SCIOS INC
Form 10-Q
November 09, 2001
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One) |X| QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the quarterly period ended September 30, 2001 OR |_| TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the transition period from _____ to _____ Commission file number: 0-11749

Scios Inc.

(Exact name of Registrant as specified in its charter) Delaware 95-3701481 (State or other jurisdiction of (I.R.S. Employer incorporation or organization) Identification No.) Scios Inc. 820 W. Maude Ave. Sunnyvale, CA 94085 (Address of principal executive offices) (Zip code) (408) 616-8200 (Registrant's telephone number including area code) Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes X No ____ - Number of shares outstanding of the issuer's common stock, par value $.001 per share, as of September 30, 2001: 45,397,905

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

SCIOS INC.

Consolidated Balance Sheets
(In thousands, except share and per share data)

ASSETS	September 30, 2001
	(Unaudited)
Current assets:	
Cash and cash equivalents	$ 69,904
Marketable securities	1,006
Accounts receivable	6,440
Inventory	428
Prepaid expenses and other assets	488
Total current assets	78,266

Marketable securities, non-current	70,666
Property and equipment, net	8,642
Other assets	4,063
TOTAL ASSETS	$ 161,637
LIABILITIES AND STOCKHOLDERS' EQUITY	
Current liabilities:	
Accounts payable	$ 6,879
Other accrued liabilities	12,116
Deferred contract revenues	128
Total current liabilities	19,123
Long-term debt	41,350
Total liabilities	60,473
Stockholders' equity:	
Preferred stock; $.001 par value; 20,000,000 shares authorized; 4,991 shares issued and outstanding	--
Common stock; $.001 par value; 150,000,000 shares authorized; 45,397,905 and 39,166,373 shares issued and outstanding, respectively	45
Treasury stock; 30,000 shares	(445)
Additional paid-in capital	545,930
Notes receivable from stockholders	(446)
Deferred compensation, net	(106)
Accumulated other comprehensive income	1,256
Accumulated deficit	(445,070)
Total stockholders' equity	101,164
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 161,637

The accompanying notes are an integral part of these consolidated financial stat

SCIOS INC.

Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)

	Three months ended September 30,	
	2001	2000
	(Unaudited)	
Revenues:		
Product sales	$ 18,330	$ --
Research and development contracts and royalties	1,284	1,192
Gain on sale of marketing rights	--	--
Psychiatric product sales, co-promotion commissions, net of expenses	--	1,624
	19,614	2,816
Costs and expenses:		
Cost of sales	2,035	--
Research and development	12,101	9,645
Marketing, general and administration	18,347	3,545
Restructuring credits	--	
	32,483	13,190
Loss from operations	(12,869)	(10,37
Other income and expense:		
Interest income	1,929	1,221
Interest expense	(653)	(91
Realized gains (losses) on securities	205	(
Other income (expense), net	221	(41
	1,702	(11
Net loss	(11,167)	(10,484

Other comprehensive income:		
Change in unrealized gain on securities	700	387
Comprehensive loss:	$ (10,467)	$ (10,097
Loss per common share:		
Basic and diluted	$ (0.25)	$ (0.28)
Weighted average number of common shares outstanding used in the calculation of net loss per share:		
Basic and diluted	45,383,394	37,881,42

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

SCIOS INC.

Consolidated Statements of Cash Flows
(In thousands)

	Nine month Septembe 2001
	(Unaudi
Cash flows from operating activities:	
Net loss	$ (33,663)
Adjustments to reconcile net loss to net cash used in operating activities:	
Depreciation and amortization	2,508
Loss on property and equipment retirement	365
Accrued long-term interest payable	2,255
Gain (loss) on sale of securities	594
Amortization of deferred compensation	311
Changes in assets and liabilities:	
Accounts receivable	(1,223)
Accounts payable	2,292
Inventories	(428)
Other accrued liabilities	1,367
Prepaid expenses and other assets	(1,822)
Deferred contract revenue	(16,065)
Restructuring (credits) charges	--
Net cash used in operating activities	(43,508)
Cash flows from investing activities:	
Purchases of property and equipment	

	(2,605)
Sales/maturities of marketable securities	282,340
Purchases of marketable securities	(286,306)
Net cash provided by (used in) investing activities	(6,571)
Cash flows from financing activities:	
Issuance of common stock and collection of notes receivable from stockholders, net	116,949
Purchase of treasury stock	(445)
Payment (issues) of notes receivable	188
Net cash provided by (used in) financing activities	116,692
Net increase (decrease) in cash and cash equivalents	66,613
Cash and cash equivalents, at beginning of period	3,291
Cash and cash equivalents, at end of period	$ 69,904

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

SCIOS INC.

Notes to Consolidated Financial Statements (unaudited)

1. Basis of Presentation

The accompanying unaudited consolidated financial statements of Scios have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not contain all of the information and footnotes required by generally accepted accounting principles in the United States of America for complete financial statements. In the opinion of management, the accompanying unaudited, consolidated financial statements reflect all adjustments (consisting of normal, recurring adjustments) considered necessary for a fair presentation of Scios' interim consolidated financial information. These consolidated financial statements and notes should be read in conjunction with the audited financial statements of Scios included in our Annual Report on Form 10-K for the year ended December 31, 2000. The results of operations for the three and nine months ended September 30, 2001 are not necessarily indicative of the operating results that may be reported for the fiscal year ending December 31, 2001 or for any other future period.

2. New Accounting Pronouncements

Financial Accounting Standards No. 141. In July 2001, the Financial Accounting Standards Board issued SFAS No. 141 "Business Combinations," which establishes financial accounting and reporting for business combinations and supersedes APB Opinion No. 16, Business Combinations, and FASB Statement No. 38, Accounting for Preacquisition Contingencies of Purchased Enterprises. It requires that all business combinations in the scope of this Statement are to be accounted for using one method, the purchase method. The provisions of this Statement apply to all business

combinations initiated after June 30, 2001, and also applies to all business combinations accounted for using the purchase method for which the date of acquisition is July 1, 2001, or later. The adoption of SFAS No. 141 had no material impact on our financial reporting and related disclosures. Financial Accounting Standards No. 142. In July 2001, the Financial Accounting Standards Board issued SFAS No. 142 "Goodwill and Other Intangible Assets," which establishes financial accounting and reporting for acquired goodwill and other intangible assets and supersedes APB Opinion No. 17, Intangible Assets. It addresses how intangible assets that are acquired individually or with a group of other assets (but not those acquired in a business combination) should be accounted for in financial statements upon their acquisition, and after they have been initially recognized in the financial statements. We will adopt SFAS No.142 beginning with the first quarter of fiscal 2002. The adoption of SFAS No. 142 is not expected to have a material impact on our financial reporting and related disclosures. In October 2001, the FASB issued Statement of Financial Accounting Standards No. 144 ("SFAS 144"), "Accounting for the Impairment or Disposal of Long-Lived Assets," which is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal periods. This Statement supersedes FASB Statement No. 121and APB 30, however, this Statement retains the requirement of Opinion 30 to report discontinued operations separately from continuing operations and extends that reporting to a component of an entity that either has been disposed of (by sale, by abandonment, or in a distribution to owners) or is classified as held for sale. This Statement addresses financial accounting and reporting for the impairment of certain long-lived assets and for long-lived assets to be disposed of. Management does not expect the adoption of SFAS 144 to have a material impact on the Company's financial position and results of operations.

3. Computation of Loss Per Share

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

	Three months ended September 30,		Nine m Sept
	20001	2000	200
Numerator			
Basic and Diluted			
Net loss	$ 11,167	$10,484	$33,6
Denominator			
Basic and Diluted			
Weighted average shares	45,383	37,881	41,5
Basic and diluted loss per share	$ 0.25	$ 0.28	$ 0.81

The potentially dilutive effect of outstanding options to purchase common stock would have been anti-dilutive as to the reported losses per share in both 2001 and 2000, and they were therefore excluded from the diluted loss per share calculations for all periods. Further, in the third quarter of 2000, we paid down the Genentech loan by issuing 4,991 shares of preferred stock. The preferred stock converts at a rate of 100:1 of common stock at Genentech's option. Although potentially dilutive, the optional settlement of the Genentech loan through the issuance of preferred stock would have been anti-dilutive in both 2001 and 2000 and was therefore excluded from the calculations. At September 30, 2001, we had 7,310,087 outstanding stock options at prices ranging from $3.81 to $27.60 per share. At September 30, 2000, we had 5,238,021 outstanding stock options at prices ranging from $3.69 to $21.13 per share. 4. Industry and Geographic Segment Information We operate in one business segment, using one measurement of profitability for our business. We receive revenue from product sales and from licensing and development of products from partners in the United States, Europe and Asia Pacific. At September 30, 2001, all long-lived assets were located in the United

States. Revenues for the nine months ended September 30, 2001 were earned in the United States, from Japan for bulk Fibroblast Growth Factor ("FGF") shipments to Kaken Pharmaceuticals Co., Ltd., and royalty income from sales of Fiblast(R)spray by Kaken. All revenues from sales of Natrecor(R)were earned in the United States.

