

Edgar Filing: SCIOS INC - Form 10-K

SCIOS INC  
Form 10-K  
March 15, 2002

=====

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549

-----

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2001

OR

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

For the transition period from to

COMMISSION FILE NUMBER 0-11749

-----

SCIOS INC.  
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE 95-3701481  
(STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION) (I.R.S. EMPLOYER IDENTIFICATION NO)

820 WEST MAUDE AVENUE  
SUNNYVALE, CALIFORNIA 94085  
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES) (ZIP CODE)

Registrant's telephone number, including area code: (408) 616-8200

Securities registered pursuant to Section 12(b) of the Act: NONE  
Securities registered pursuant to Section 12(g) of the Act:  
Common Stock, \$0.001 par value

Indicate by check mark whether the registrant (1) has filed all reports  
required to be filed by Section 13 or 15(d) of the Securities Exchange Act of  
1934 during the preceding 12 months (or for such shorter period that the  
registrant was required to file such reports), and (2) has been subject to such  
filing requirements for the past 90 days. YES  NO

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405  
of Regulation S-K is not contained herein, and will not be contained, to the  
best of registrant's knowledge, in definitive proxy or information statements  
incorporated by reference in Part III of this Form 10-K or any amendment to

# Edgar Filing: SCIOS INC - Form 10-K

this Form 10-K. [ ]

The approximate aggregate market value of voting stock held by nonaffiliates of the registrant as of December 31, 2001 was \$1,093,780,520.

As of December 31, 2001, 46,015,167 shares of the registrant's Common Stock were outstanding.

## DOCUMENTS INCORPORATED BY REFERENCE

Documents	Form 10-K Part
-----	-----
Definitive Proxy Statement with respect to the 2002 Annual Meeting of Stockholders	Part III

=====

In this Form 10-K, "Scios", "we", "us", and "our" refer to Scios Inc. The following discussion 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, but are not limited to, those discussed under "Risk Factors".

## PART I

### ITEM 1. BUSINESS

#### OVERVIEW

We are a biopharmaceutical company developing novel treatments for cardiovascular and inflammatory diseases. Our disease-based technology platform integrates expertise in protein biology with computational and medicinal chemistry to identify novel targets and rationally design small molecule compounds for large markets with unmet medical needs. We launched Natrecor (R) following U.S. Food and Drug Administration, or FDA, approval of Natrecor (nesiritide) for the treatment of acute congestive heart failure, or CHF, on August 13, 2001, and recorded sales of \$14.1 million for the year ended December 31, 2001. We are focused on the development of three product candidates, Natrecor for the treatment of acute congestive heart failure, SCIO-469, an oral, small molecule inhibitor of p38 kinase for the treatment of rheumatoid arthritis (RA); and small molecule inhibitors of the receptor for TGF-beta, a cytokine that has been implicated in diseases characterized by chronic scar formation, or fibrosis.

We were incorporated in California in 1981 under the name California Biotechnology Inc. and reincorporated in Delaware in 1988. We changed our name to Scios Inc. in February 1992, and to Scios Nova Inc. in September 1992 following our acquisition of Nova Pharmaceuticals, Inc. We returned to using the name Scios Inc. in March 1996. Since September 1999, our principal executive offices have been located at 820 West Maude Avenue, Sunnyvale, California 94085. Our telephone number is (408) 616-8200.

Our corporate website is located at [www.sciosinc.com](http://www.sciosinc.com). We do not intend for information found on our website to be part of this document.

We own various copyrights, trademarks and trade names used in our business including the following: Natrecor(R) and Fiblast(R). This document also

## Edgar Filing: SCIOS INC - Form 10-K

includes trademarks, service marks and trade names of other companies, including the following: Gliadel(R), Biodel(R), Enbrel(R), Remicade(R), Celebrex(R), Vioxx(R), Anakinra(R), Tezosentan(R), Risperdal(R), Simdax(R), Paxil(R), Eskalith(R), Eskalith CR(R), Stelazine(R), Thorazine(R) and Parnate(R).

### RECENT DEVELOPMENTS

Since December 31, 2000, the following significant developments have occurred with respect to our business:

#### NATRECOR

- .. On August 13, 2001, we received final approval from the FDA to market Natrecor 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 to the FDA in January 2001. 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. On July 10, 2001, we received from the FDA an approvable letter for Natrecor. 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. During July 2001, the District Office of the FDA completed the pre-approval inspection and recommended approval of the Natrecor NDA. During August 2001, the final negotiations on the drug's label were completed.
- .. Since August 2001, we have sold Natrecor to about 60% of our approximately 2000-targeted academic and community hospitals. We focused on 2000 of the more than 5000 hospitals in the United States because 80% of the acute heart failure patients in this country are treated in those targeted hospitals. In addition, to enhance our hospital and physician access, we aggressively pursued contracts with group purchasing organizations, or GPOs. These GPOs contract for hundreds of their member hospitals and, as a group, assist us in gaining access for Natrecor and our cardiovascular specialists in thousands of hospitals. Currently, we have signed GPO arrangements with Owen, Consorta, Amerinet, and Premier. In addition to GPO agreements, Kaiser Hospital has put Natrecor on its formulary for its Northern and Southern California

2

hospitals. We also recently finalized a purchasing agreement with the Veteran's Administration, which allowed Natrecor to be placed on the Federal Supply Schedule.

