the option of the holders into shares of Scios common stock at any time prior to redemption, repurchase or maturity initially at a conversion price of \$39.30. 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 Transnational Corp., which we later amended in November 2001. As part of the agreement, PharmaBio Development, Inc., 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 \$20.3 million through September 30, 2002, and will receive the remaining \$9.7 million over the next 8 months. As part of the funding agreement, we pay PharmaBio a declining royalty, up to a maximum of \$65 million, on net sales of Natrecor in the United States and Canada through early 2008. As of September 30, 2002, we have paid PharmaBio \$0.9 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. 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 March 2002, we finalized an agreement with Glaxo Group Ltd. to license Natrecor to Glaxo Group Ltd., an affiliate of GlaxoSmithKline, in all European markets. Under the terms of the agreement, Glaxo Group Ltd. 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 Natrecor 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 Glaxo Group Ltd. The companies will work together to continue clinical development of Natrecor in Europe. In September 2002, Glaxo Group Ltd. submitted a Marketing Authorization Application for nesiritide with the European Agency for the Evaluation of Medicinal Products. Glaxo Group Ltd. 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. In August 2002, we entered into an agreement, which expires 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 in September 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 also has operating leases covering certain laboratory and computer equipment.

We have entered into a long-term supply agreement with BioChemie for the supply of bulk Natrecor. The agreement provides for the purchase of at least 25 kg of bulk solution over an eight-year period after the first delivery of commercialized

quantities, at a maximum price of 24.5 million Euro (which equaled approximately \$24.2 million at September 30, 2002). As of September 30, 2002, the remaining minimum purchase commitment to this manufacturer was 22 kg of bulk solution at a maximum price of 21.6 million Euro (which equaled approximately \$21.3 million at September 30, 2002).

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 \$51.0 million in the nine months ended September 30, 2002 was primarily attributable to the net loss of \$69.6 million, partially offset by a decrease in net operating assets of \$3.7 million, accrued interest expense of \$7.8 million, depreciation of \$3.8 million, allowance for bad debts, returns and discounts of \$1.7 million and amortization of debt discount of \$1.4 million.

Net cash used in investing activities of \$94.5 million in the nine months ended September 30, 2002 was mainly due to purchases of marketable securities of \$151.0 million, purchases of restricted marketable securities of \$24.1 million to collateralize the first six interest payments for the subordinated convertible notes and purchases of property and equipment of \$3.8 million, partially offset by sales/maturities of marketable securities of \$84.5 million.

Net cash provided by financing activities of \$122.2 million in the nine months ended September 30, 2002 was due to the net proceeds from the issuance of subordinated convertible notes of \$144.8 million after deducting payments for debt issue costs of \$5.2 million, the funding from the PharmaBio commercialization agreement of \$10.3 million and the issuance of common stock of \$7.7 million through the exercise of employee stock options and employee stock purchase plan, partially offset by the repayment of the Genentech loan and accrued interest of \$34.1 million, purchases of treasury stock of \$5.6 million and the payments to PharmaBio under the commercialization agreement of \$0.9 million.

We expect our existing cash, cash equivalents and marketable securities, proceeds from existing collaborations, our agreement with PharmaBio, and our marketing agreement with Glaxo Group Ltd. 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 as of September 30, 2002 for the years ending December 31, 2002 through December 31, 2006 and thereafter:

	<b>Facilities Leases</b>	<b>Equipment Operating Leases</b>	<b>Long- term Debt</b>	<b>Manufacturing Purchase Commitments</b>
	(in thousands)			
2002	\$ 479	\$ 35	\$	\$ 2,904
2003	3,100	105	32,061	2,904
2004	4,112		32,264	2,904
2005	4,143		24,727	2,904
2006	4,273		21,646	2,904
Thereafter	43,989		174,750(1)	6,777
<b>Total</b>	<b>\$ 60,096</b>	<b>\$ 140</b>	<b>\$ 285,448</b>	<b>\$ 21,297</b>

(1) Long-term debt obligation after 2006 includes the \$150.0 million aggregate principal amount outstanding of 5.5% convertible subordinated notes due in 2009. The notes are convertible at the option of the holders into shares of Scios common stock at any time prior to redemption, repurchase or maturity at a conversion price of \$39.30.