5. Gain on Sale of Marketing Rights

In the first quarter of 2001, the marketing rights for psychiatric product sales were sold to GlaxoSmithKline, or GSK. The marketing rights were originally licensed from GSK under a 1990 licensing agreement. In order to effect the purchase, the licensing agreement was terminated effective March 31, 2001, and we received from GSK $4.0 million in 2001, and will receive $3.0 million in 2002 and $2.5 million in 2003. We recognized a one-time gain on the sale of $9.4 million, which has been classified on the statement of operations under the caption Gain on Sale of Marketing Rights. In addition, we ended the deployment of our Psychiatric Sales Marketing Division sales force and terminated certain full-time support personnel. Severance payments for these personnel amounted to approximately $788,000. 6. Notes Receivable from Officers At September 30, 2001, we had notes receivable from three officers. The first note is in the amount of $179,466 with interest at 6.30% per annum, due and payable on October 31, 2001. The loan was granted in connection with the payment of income taxes for restricted stock granted to the officer. This loan is collateralized by the vested portion of the officer's common stock and is classified with other current assets on the balance sheet at September 30, 2001. This loan was re-paid in November 2001. The second note is in the amount of $280,040 with interest at 5.18% per annum, due and payable on February 28, 2002. The loan was granted in connection with the payment of income taxes for restricted stock granted to the officer. This loan is collateralized by the vested portion of the officer's stock options and is classified with other current assets on the balance sheet at September 30, 2001. The third note is in the amount of $8,333 with interest at 5.82% per annum. This loan will be forgiven in 2002 based on the continued employment of the officer and is collateralized by the officer's residence. The loan was granted in connection with a housing subsidy for the officer to live in California. This note balance is classified with other assets on the balance sheet at September 30, 2001.

7. Equity Financing

During the second quarter of 2001, we raised approximately $113.0 million, net of expenses, through the issuance of 5,750,000 shares of common stock at $21 per share.

8. Lease Commitments

We lease four 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.

Future minimum payments under these leases are as follows:

	(in thousands)
2002	$ 1,825
2003	$ 2,069
2004	$ 917
2005	$ 948
2006	$ 979
2007	$ 1,010
2008	$ 868

9. Stockholder Approval of Stock Plans

On May 8, 2001, the stockholders approved an amendment to the 1992 Equity Incentive Plan adding 1.5 million shares of common stock to this plan. In addition, an Employee Stock Purchase Plan was approved by the stockholders with an initial allocation of 375,000 shares of common stock.

10. New Accounting Policies

Product Sales Revenue from Natrecor(R)product sales is recognized upon receipt of a purchase order and product shipment, provided no significant obligations remain and collection of the receivables is deemed probable. Provisions for discounts and rebates to customers and returns are provided for in the same period the related sales are recorded. Product sales consist of revenue from Natrecor(R)and from bulk Fibroblast Growth Factor or FGF. The FDA approved Natrecor(R)on August 13, 2001. This was the first quarter in which we recorded sales of Natrecor(R). In the third quarter of 2001, we recorded the last shipment of bulk FGF to Kaken in Japan. Kaken will manufacture future bulk FGF. Inventory Inventories are stated at the lower of cost (first-in, first-out basis) or market. Cost includes material and conversion costs. Prior to FDA approval, materials and the production of Natrecor(R)was expensed and charged in the Statement of Operations to Research and Development.

11. Innovex, PharmBio, and Scios Amended Agreement

On October 24, 2001 Scios, Innovex and Innovex's sister company, PharmaBio, executed a letter of intent to amend the January 10, 2001 agreement in relation to the Natrecor(R)sales force and the infrastructure supporting it. The amendment will enable Scios, at its option, to assume control of the Natrecor(R)sales force in June 2003, one year ahead of schedule. In addition, we eliminated the $5.0 million line of credit provided by PharmaBio to Scios. Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations The following discussion should be read in conjunction with our audited consolidated financial statements, including the related notes, contained in our Annual Report on Form 10-K for the year-ended December 31, 2000. The following discussion also contains forward-looking statements about our plans, objectives and future results. These forward-looking statements are based on our current expectations, and we assume no obligation to update this information. Realization of these plans and results involves risks and uncertainties, and our actual results could differ materially from those discussed here. Factors that could cause or contribute to such differences include those set forth under "Risk Factors" in this Report on Form 10-Q.

Overview

We are a biopharmaceutical company developing novel drugs for the potential treatment of cardiovascular and inflammatory diseases. Our disease-based technology platform integrates expertise in protein biology with computational and medicinal chemistry to identify novel targets and rationally design small molecule compounds for large markets with unmet medical needs. We employ approximately 415 people. Natrecor(R), our treatment for acute Congestive Heart Failure, or acute CHF, was approved by the FDA in the third quarter of 2001 and is currently marketed by our 168-person sales force. SCIO-469, an oral small molecule inhibitor of p38 kinase, is our lead development candidate for the treatment of rheumatoid arthritis. On August 13, 2001, we received final approval from the FDA to market Natrecor(R)for the intravenous treatment of patients with acutely decompensated congestive heart failure. We submitted an amendment to our New Drug Application, or NDA, for Natrecor(R)to the U.S. Food and Drug Administration, or FDA, in January 2001, and the FDA's Cardiovascular and Renal Drugs Advisory Committee reviewed our amended NDA on May 25, 2001. The recommendation of that Committee was for unanimous approval of Natrecor(R). On July 10, 2001, we received from the FDA an approvable letter for Natrecor(R). The approvable letter was issued with two items to be completed: the pre-approval inspection of our facility and the final negotiations on the drug's label. In July 2001, the District Office of the FDA completed the pre-approval inspection and recommended approval of the Natrecor(R)New Drug Application. During August 2001, the final negotiations on the drug's label were completed. During January 2001, we completed a Phase Ia clinical trial with single oral doses of SCIO-469 in healthy volunteers. In February 2001, a Phase Ib clinical trial was initiated with 20 healthy volunteers to evaluate the safety and tolerability of multiple oral doses of SCIO-469 over a two-week period. The Phase Ib trial was completed in April 2001. Based on the results of these trials, we filed an Investigational New Drug application with FDA in November 2001 for a Phase II study with SCIO-469. The study is expected to begin enrollment of Rheumatoid Arthritis patients in January 2002. In March 2001, we initiated the PROACTION (Prospective Randomized Outcomes Study of Acutely Decompensated Congestive Heart Failure Treated Initially in Outpatients

with Natrecor(R)) trial, a pilot study designed to compare the clinical effects, safety profile and economic impact of standard therapy plus Natrecor(R)to standard therapy plus placebo. The PROACTION trial has an enrollment target of 250 acute CHF patients. An interim data analysis of the first 145 patients enrolled was completed in the third quarter of 2001. The early interpretation of the data, which may change based on the final data analysis, suggest that Natrecor(R)can be safely administered in the emergency department setting, and patients treated with Natrecor may be less likely to be admitted to the hospital for heart failure from the emergency department. Final results of the PROACTION study is expected to be reported in the first quarter of 2002. In April 2001, Kaken Pharmaceuticals Co., Ltd. received notice from the Japanese Ministry of Health and Welfare that they have been granted marketing approval for Fiblast(R)Spray for the treatment of recalcitrant dermal ulcers. The active ingredient in Fiblast(R)Spray is recombinant basic Fibroblast Growth Factor, or FGF, which Kaken licensed from us in 1988. Based on this approval, we recognized $15.9 million in revenue during 2001 following shipment of FGF to Kaken in Japan. For the quarters ended June 30, 2001 and September 30, 2001, we recorded product sales of $2.1 million and $13.8 million, respectively . Additionally, in the third quarter, we received royalty payments of $0.2 million from sales of Fiblast(R). In May 2001, we expanded our research collaboration with Medtronic, Inc. to study the effects of Natrecor(R)in combination with Medtronic's heart failure devices and implantable infusion systems. In the first of a planned program of pilot clinical studies, we will evaluate the hemodynamic and clinical effects of Natrecor(R), including the effects on spontaneous activity and controlled exercise tolerance, using information collected by Medtronic's Chronicle(R)Implantable Hemodynamic Monitor (IHM) both during and after infusions of Natrecor(R). The pilot feasibility study began in the third quarter of 2001 at the Karolinska Hospital in Stockholm. The Chronicle IHM is an implanted system designed to measure and record hemodynamic variables over time such as right ventricular systolic and diastolic pressures, estimated pulmonary artery diastolic pressure, heart rate and activity. The Chronicle IHM is not yet approved for marketing in the United States or Europe. During the second quarter of 2001, we raised approximately $113.0 million, net of expenses, through the issuance of 5,750,000 shares of common stock. This equity financing significantly strengthened our financial position and gave us the financial flexibility to launch and market Natrecor(R)while developing our promising pipeline, most importantly our p38 kinase inhibitor for rheumatoid arthritis. On October 24, 2001 Scios, Innovex and Innovex's sister company, PharmaBio, executed a letter of intent to amend the January 10, 2001 agreement in relation to the Natrecor(R)sales force and the infrastructure supporting it. The amendment will enable Scios, at its option, to assume control of the Natrecor(R)sales force in June 2003, one year ahead of schedule. In addition, we eliminated the $5.0 million line of credit provided by PharmaBio to Scios.

Results of Operations

Three Months Ended September 30, 2001 and 2000 Revenues Product Sales. Product sales for the three months ended September 30, 2001 were $18.3 million versus none for the three months ended September 30, 2000. The increase was due to sales of bulk FGF to Kaken and our sales of Natrecor(R). During the third quarter of 2001, we recorded $13.8 million of bulk FGF product sales to Kaken in Japan. Further, Natrecor(R)received FDA approval on August 13, 2001, and we recorded $4.5 million in Natrecor(R)product sales this quarter. Research and Development Contract Revenues and Royalties Research and development contract revenues and royalties were $1.3 million for the three months ended September 30, 2001 and $1.2 million for the three months ended September 30, 2000. These contract revenues reflect our research collaboration agreements with Eli Lilly and Company, DuPont Pharmaceutical Company, and other licensing fees and royalties. The research collaboration agreement with Dupont Pharmaceutical Company ended effective December 2000. Psychiatric Product Sales and Co-Promotion Commissions. Psychiatric product sales and co-promotion commissions for the three months ended September 30, 2001 were none versus $1.6 million for the three months ended September 30, 2000. Scios no longer sells or co-promote the psychiatric products after March 31, 2001. Costs and Expenses Cost of Sales. Cost of sales were $2.0 million and none for the three months ended September 30, 2001 and 2000, respectively. The increase in expenses were mainly due to the cost to manufacture and distribute Natrecor(R), royalty payments to the Biotechnology Research Partners, LTD. on revenues generated from the sales of bulk FGF to Kaken, and cost of shipping bulk FGF to Kaken in Japan. Prior to FDA approval, materials and the cost of production of Natrecor(R)were expensed and charged to Research and Development. Research and Development. Research and development expenses were $12.1 million and $9.6 million

for the three months ended September 30, 2001 and 2000, respectively. The increase in expenses of $2.5 million in expenses were mainly attributable to clinical expenses related to Natrecor(R), research expenses related to our p38 kinase inhibitor program, associated expenses to develop the Acute Decompensated Heart Failure National Registry (ADHERE) database, and hiring of 13 Scientific Affairs Managers to support the launch of Natrecor(R). Marketing, General and Administrative. Marketing, general and administrative expenses were $18.3 million and $3.5 million for the three months ended September 30, 2001 and 2000, respectively. The increase of $14.8 million in expenses for the 2001 quarter is largely attributable to the costs associated with the commercialization of Natrecor(R). These expenses consist of the building of a marketing and sales force infrastructure that includes the recruiting of Cardiovascular Sales Representatives, Area Business Directors, and Area Business Managers. Other costs included launch activities, developing and producing promotional materials, and obtaining and analyzing marketing research data. Other Income (Expense), net Net other income (expense) was $1.7 million and $(0.1) million for the three months ended September 30, 2001 and 2000, respectively. The increase of $1.8 million in other income and expense was principally due to the $0.7 million increase in interest income due to the higher cash balances from quarter to quarter, lower interest expense of $0.2 million due to lower rates, and realized gains on marketable securities of $0.2 million. Nine Months Ended September 30, 2001 and 2000 Revenues Product Sales. Product sales for the nine months ended September 30, 2001 were $20.4 million versus none for the nine months ended September 30, 2000. The increase was due to sales of bulk FGF to Kaken and our sales of Natrecor(R). Based on the product approval of Fiblast(R)Spray in Japan, we recorded $15.9 million of bulk FGF product sales to Kaken in Japan during the second and third quarters of 2001. In addition, we recorded Natrecor(R)sales of $4.5 million in the third quarter following FDA approval on August 13, 2001. Research and Development Contract Revenues and Royalties. Research and development contract revenues and royalties were $3.9 million for the nine months ended September 30, 2001 and $4.6 million for the nine months ended September 30, 2000. These contract revenues reflect our research collaboration agreements with Eli Lilly and Company, DuPont Pharmaceutical Company, and other licensing fees and royalties. The decrease of $0.7 million is primarily due to the fact that the collaborative research phase of our research collaboration agreement with DuPont Pharmaceutical Company ended in December 2000. Gain on Sale of Marketing Rights. In the first quarter of 2001, we sold our marketing rights for certain psychiatric products licensed to GSK. The marketing rights were originally licensed from GSK under a 1990 licensing agreement. In order to effect the purchase, we terminated the licensing agreement effective March 31, 2001, and we received from GSK $4.0 million in 2001, and will receive $3.0 million in 2002, and $2.5 million in 2003. We recognized a one-time gain of $9.4 million related to the sale. Psychiatric Product Sales and Co-Promotion Commissions. Psychiatric product sales and co-promotion commissions for the nine months ended September 30, 2001 were $3.1 million versus $4.5 million for the nine months ended September 30, 2000. The $3.1 million represents final co-promotion commissions as we no longer sell or co-promote psychiatric products after March 31, 2001. Costs and Expenses Cost of Sales. Cost of sales were $2.0 million and none for the nine months ended September 30, 2001 and 2000, respectively. The increases in expenses were mainly due to the cost to manufacture and distribute Natrecor(R), royalty payments to the Biotechnology Research Partners, LTD. on revenues generated from the sales of bulk FGF to Kaken, and cost of shipping bulk FGF to Kaken in Japan. Prior to FDA approval, materials and the cost of production of Natrecor(R)were expensed and charged to Research and Development. Research and Development. Research and development expenses were $34.7 million and $30.2 million for the nine months ended September 30, 2001 and 2000, respectively. The increase in expenses were mainly attributable to clinical expenses related to Natrecor(R), research expenses related to our p38 kinase inhibitor program, associated expenses to develop the Acute Decompensated Heart Failure National Registry (ADHERE) database, hiring of 13 Scientific Affairs Managers to support the Natrecor(R)launch, and materials and cost of production of Natrecor(R)prior to FDA approval. Marketing, General and Administrative. Marketing, general and administrative expenses were $35.1 million and $9.8 million for the nine months ended September 30, 2001 and 2000, respectively. The increase of $25.3 million in expenses in 2001 is largely attributable to the costs associated with the pre-commercialization of Natrecor(R). These expenses include the building of a marketing and sales force infrastructure, which consist of the recruiting of Cardiovascular Sales Representatives, Area Business Directors, and Area Business Managers. In addition, other expenses reflect the development and production of promotional materials, and obtaining and analyzing marketing research data. Restructuring charges (credits). On completion of our 1999 corporate restructuring, we recorded a $1.0 million credit in 2000 relating to the unused portion of the restructuring reserve. Other Income (Expense), net Net other expense was $1.3 million and $(0.4) million for the nine

months ended September 30, 2001 and 2000, respectively. The increase of $1.7 million in other income and expense was principally due lower interest expense of $0.7 million, and realized gains on marketable securities of $0.8 million.