#### Recent Accounting Pronouncements

In August 2001, the Financial Accounting Standards Board ( FASB ) issued Statement of Financial Accounting Standards No. 143 ( SFAS 143 ), Accounting for Asset Retirement Obligations, which is effective for fiscal years beginning after June 15, 2002. SFAS 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. SFAS 143 requires, among other things, that the retirement obligations be recognized when they are incurred and displayed as liabilities on the balance sheet. In addition, the asset's retirement costs are to be capitalized as part of the asset's carrying amount and subsequently allocated to expense over the asset's useful life. We believe that the adoption of SFAS 143 will not have a material effect on Scios' financial position or results of operations.

In April of 2002, the FASB issued Statement of Financial Accounting Standards No. 145 ( SFAS 145 ), Rescission of FASB Statements No.4, 44 and 64, Amendment of FASB Statement No.13, and Technical Corrections, which is effective for fiscal years beginning after May 15, 2002. Under SFAS 145, gains and losses from the extinguishments of debt should be classified as extraordinary items only if they meet the criteria of Accounting Principles Board Opinion No.30. SFAS 145 also addresses financial accounting and reporting for capital leases that are modified in such a way as to give rise to a new agreement classified as an operating lease. We believe that the adoption of SFAS 145 will not have a material effect on Scios' financial position or results of operations.

In June of 2002, the FASB issued Statement of Financial Accounting Standards No. 146 ( SFAS 146 ), Accounting for Costs Associated with Exit or Disposal Activities, which is effective for exit or disposal activities initiated after December 31, 2002. SFAS 146 nullifies Emerging Issues Task Force Issue No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring). Under SFAS 146, a liability is required to be recognized for a cost associated with an exit or disposal activity when the liability is incurred. SFAS 146 applies to costs associated with an exit activity that does not involve an entity newly acquired in a business combination or with a retirement or disposal activity covered by FASB Statements No.143 and 144. We believe that the adoption of SFAS 146 will not have a material effect on Scios' financial position or results of the 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.*

***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. We had a net loss of \$69.6 million for the nine months ended September 30, 2002, and as of September 30, 2002, we had an accumulated deficit of approximately \$543.5 million.

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

sales of Natreco 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 twelve 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 or market acceptance 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.

***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 nine months ended September 30, 2002. 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 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 GmbH 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 Laboratories 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 2002 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. Veletri, 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 recently completed Phase II clinical trials with Veletri for the treatment of acute congestive heart failure. 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 Veletri 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. Current commercial competition for rheumatoid arthritis treatments include generic methotrexate, the injectible TNF inhibitors such as Centocor's Remicade (Centocor is a subsidiary of Johnson & Johnson) and Amgen's Enbrel and their recent launch of an injectible interleukin-1 inhibitor, Kineret. 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 and our other product candidates in international markets, our market opportunities will be limited.***

We have not yet obtained 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 Glaxo Group Ltd. for marketing, promotion and sales activities.***

In March 2002, we entered into an agreement with Glaxo Group Ltd., an affiliate of GlaxoSmithKline, in all European markets. Under the terms of the agreement, Glaxo Group Ltd. 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 net sales of Natrecor in the identified European markets. Accordingly, our revenue from sales of Natrecor in Europe will be highly dependent on Glaxo Group Ltd.'s ability to effectively market and sell Natrecor. We will be responsible for the manufacture and supply of bulk active pharmaceutical ingredient to Glaxo Group Ltd.

In September 2002, Glaxo Group Ltd. submitted a Marketing Authorization Application for nesiritide with the European Agency for the Evaluation of Medicinal Products. If Glaxo Group Ltd. receives the necessary approvals, Glaxo Group Ltd. 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.***

We plan to partner with other companies for the sale of Natrecor and our other product candidates outside of the United States. We cannot assure you that we will be able to enter into such arrangements on favorable terms or at all. In addition, partnering arrangements could result in lower levels of income to us than if we marketed our products entirely on our own. In the event that we are unable to enter into a partnering arrangement for Natrecor 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.