Liquidity and Capital Resources

To date, our operations and capital requirements have been financed primarily with the proceeds of public and private sales of common stock and preferred stock, research and development partnerships, collaborative agreements with pharmaceutical firms, product sales and investment income. During the second quarter of 2001, we raised approximately $113.0 million, net of expenses, through a public offering of 5,750,000 shares of common stock, which significantly strengthened our financial position. At September 30, 2001, our combined cash, cash equivalents and marketable securities (both current and non-current) totaled $141.6 million. In the first quarter of 2001 we entered into a sales and marketing alliance with Innovex, a subsidiary of Quintiles Transnational Corp. As part of the three and half year agreement, PharmaBio Development, Inc., an affiliate of Innovex, agreed to fund $30.0 million of our costs to launch Natrecor(R)over the first 24 months of the commercialization of Natrecor(R)' and to loan us up to $5.0 million. Of the $30.0 million, $10.0 million is expected to be paid to us in the 4th quarter of 2001 and $20.0 million in 2002 and 2003. Under the agreement, Innovex will identify, hire, train and deploy a dedicated cardiology and emergency medicine sales force to launch and market Natrecor(R). On October 24, 2001 Scios, Innovex and Innovex's sister company, PharmaBio, executed a letter of intent to amend the January 10, 2001 agreement in relation to the Natrecor(R)sales force and the infrastructure supporting it. The amendment will enable Scios, at its option, to assume control of the Natrecor(R)sales force in June 2003, one year ahead of schedule. In addition, we eliminated the $5.0 million line of credit provided by PharmaBio to Scios. During September 2001, we announced today that the Board of Directors authorized the repurchase of up to $10.0 million of Scios common stock. The repurchases are to be made through open-market transactions at the discretion of management and as market conditions warrant. During the third quarter of 2001, we re-purchased $445,000 or 30,000 common stocks. Net cash used in operating activities of $44.1 million in the nine months ended September 30, 2001 was primarily attributable to the loss of $33.7 million and decreases in operating assets and liabilities of $15.8 million, partially offset by non-cash expenses of $5.4 million. Net cash used by investing activities of $6.0 million in the nine months ended September 30, 2001 consisted of net purchases of marketable securities of $3.4 million and purchases of property and equipment of $2.6 million. Net cash provided by financing activities of $116.7 million in the nine months ended September 30, 2001 was due to the net proceeds from the issuance of common stock and collection of notes receivable of $116.9 million; offset in part by the repurchase of 30,000 shares of Scios common stock. The stock was recorded as treasury stock of $0.5 million. We anticipate that our existing cash, cash equivalents and marketable securities and proceeds from proceeds from product sales, existing collaborations, including our agreement with Innovex and PharmaBio, and future expected sales of our products will enable us to maintain our current and planned operations for the next twenty-four months. In the long-term, we may need to arrange additional financing for the operation of our business, including the commercialization of our products currently under development. We will consider collaborative arrangements and additional public or private financing, including additional equity financing. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects and the general conditions of the financial markets. New Accounting Pronouncements Financial Accounting Standards No. 141. In July 2001, the Financial Accounting Standards Board issued SFAS No. 141 "Business Combinations," which establishes financial accounting and reporting for business combinations and supersedes APB Opinion No. 16, Business Combinations, and FASB Statement No. 38, Accounting for Preacquisition Contingencies of Purchased Enterprises. It requires that all business combinations in the scope of this Statement are to be accounted for using one method, the purchase method. The provisions of this Statement apply to all business combinations initiated after June 30, 2001, and also applies to all business combinations accounted for using the purchase method for which the date of acquisition is July 1, 2001, or later. The adoption of SFAS No. 141 had no material impact on our financial reporting and related disclosures. Financial Accounting Standards No. 142. In July 2001, the Financial Accounting Standards Board issued SFAS No. 142 "Goodwill and Other Intangible Assets," which establishes financial accounting and reporting for acquired goodwill and other intangible assets and supersedes APB Opinion No. 17, Intangible Assets. It addresses how intangible assets that are acquired individually or with a group of other assets (but not those acquired in a business combination) should be accounted for in financial statements upon their acquisition, and after they have

been initially recognized in the financial statements. We will adopt SFAS No.142 beginning with the first quarter of fiscal 2002. The adoption of SFAS No. 142 is not expected to have a material impact on our financial reporting and related disclosures. In October 2001, the FASB issued Statement of Financial Accounting Standards No. 144 ("SFAS 144"), "Accounting for the Impairment or Disposal of Long-Lived Assets," which is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal periods. This Statement supersedes FASB Statement No. 121and APB 30, however, this Statement retains the requirement of Opinion 30 to report discontinued operations separately from continuing operations and extends that reporting to a component of an entity that either has been disposed of (by sale, by abandonment, or in a distribution to owners) or is classified as held for sale. This Statement addresses financial accounting and reporting for the impairment of certain long-lived assets and for long-lived assets to be disposed of. Management does not expect the adoption of SFAS 144 to have a material impact on the Company's financial position and results of operations.

Risk Factors

You should carefully consider the risks described below before making an investment decision. Our business, financial condition or results of operations could be harmed by any of these risks. The risks described below are not the only ones facing our company. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations. This document also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of the risks faced by us, including those described below and elsewhere in this document.

Risks Related to Natrecor® (nesiritide)

If Natrecor(R)does not gain market acceptance, our business will suffer. Natrecor(R)may not gain market acceptance among physicians, patients, healthcare payors and the medical community. We will need to educate doctors and other healthcare advisors of the safety and clinical efficacy of Natrecor(R)and its potential advantages over other treatments. The degree of market acceptance of Natrecor(R)will also depend on a number of factors, including: |X| the degree of clinical efficacy and safety; |X| cost-effectiveness of Natrecor(R); |X| its advantage over alternative treatment methods; and |X| reimbursement policies of government and third party payors. To the extent market acceptance of Natrecor(R)is limited, our revenues may suffer.

If the FDA determines that our third-party manufacturing facilities are not adequate, 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(R). Natrecor(R)is manufactured for us by Biochemie GmbH, a subsidiary of Novartis, in Austria and is shipped in powder form to Abbott Laboratories in McPherson, Kansas where it is blended, filled and packaged for shipment. Although each facility has previously passed FDA inspections, future inspections may find deficiencies in the facilities or processes that may delay or prevent the manufacture or sale of Natrecor(R). If deficiencies are identified, we may lose the ability to supply and sell Natrecor(R)extended periods of time.

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

We rely on third parties for the manufacture of bulk drug substances and final drug product for clinical and commercial purposes relating to Natrecor(R). Biochemie GmbH is responsible for manufacturing Natrecor(R)in bulk quantities and Abbott Laboratories is responsible for blending, filling and packaging Natrecor(R), and if they encounter problems in these processes, our revenues from future sales of Natrecor(R)could decrease. Natrecor(R)is manufactured using industry-accepted recombinant manufacturing techniques, which must be conducted under strict controls and tight timelines. Natrecor(R)is subject to strict quality control testing during all phases of production and prior to its release to the market. Any quality control testing failures could lead to a reduction in the available supply of Natrecor(R). Biochemie depends on outside vendors for the timely supply of raw materials used to produce our

products, including Natrecor(R). Once a supplier's materials have been selected for use in Biochemie's manufacturing process, the supplier in effect becomes a sole or limited source of that raw material due to regulatory compliance procedures. We depend on these third parties to perform their obligations effectively and on a timely basis. If these third parties fail to perform as required, our ability to deliver Natrecor(R)on a timely basis would be impaired. In addition, in the event of a natural disaster, equipment failure, power failure, strike or other difficulty, we may be unable to replace our third party manufacturers in a timely manner and would be unable to manufacture Natrecor(R)to meet market needs. The success of Natrecor(R)is highly dependent on our partner, Innovex L.P., a division of Quintiles Transnational Corp., for marketing, promotion and sales activities. We believe that for Natrecor(R)to be widely adopted, the efforts of an experienced sales force are needed. We have limited experience in managing or operating a marketing organization. Accordingly, we have entered into an exclusive agreement with Innovex to co-promote and sell Natrecor(R)in the United States. As part of our agreement with Innovex, we have hired a sales force of approximately 170 people solely dedicated to the sale of Natrecor(R). If Innovex and we fail to devote appropriate resources to promote, sell and distribute Natrecor(R), sales of Natrecor(R)could be reduced. If Innovex breaches or terminates its agreement with us or otherwise fails to conduct its Natrecor(R)-related activities in a timely manner or if there is a dispute about its obligations, we may need to seek another partner. In that event, we cannot assure you that we will be able to obtain another partner on favorable terms, if at all.

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

PharmaBio has agreed to fund $30.0 million of our costs to launch Natrecor(R)over the first 24 months of Natrecor(R)'s commercialization. Of the $30.0 million, we anticipate that $10.0 million will be paid to us in 2001. If PharmaBio breaches or terminates its agreement with us or otherwise fails to fulfill its financial obligations under the agreement and we are unable to secure alternative funding, we may lose our ability to successfully market Natrecor(R). In the area of acute CHF, we face competition from companies with substantial financial, technical and marketing resources, which could limit our future revenues from Natrecor(R). Many therapeutic options are available for patients with acute CHF. Currently used drugs fall into three main categories: vasodilators, inotropes, and diuretics. Natrecor(R)would compete against both vasodilators and inotropes in the acute CHF market. Many of these drugs are available in generic formulation with an associated low cost. In addition, milrinone, an inotrope, is currently promoted by Sanofi-Synthelabo Inc. We may not be able to compete effectively with these long-standing current forms of therapy. In addition, Natrecor(R)costs more than many of these existing drugs, which may harm our competitive position relative to these drugs. New drugs in development for the treatment of acute CHF would also compete with Natrecor(R)if approved by the FDA or other regulatory agencies. Tezosentan(R), a non-selective endothelin receptor antagonist, is being developed by Actelion LTD. and has been evaluated in Phase III clinical trials as a vasodilator for the treatment of acute CHF. In addition, Abbott had previously submitted an NDA for Simdax(R), a calcium sensitizer described as an inotrope, but withdrew the application in 2000. To our knowledge, Abbott has not announced its intent to refile an NDA for Simdax(R). If any such new drug in development is approved by the FDA or other regulatory agencies, we may not be able to compete effectively with these new forms of therapy. If we fail to gain approval for Natrecor(R)and our other product candidates in international markets, our market opportunities will be limited. We have not yet filed for marketing clearance for the use of Natrecor(R)or any other product candidates in foreign countries, and we may not be able to obtain any international regulatory approvals for Natrecor(R)or any other product we develop. If we fail to obtain those approvals or if such approvals are delayed, the geographic market for Natrecor(R)or our other product candidates would be limited.

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

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

sales force to successfully market and commercialize those products. If we fail to enter into partnering arrangements for our products and are unable to develop an effective international sales force, our revenues would be limited.

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

In order to expand the medical uses, or therapeutic indications, for which we may market Natrecor(R), we must successfully complete additional clinical trials, which could be lengthy and expensive and will require the allocation of both substantial management and financial resources. Thereafter, we will have to apply separately to the FDA for clearance to market Natrecor(R)for other indications. We cannot assure you that we will be able to successfully complete the required clinical trials or that the FDA will approve Natrecor(R)for any additional indications. In addition, even if Natrecor(R)is approved by the FDA, we cannot exclude the possibility that serious adverse events related to the use of Natrecor(R)might occur in the future, which could either limit its use or cause the FDA to revoke our approval to market Natrecor(R).

Other Risks Related to Scios

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

We may not be able to achieve or earn a profit in the future. We began operations in December 1981, and since that time, with the sole exception of 1983, we have not earned a profit on a full-year basis. Our losses have historically resulted primarily from our investments in research and development. As of September 30, 2001, we had an accumulated deficit of approximately $445.1 million. To date, nearly all of our revenues have come from: |X| sales of Natrecor beginning in August 2001; |X| sales of bulk FGF and royalties from Fiblast(R)Spray sales to Kaken in Japan; |X| one-time signing fees from our corporate partners under agreements supporting the research, development and commercialization of our product candidates; |X| one-time payments from our corporate partners when we achieved regulatory or development milestones; |X| research funding from our corporate partners; and |X| our psychiatric sales and marketing division. We expect that our research, development and clinical trial activities and regulatory approvals, together with future general and administrative activities and the costs associated with launching and commercializing our product candidates and launching and commercializing Natrecor(R)in the United States, will result in significant expenses for the foreseeable future. Our operating results are subject to fluctuations that may cause our stock price to decline. Our revenues and expenses have fluctuated significantly in the past. This fluctuation has in turn caused our operating results to vary significantly from quarter to quarter and year to year. We expect the fluctuations in our revenues and expenses to continue, and thus, our operating results should also continue to vary significantly. These fluctuations may be due to a variety of factors including: |X| our success in selling Natrecor(R); |X| the timing and realization of milestone and other payments from our corporate partners; |X| the timing and amount of expenses relating to our research and development, product development and manufacturing activities; and

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

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

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

We depend on our key scientific and management personnel. Our ability to pursue the development of our current and future product candidates depends largely on retaining the services of our existing personnel and hiring additional qualified scientific personnel to perform research and development. We also rely on personnel with expertise in clinical testing, government regulation, manufacturing and marketing. Attracting and retaining qualified personnel

will be critical to our success. We may not be able to attract and retain personnel on acceptable terms given the competition for such personnel among biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions. Failure to retain our key scientific and management personnel or to attract additional highly qualified personnel could delay the development of our product candidates and harm our business.

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

We face the risk of failure normally found in developing biotechnology products based on new technologies. Successfully developing, manufacturing, introducing and marketing our early-stage product candidates will require several years and substantial additional capital.

Our operations depend on compliance with complex FDA and comparable international regulations. If we fail to obtain approvals on a timely basis or to achieve continued compliance, the commercialization of our products could be delayed.

We cannot assure you that we will receive the regulatory approvals necessary to commercialize our product candidates, which could cause our business to fail. Our product candidates are subject to extensive and rigorous government regulation by the FDA and comparable agencies in other countries. The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertising, promotion, sale and distribution of biopharmaceutical products. If our potential products are marketed abroad, they will also be subject to extensive regulation by foreign governments. In addition, we have only limited experience in filing and pursuing applications necessary to gain regulatory approvals, which may impede our ability to obtain such approvals. The results of preclinical studies and clinical trials of our products may not be favorable. In order to obtain regulatory approval for the commercial sale of any of our product candidates, we must conduct both preclinical studies and human clinical trials. These studies and trials must demonstrate that the product is safe and effective for the clinical use for which we are seeking approval. We are currently planning to conduct Phase II clinical trials of our lead p38 kinase inhibitor small molecule compound. The results of these or other clinical trials that we may conduct in the future may not be successful. Adverse results from our current or any future trials would harm our business. We also face the risk that we will not be permitted to undertake or continue clinical trials for any of our product candidates in the future. Even if we are able to conduct such trials, we may not be able to satisfactorily demonstrate that the products are safe and effective and thus qualify for the regulatory approvals needed to market and sell them. Results from preclinical studies and early clinical trials are often not accurate indicators of results of later-stage clinical trials that involve larger human populations.

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

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

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

We are engaged in a field characterized by extensive research efforts and rapid technological development. New drug discoveries and developments in our field and other drug discovery technologies are accelerating. Our competitors may develop technologies and products that are more effective than any we develop or that render our technology and potential products obsolete or noncompetitive. In addition, our potential products could become unmarketable if new industry standards emerge. To be successful, we will need to enhance our product candidates and design, develop and market new product candidates that keep pace with new technological and industry developments. Many other companies are targeting the same diseases and conditions as we are. Competitive products from other companies could significantly reduce the market acceptance of our products. The markets in which we compete are well established and intensely competitive. We may be unable to compete successfully against our current and future

competitors. Our failure to compete successfully may result in pricing reductions, reduced gross margins and failure to achieve market acceptance for our potential products. Our competitors include pharmaceutical companies, biotechnology companies, chemical companies, academic and research institutions and government agencies. For example, many pharmaceutical and biotechnology companies have initiated research programs similar to ours. Many of these organizations have substantially more experience and more capital, research and development, regulatory, manufacturing, sales, marketing, human and other resources than we do. As a result, they may: |X| develop products that are safer or more effective than our product candidates;

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

|X| devote greater resources to market or sell their products; |X| adapt more quickly to new technologies and scientific advances; |X| initiate or withstand substantial price competition more successfully than we can; |X| have greater success in recruiting skilled scientific workers from the limited pool of available talent; |X| more effectively negotiate third-party licensing and collaboration arrangements; and |X| take advantage of acquisition or other opportunities more readily than we can. In addition, our product candidates, if approved and commercialized, will compete against well-established existing therapeutic products that are currently reimbursed by government health administration authorities, private health insurers and health maintenance organizations. We face and will continue to face intense competition from other companies for collaborative arrangements with pharmaceutical and biotechnology companies, for relationships with academic and research institutions and for licenses to proprietary technology. In addition, we anticipate that we will face increased competition in the future as new companies enter our markets and as scientific developments continue to expand the understanding of various diseases. While we will seek to expand our technological capabilities to remain competitive, research and development by others may render our technology or product candidates obsolete or noncompetitive or result in treatments or cures superior to any therapy developed by us.