***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.***

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 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.

***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.

***We are at risk of securities class action litigation.***

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

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

Our certificate of incorporation and bylaws contain provisions that could make it more difficult for our stockholders to replace or remove our officers and 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.

These provisions could also result in entrenchment of our existing management.

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 September 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 convertible subordinated notes.***

At September 30, 2002, we had total indebtedness of \$179.5 million, including indebtedness under our \$150.0 million of convertible subordinated notes due 2009. This significant indebtedness 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 convertible subordinated 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 convertible subordinated 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 for cash 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 outstanding convertible subordinated notes due 2009 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. Although we do not presently have any other indebtedness that has similar features, we are not prohibited from incurring such indebtedness in the future. Any such additional indebtedness would exacerbate the risks described above.

**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 September 30, 2002 of 10%, the fair value of our total investment portfolio as of September 30, 2002 would have potentially incurred a loss of \$252,000.

As of September 30, 2002, we had cash and cash equivalents of \$35.0 million, marketable securities of \$138.1 million and restricted marketable securities of \$24.1 million. Overall average duration to maturity for all cash and marketable securities is 0.8



years with 47% of the portfolio under one year and the remaining 53% between one and three years. The average interest rate earned on the portfolio was 2.8%. At September 30, 2002, the portfolio was broken down by the following investment categories: corporate securities 12%, government securities 45%, mortgages 2%, money market 22% and asset-backed securities 19%.

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. The notes are convertible into shares of Scios 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 Scios common stock.

Our exposure to foreign currency fluctuations is currently limited to our supply contract for Natrecor, which is denominated in the Euro; the Glaxo Group Ltd. agreement, which is denominated in the British Pound; and the royalty income from sales of Fibblast 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**

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 2. Change in Securities and Use of Proceeds**

On August 5, 2002, we completed the sale of \$150.0 million of 5.50% convertible subordinated notes due August 15, 2009 through a private placement to qualified institutional buyers pursuant to Rule 144A. We received \$144.7 million in net proceeds from the sale of the notes after deducting the initial purchasers' discount and offering expenses. The notes are convertible at the option of the holders into shares of Scios common stock initially at a conversion price of \$39.30 at any time through maturity, 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 \$24.0 million in U.S. government securities as collateral for the first six scheduled interest payments due on the notes. We used a portion of the proceeds to repay \$34.1 million of outstanding indebtedness and intend to use 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 6. Exhibits and reports on Form 8-K**

##### **(a) Exhibits**

- 10.55 Lease agreement dated August 16, 2002 for premises located at 6500 Paseo Padre Parkway, Fremont, California (portions of the exhibit have been omitted pursuant to a request for confidential treatment).
- 10.56 Lease agreement dated August 16, 2002 for premises located at 6422 Commerce Drive,

Fremont, California (portions of the exhibit have been omitted pursuant to a request for confidential treatment).

- 10.57 Processing and Supply Agreement - Natrecor BNP between Abbott Laboratories and Scios Inc., made effective as of December 1, 1997 (portions of the exhibit have been omitted pursuant to a request for confidential treatment).
- 10.58 Cross-License Agreement, made and entered into as of May 13, 1998, by and between Shionogi & Co., Ltd. and Scios Inc., as modified on March 5, 2002 (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.

Report on Form 8-K Filed on August 14, 2002. On August 14, 2002, Scios Inc. filed a certification for its Quarterly Report on Form 10-Q for the quarter ended June 30, 2002 by the chief executive officer and chief financial officer, as required by 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002.

**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.

November 12, 2002

By:

/s/ RICHARD B. BREWER

Richard B. Brewer, President and CEO

November 12, 2002

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
  - 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: November 12, 2002

/s/ RICHARD B. BREWER

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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
  - 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: November 12, 2002

/s/ DAVID W. GRYSKA

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David W. Gryska  
Senior Vice President and Chief Financial Officer