If we are unable to protect our intellectual property rights adequately, the value of our potential products could be diminished.

Our success is dependent in part on obtaining, maintaining and enforcing our patents and other proprietary rights. Patent law relating to the scope of claims in the biotechnology field in which we operate is still evolving and surrounded by a great deal of uncertainty. Accordingly, we cannot assure you that our pending patent applications will result in issued patents. Because certain U.S. patent applications may be maintained in secrecy until a patent issues, we cannot assure you that others have not filed patent applications for technology covered by our pending applications or that we were the first to invent the technology. Other companies, universities and research institutions have or may obtain patents and patent applications that could limit our ability to use, manufacture, market or sell our product candidates or impair our competitive position. As a result, we may have to obtain licenses from other parties before we could continue using, manufacturing, marketing or selling our potential products. Any such licenses may not be available on commercially acceptable terms, if at all. If we do not obtain required licenses, we may not be able to market our potential products at all or we may encounter significant delays in product development while we redesign potentially infringing products or methods. In addition, although we own a number of patents, including issued patents and patent applications relating to Natrecor(R)and certain of our p38 kinase inhibitors, the issuance of a patent is not conclusive as to its validity or enforceability, and third parties may challenge the validity or enforceability of our patents. We cannot assure you how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court or in other proceedings. It is possible that a competitor may successfully challenge our patents or that challenges will result in limitations of their coverage. In addition, the cost of litigation to uphold the validity of patents can be substantial. If we are unsuccessful in such litigation, third parties may be able to use our patented technologies without paying licensing fees or royalties to us. Moreover, competitors may infringe our patents or successfully avoid them through design innovation. To prevent infringement or unauthorized use, we may need to file infringement claims, which are expensive and time- consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or may refuse to stop the other party from using the technology at issue on the grounds that its technology is not covered by our patents. Policing unauthorized use of our intellectual

property is difficult, and we cannot assure you that we will be able to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. In addition to our patented technology, we also rely on unpatented technology, trade secrets and confidential information. We may not be able to effectively protect our rights to this technology or information. Other parties may independently develop substantially equivalent information and techniques or otherwise gain access to or disclose our technology. We require each of our employees, consultants and corporate partners to execute a confidentiality agreement at the commencement of an employment, consulting or collaborative relationship with us. However, these agreements may not provide effective protection of our technology or information or, in the event of unauthorized use or disclosure, they may not provide adequate remedies. If we fail to negotiate or maintain successful arrangements with third parties, our development and marketing activities may be delayed or reduced. We have entered into, and we expect to enter into in the future, arrangements with third parties to perform research, development, regulatory compliance, manufacturing or marketing activities relating to some or all of our product candidates. If we fail to secure or maintain successful collaborative arrangements, our development and marketing activities may be delayed or reduced. We may be unable to negotiate favorable collaborative arrangements that, if necessary, modify our existing arrangements on acceptable terms. Most of our agreements can be terminated under certain conditions by our partners. In addition, our partners may separately pursue competing products, therapeutic approaches or technologies to develop treatments for the diseases targeted by us or our efforts. Even if our partners continue their contributions to the collaborative arrangements, they may nevertheless determine not to actively pursue the development or commercialization of any resulting products. Also, our partners may fail to perform their obligations under the collaborative arrangements or may be slow in performing their obligations. In these circumstances, our ability to develop and market potential products could be severely limited.

Risks Related to our Industry

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

We may be required to defend lawsuits or pay damages in connection with the alleged or actual harm caused by our product candidates.

We face an inherent business risk of exposure to product liability claims in the event that the use of our product candidates is alleged to have resulted in harm to others. This risk exists in clinical trials as well as in commercial distribution. In addition, the pharmaceutical and biotechnology industries in general have been subject to significant medical malpractice litigation. We may incur significant liability if product liability or malpractice lawsuits against us are successful. Although we maintain product liability insurance, we cannot be sure that this coverage is adequate or that it will continue to be available to us on acceptable terms.

We use hazardous materials in our business, and any claims relating to improper handling storage or disposal of these materials could harm our business.

Our research and development activities involve the controlled use of hazardous materials, chemicals, biological agents and radioactive compounds. We are subject to federal, state and local laws and regulations governing the use,

manufacture, storage, handling and disposal of such materials and certain waste products. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by such laws and regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any resulting damages, and any such liability could exceed our resources. We may be required to incur significant costs to comply with these laws in the future. Failure to comply with these laws could result in fines and the revocation of permits, which could prevent us from conducting our business.

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

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

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

We are at risk of securities class action litigation. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology companies have experienced greater than average stock price volatility in recent years. Several years ago, we were the subject of a securities class action lawsuit, which was eventually dismissed with a determination that the plaintiffs had no basis for their claim. If we face such litigation in the future, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business. We have implemented provisions in our charter documents that may ultimately delay, discourage or prevent a change in our management or control of us. Our certificate of incorporation and bylaws contain provisions that could make it more difficult for our stockholders to replace or remove our directors or to effect any other corporate action. These provisions include those which: |X| prohibit holders of less than ten percent of our outstanding capital stock from calling special meetings of stockholders; |X| prohibit stockholder action by written consent, thereby requiring stockholder actions to be taken at a meeting of our stockholders; and

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

Moreover, our certificate of incorporation does not provide for cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates. Some of the above provisions may also have possible anti-takeover effects, which may make an acquisition of us by a third party more difficult, even if such an acquisition could be beneficial to our stockholders. In addition, our certificate of incorporation also authorizes us to issue up to 20,000,000 shares of preferred stock in one or more different series with terms to be determined by our board of directors at time of issuance. As of September 30, 2001, 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.

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. We attempt to place our investments with high quality issuers and, by policy, limit the amount of credit exposure to any one issuer and do not use derivative financial instruments in our investment portfolio. We maintain an investment portfolio of various issuers, types and maturities, which consist of both fixed and variable rate financial instruments. These securities are classified as available-for-sale, and consequently, are recorded on the balance sheet at fair value with unrealized gains or losses reported as a separate component in stockholders' equity, net of applicable taxes. At any time, sharp changes in interest rates can affect the value of our investment portfolio and its interest earnings. Currently, we do not hedge these interest rate exposures. However, through our money manager, we maintain management control systems to monitor interest rate risk. The risk management control systems use analytical techniques as well as other procedures to review interest rate risk. Assuming a hypothetical interest rate increase of 10%, the fair value of our total investment portfolio as of September 30, 2001 would have potentially incurred a loss of $263,000. Our exposure to foreign currency fluctuations is currently limited to our supply contract for Natrecor(R), which is denominated in German Marks. Changes in the exchange rate between German Marks and the U.S. dollar could adversely affect our manufacturing costs. All of our other contracts are denominated in U.S. dollars. Exposure to foreign currency exchange rate risk may change over time as our business evolves and our products are introduced into international markets. Currently, we do not hedge against any foreign currencies and, as a result, could incur unanticipated gains or losses.

PART II. OTHER INFORMATION

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits 10.48 First Amendment dated May 28, 2001 to Sublease Agreement dated May 24, 1999 for premises located at 749 North Mary Ave, Sunnyvale, California. 10.49 Amendment No. 5 dated July 24, 2001 to Lease Agreement dated January 22, 1993 for premises located at 820 Maude Avenue, Sunnyvale, California. 10.50 Letter dated June 10, 2001 to Extend Leases for premises located at 820 Maude Avenue, Sunnyvale, California. (b) Reports on Form 8-K

Report on Form 8-K Filed on July 13, 2001. On July 10, 2001, Scios Inc., announced that it received a letter from the U.S. Food and Drug Administration stating that the Natrecor® (nesiritide) New Drug Application was approvable.

Report on Form 8-K Filed on August 13, 2001. On August 13, 2001, Scios Inc. announced that it has received final approval from the U.S. Food and Drug Administration (FDA) to market Natrecor® (nesiritide) for the intravenous treatment of patients with acutely decompensated congestive heart failure who have shortness of breath (i.e., dyspnea) at rest or with minimal activity.

Report on Form 8-K Filed on September 20, 2001. On September 20, 2001, Scios Inc. announced that, effective immediately, its Board of Directors authorized the repurchase of up to $10 million of Scios common stock.

Exhibit 10.48

First Amendment to Sublease Agreement Sublandlord: Trimble Navigation Limited Date: May 28, 2001 Subtenant: Scios Inc. Subject Properties 749 N. Mary Avenue, Sunnyvale, CA 94086 THIS FIRST AMENDMENT TO SUBLEASE ("Amendment") is made as of May 28, 2001 by and between Trimble Navigation Limited ("Trimble") and Scios Inc. ("Scios"). RECITALS A. Trimble and Scios have previously entered into that certain Sublease Agreement dated March 25, 1999 which Sublease covers certain Premises commonly known as 749 N. Mary Avenue, Sunnyvale, CA 94086 (the "749 N. Mary Sublease").

B. Under the terms of Section 7.2 of the parties aforesaid 749 N. Mary Sublease, Scios may exercise an option to extend the Sublease Term for one period of eleven (11) months from February 1, 2002 through December 31, 2002 (Option Term). Scios now wishes to exercise such option.

C. In addition, Scios wishes to further extend its sublease of the Premises for an additional twelve- (12) month period from January 1, 2003 through December 31, 2003 (extended Sublease Term). Trimble is willing to agree to such additional extended sublease period.

AGREEMENT NOW THEREFORE, in consideration for the agreements of Trimble and Scios contained herein and other valuable consideration, Trimble and Scios hereby amend their 749 N. Mary Sublease as follows: 1. Extended Sublease Term. The term of the 749 N. Mary Sublease shall be extended for the period commencing on February 1, 2002 and terminating on December 31, 2003 ("Extended Sublease Term"). 2. Extended Sublease Term Base Rent. Base Rent due and payable by Subtenant to Sublandlord during the Extended Sublease Term shall be as follows: Dates Base Rental Rate Monthly Rent ----- ---------- ---------- February 1,2002- $1.95/SF/Mo $65,520.00/Mo December 31,2002 January 1, 2002- $2.20/SF/Mo $73,920.00/Mo December 31, 2003

3. Extension Condition; Cross Default. Sublandlord s agreement to extend the term of the 749 N. Mary Sublease from January 1, 2003 through December 31, 2003 under the terms of this First Amendment to Sublease is conditioned upon Subtenant s execution of that certain Sublease Agreement with respect to premises located at 617 N. Mary Ave., Sunnyvale, CA. (the 617 N. Mary Sublease) concurrently herewith. Subtenant hereby agrees that a default beyond any applicable cure period by Subtenant under the terms of the 617 N. Mary Sublease as amended shall be a default under the Sublease entitling the Sublandlord immediately to exercise its remedies thereunder.

4. Master Landlord Consent; Deemed exercise of Extension Option in Absence of Master Landlord s Consent. Subtenant acknowledges and agrees that Sublandlord s ability to extend the period of the 749 N. Mary Sublease from January 1, 2003 through December 31, 2003 is conditioned on the prior written consent of Master Landlord as provided in the Master Lease. Should Master Landlord refuse its consent to such extension of the term of the 749 N. Mary Sublease from January 1, 2003 through December 31, 2003 on terms acceptable to Sublandlord, this Amendment shall be deemed to be amended by the exclusion of the extension of the term from January 1, 2003 through December 31, 2003. In the event of such refusal to consent (1) Sublandlord shall not be responsible to Subtenant for any other costs or expenses Subtenant may have incurred by reason of its entering into this Amendment, and (2) Subtenant shall be deemed to have effectively exercised it option to extent the term of the Sublease in accordance with Section 7.2 of the 749 N. Mary Sublease, and the new expiration date of the term of the 749 N. Mary Sublease shall be December 31, 2002.

5. Entire Agreement. This Amendment contains the entire agreement of the parties

hereto with respect to its subject matter, and no representations, inducements, promises or agreements, oral or otherwise, between the parties, not embodied herein shall be of any force and effect.

5. Full Force and Effect. The parties acknowledge and agree that all other terms and conditions of the 749 N. Mary Sublease shall remain unchanged and in full force and effect. WITH INTENT TO BE BOUND, Trimble and Scios have signed this First Amendment to Sublease Agreement on the date set forth below. Trimble Navigation Limited By____/S/ Mary Ellen Genovese Date:___05/25/02_____ ---------- ---------- Mary Ellen Genovese Address for Notice: ---------- Chief Financial Officer ---------- Trimble Navigation Limited Real Estate Dept. P.O. Box 3642 Sunnyvale, CA. 94088-3642 Scios Inc. By /S/ David W. Gryska Date:05/25/01 ----------

_____ David W. Gryska Address for Notice: ---------- Chief Financial Officer - Scios Inc. 820 West Maude Avenue Sunnyvale, CA 94086

Exhibit 10.49

June 10, 2001 By Certified Mail John Arrillaga, Trustee Richard T. Peery, Trustee Perry/Arrillaga 2560 Mission College Blvd. Suite 101 Santa Clara, Ca. 95054 Re: Exercise of Options to Extend Through August 31, 2008; 810 and 820 West Maude Avenue, Sunnyvale, CA. Gentlemen: Scios Inc, (formerly known as Scios Nova Inc.) hereby exercises its right to extend the terms of the following two leases (collectively, the "Leases"): a) Lease Agreement dated January 22, 1993 regarding the premises located at 810 West Maude Avenue, Sunnyvale, CA (the address of which was changed to 820 West Maude Avenue as reflected in the Amendment No. 2), as amended by Amendment

No. 1 dated September 1, 1993, Amendment No. 2 dated December 27, 1993, Amendment No. 3 dated March 1, 1994, Landlords Consent to Assignment dated March 20, 1995, and Amendment No. 4 dated December 7, 1995: and

b) Lease Agreement dated November 17, 1995 regarding the premises located at 810 West Maude Avenue, Sunnyvale, CA.

As a Consequence of such exercise, the term of each of the Leases is hereby extended to August 31, 2008, in accordance with the terms of each Lease.

Sincerely, Scios Inc. By___/S/David W. Gryska ---------- Name: David W. Gryska Title: Chief Financial Officer cc: Anna B. Pope, Esq.

Exhibit 10.50

AMENDMENT NO. 5

TO LEASE

THIS AMENDMENT NO. 5 is made and entered into this 15th day of June, 2001, by and between JOHN ARRILLAGA, Trustee, of his Successor Trustee UTA dated 7/20/77 (JOHN ARRILLAGA SURVIVOR'S TRUST) (previously known as the "John Arrillaga Separate Property Trust") as amended, and RICHARD T. PEERY, Trustee, or his Successor Trustee UTA dated 7/20/77 (RICHARD T. PEERY SEPARATE PROPERTY TRUST) as amended, collectively as LANDLORD, and SCIOS INC., a Delaware corporation, as TENANT. RECITALS

A. WHEREAS, by Lease Agreement dated January 22, 1993 Landlord leased to Alpha 1 Biomedicals, Inc., a Delaware corporation 15,018 ± square feet of that certain 51,680 ± square foot building located at 810 W. Maude Ave., Sunnyvale, California, the details of which are more particularly set forth in said January 22, 1993 Lease Agreement, and B. WHEREAS, said Lease was amended by Amendment No. 1 dated September 1, 1993 by changing the classification of parking spaces as set forth in Paragraph 45 of said Lease Agreement from sixty-four (64) nonexclusive parking spaces to eight (8) exclusive parking spaces and fifty-six (56) nonexclusive parking spaces, and, C. WHEREAS, said Lease was amended by Amendment No. 2 dated December 27, 1993 which: (i) changed the street address of Tenant s Leased Premises to 820 West Maude Avenue, (ii) increased the total square footage leased by 11,902 ± square feet or from 15,018 ± 26,920 ± square feet, (iii) extended the Lease Term for three (3) years five (5) months commencing on September 1, 1998 and ending on January 31, 2002, (iv) amended the Basic Rent schedule to reflect the increase in square footage and Term, (v) deleted Paragraph 46 (FIRST OPTION TO EXTENT LEASE FOR FIVE (5) YEARS) in its entirety and, (vi) replaced Paragraph 47 (SECOND OPTION TO EXTEND LEASE FOR FIVE (5) YEARS), and, D. WHEREAS, said Lease was amended by Amendment No. 3 dated March 1, 1994 which changed the effective date of the increase in square footage from February 1, 1994 to March 1, 1994 and amended the Basic Rent and Aggregate Rent accordingly, and, E. WHEREAS, said Lease was amended by Landlord s Consent to Assignment dated March 20, 1995 which was acknowledged the assignment of said Lease from Alpha 1 Biomedicals, Inc., to Scios Nova, Inc., and F. WHEREAS, said Lease was amended by Amendment No. 4 dated December 7, 1995 which added a Lease Co-Terminous Paragraph and a Cross Default Paragraph, and, G. WHEREAS, said Lease was amended by Letter Agreement dated September 17, 1996 whereby Landlord acknowledged Tenant s name change from Scios Nova, Inc. , a Delaware corporation to Scios Inc. , a Delaware corporation, effective March 26, 1996, and, H. WHEREAS, it is now the desire of the parties hereto amend the Lease by (i) extending the Term for six (6) years, seven (7) months, changing the Termination Date from January 31, 2002 to August 31, 2008, (ii) amending the Basic Rent schedule and Aggregate Rent accordingly, (iii) increasing the Security Deposit required under the Lease, (iv) amending Lease Paragraphs 9 (Taxes), and 12 (Property Insurance), (v) replacing Lease Paragraphs 10 (Liability Insurance), and 36 (Limitation of Liability), and (vi) adding paragraph (Authority to Execute) to said Lease Agreement as hereinafter set forth.

AGREEMENT NOW THEREFORE, for the valuable consideration, receipt of which is hereby acknowledged, and in consideration of the hereinafter mutual promises, the parties hereto do agree as follows: 1. TERM OF LEASE: Pursuant to Paragraph 8 of Amendment No. 2, Tenant has exercised its Option to Extend. Therefore it is ---------- agreed between the parties that the Term of said Lease Agreement shall be extended for an additional six (6) year, seven (7) month period, and the Lease Termination Date shall be changed from January 31, 2002 to August 31, 2008. 2. BASIC RENTAL FOR EXTENDED TERM OF LEASE: The monthly Basic Rental for the Extended Term of Lease shall be as follows: ---------- On February 1, 2002, the sum of THIRTY THREE THOUSAND SIX HUNDRED FIFTY AND NO/100 DOLLARS ($33,650.00) shall be due, and a like sum due on the first day of each month thereafter through and including August 1, 2002. On September 1, 2002, the sum of THIRTY FOUR THOUSAND NINE HUNDRED NINETY SIX AND NO/100 DOLLARS ($34,996.00) shall be due, and a like sum due on the first day of each month thereafter through and including August 1, 2003. On September 1, 2003,

the sum of THIRTY SIX THOUSAND THREE HUNDRED FORTY TWO AND NO/100 DOLLARS ($36,342.00) shall be due, and a like sum due on the first day of each month thereafter through and including August 1, 2004. On September 1, 2004, the sum of THIRTY SEVEN THOUSAND SIX HUNDRED EIGHTY EIGHT AND NO/100 DOLLARS ($37,688.00) shall be due, and a like sum due on the first day of each month thereafter through and including August 1, 2005. On September 1, 2005, the sum of THIRTY NINE THOUSAND THIRTY FOUR AND NO/100 DOLLARS ($39,034.00) shall be due, and a like sum due on the first day of each month thereafter through and including August 1, 2006. On September 1, 2006, the sum of FORTY THOUSAND THREE HUNDRED EIGHTY AND NO/100 DOLLARS ($40,380.00) shall be due, and a like sum due on the first day of each month thereafter through and including August 1, 2007. On September 1, 2007, the sum of FORTY ONE THOUSAND SEVEN HUNDRED TWENTY SIX AND NO/100 DOLLARS ($41,726.00) shall be due, and a like sum due on the first day of each month thereafter through and including August 1, 2008. The Aggregate Basic Rent for the Lease shall be increased by $2,997,542.00 or from $2,756.477.80 to $5,754,019.80. 3. SECURITY DEPOSIT: Tenant's Security Deposit shall be increased by $5,384.00, or from $67,300.00 to $72,684.00, payable upon ---------- Tenant's execution of this Amendment No. 5. 4. TAXES: Lease Paragraph 9 ("Taxes") shall be amended to include the following language: -----

The term Real Estate Taxes shall also include supplemental taxes related to the period of Tenant s Lease Term whenever levied, including any such taxes that may be levied after the Lease Term has expired .

5. PROPERTY INSURANCE: Lease Paragraph 12 ("Property Insurance") is hereby amended to include the following: "Tenant ---------- acknowledges that as part of the cost of insurance policies for the Premises, Tenant is responsible for the payment of insurance deductibles on insurance claims as they relate to the Premises". 6. LIABILITY INSURANCE: Lease Paragraph 10 ("Liability Insurance") shall be deleted and replaced in its entirety by the ---------- following: "10. LIABILITY INSURANCE: Tenant, at Tenant's expense, agrees to keep in force during the Team of this Lease a ---------- policy of commercial general liability insurance with combined single limit coverage of not less than Two Million Dollars ($2,000,000) per occurrence for bodily injury and property damage occurring in, on or about the Premises, including parking and landscaped areas. Such insurance shall be primary and noncontributory as respects any insurance carried by Landlord. The policy or polices effecting such insurance shall name Landlord as additional insureds, and shall insure any liability of Landlord, contingent or otherwise, as respects acts or omissions of Tenant, its agents, employees or invitees or otherwise by any conduct or transactions of any of said persons in or about or concerning the Premises, including any failure of Tenant to observe or perform any of its obligations hereunder; shall be issued by an insurance company admitted to transact business in the State of California; and shall provide that the insurance effected thereby shall not be canceled, except upon thirty (30) days' prior written notice to Landlord. A certificate of insurance of said policy shall be delivered to Landlord. If, during the Term of this Lease, in the considered opinion of Landlord's Lender, insurance advisor, or counsel, the amount of insurance described in this Paragraph is not adequate, Tenant agrees to increase said coverage to such reasonable amount as Landlord's Lender, insurance advisor, or counsel shall deem adequate." 7. LIMITATION OF LIABILITY: Lease Paragraph 36 ("Limitations of Liability") shall be deleted and replaced in its entirety by the following: "36. LIMITATION OF LIABILITY: In consideration of the benefits accruing hereunder, Tenant and all successors and ---------- assigns covenant and agree that, in the event of any actual or alleged failure, breach or default hereunder by Landlord: (i) the sole and exclusive remedy shall be against Landlord's interest in the Premises leased herein; (ii) no partner of Landlord shall be sued or named as a party in any suit or action (except as may be necessary to secure jurisdiction of the partnership); (iii) no service of process shall be made against any partner of Landlord (except as may be necessary to secure jurisdiction of the partnership); (iv) no partner of Landlord shall be required to answer or otherwise plead to any service of process; (v) no judgement will be taken against any partner of Landlord; (vi) any judgement taken against any partner of Landlord may be vacated and set aside at any time without hearing; (vii) no writ of execution will ever be levied against the assets of any partner of Landlord; (viii) these covenants and agreements are enforceable both by Landlord and also by any partner of Landlord.

Tenant agrees that each of the foregoing covenants and agreements shall be applicable to any covenant or agreement either expressly contained in this Lease or imposed by statute or at common law.

8. AUTHORITY TO EXECUTE. The parties executing this Agreement hereby warrant and represent that they are properly authorized to execute this Agreement and bind the parties on behalf of whom they execute this Agreement and to all of the terms, covenants and conditions of this Agreement as they relate to the respective parties hereto.

EXCEPT AS MODIFIED HEREIN, all other terms, covenants, and conditions of said January 22, 1993 Lease Agreement shall remain in full force and effect. IN WITNESS WHEREOF, Landlord and Tenant have executed this Amendment No. 5 to Lease as of the day and year least written below. LANDLORD: TENANT: JOHN ARRILLAGA SURVIVOR'S SCIOS INC., TRUST a Delaware corporation By/s/ John Arrillaga By/s/ David W. Gryska ---------- ---------- John Arrillaga, Trustee Date: 7/24/01 David W. Gryska ---------- ---------- Print or Type Name RICHARD T. PERRY SEPARATE Title: CFO ---------- PROPERTY TRUST By/s/ Richard T. Peery Date: 7/20/01 ---------- ---------- Richard T. Peery, Trustee Date: 7/24/01 ---------- 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 8, 2001 By: /s/ Richard B. Brewer ---------- Richard B. Brewer, President and CEO November 8, 2001 By: /s/ David W. Gryska ---------- David W. Gryska, Senior Vice President and CFO 2