- .. In January 2001, we entered into a marketing alliance with Innovex, a division of Quintiles, to commercialize Natrecor in North America. Innovex has and will continue to deliver a wide range of sales and marketing solutions for us, including hiring, training and deploying a dedicated cardio and emergency medicine sales force of approximately 168 salespeople at our cost. In December 2001, we amended the January 2001 agreement in relation to the Natrecor sales force and the infrastructure supporting it. The amendment will enable us, at our option, to assume control of the Natrecor sales force in June 2003, one year ahead of schedule. Under the amended agreement, PharmaBio, a corporate venture group related to Quintiles, will still provide the \$30.0 million in funding to commercialize Natrecor, however the \$5.0 million line of credit was eliminated which PharmaBio was scheduled to provide.
- .. In March 2001, we initiated the PROACTION, or Prospective Randomized Outcomes

## Edgar Filing: SCIOS INC - Form 10-K

Study of Acutely Decompensated Congestive Heart Failure Treated Initially in an Outpatient setting with Natreacor, trial, a pilot study designed to compare the clinical effects, safety profile and economic impact of standard therapy plus Natreacor to standard therapy plus placebo. The PROACTION trial completed enrollment of 250 acute CHF patients in December 2001. We expect to complete the study period follow-up and data analysis in the first half of 2002. These patients were treated in the emergency department or observation unit of a hospital, where the majority of the approximately one million hospitalizations each year for acute CHF begin. A preliminary review of the blinded data should confirm the ease of use and beneficial safety profile of Natreacor when administered in a less monitored clinical setting. Review of the blinded data is also expected to demonstrate that the rate of admissions from the emergency department is much lower than assumed when the study was designed. Although useful clinical, safety, and economic data pertaining to the emergency department may result from this trial, the probability of finding statistically significant and pharmoeconomic differences between Natreacor and placebo on in-hospital costs is unlikely.

- .. In May 2001, we expanded our existing research collaboration with Medtronic to initiate a clinical study to evaluate the hemodynamic, endocrine and clinical effects of Natreacor using information collected by Medtronic's Chronicle Implantable Hemodynamic Monitor both during and after infusions of Natreacor. This study began in July 2001 at the Karolinska Hospital in Stockholm and is ongoing.
- .. In October 2001, we launched a nationwide registry to collect and analyze demographic and treatment data about patients hospitalized due to acutely decompensated heart failure. ADHERE, the Acute Decompensated HEArt failure national REgistry, is expected to have a unique database of information of tens of thousands of patients gathered from approximately 300 U.S. hospitals over the next several years. We believe ADHERE will help clinicians better determine factors associated with improved clinical outcomes in acute CHF, the primary cause of more than one million hospital admissions in the U.S. each year. ADHERE should also provide comprehensive demographic and treatment data on a wide range of hospitalized heart failure patients. By tracking how these very sick patients are treated over time, we can use this information to identify optimal treatment strategies for them and develop comprehensive acute heart failure guidelines. As of February 28, 2002, 3,064 patients have been enrolled in the ADHERE Registry.
- .. In December 2001, we entered into a binding summary of terms with Glaxo Group Ltd., an affiliate of GlaxoSmithKline, or GSK, in which we will license Natreacor to GSK in all European markets. Under the terms of the agreement, GSK will have the rights to sell and distribute the product for which we will receive an up-front fee and milestone payments totaling (Pounds)15.0 million British Pounds (which at December 31, 2001 equaled approximately \$22 million U.S. Dollars), in addition to future royalties in the identified countries. We will manufacture and supply the bulk product to GSK. Both companies will work together to continue clinical development of Natreacor in Europe. In order to obtain European approval for Natreacor, GSK expects to use the extensive clinical data we submitted to obtain approval from the FDA in August 2001. The companies plan to launch Natreacor in Europe in the first half of 2004. Scios and GSK executed the binding summary of terms in December 2001 and expect to finalize their full agreement incorporating the terms in March 2002. Pending completion of the full agreement, the parties have commenced their respective performance obligations as required under the detailed terms and conditions of the binding summary of terms.
- .. In January 2002, we initiated the FUSION, or Management of Patients with CHF After Hospitalization with Follow Up Serial Infusions Of Natreacor, study, a multi-center, randomized, open-label pilot study that will be conducted at approximately 40 U.S. sites and will enroll over 200 patients. Patients will

## Edgar Filing: SCIOS INC - Form 10-K

be randomized to receive either their usual long-term cardiac medications, with or without IV inotropes, or serial infusions of Natrecor in addition to their usual long-term cardiac medications, excluding IV inotropes. All treatment groups will have weekly outpatient visits, and Natrecor patients will receive infusions for 4 to 6 hours at each weekly visit. Patients will receive study treatment for 12 weeks, followed by a one-month follow up period. Data from the FUSION study are expected to be available in the first quarter of 2003. As of February 28, 2002, 15 patients have been enrolled in the study.

3

### P38 KINASE INHIBITOR PROGRAM

.. In January 2001, we completed a Phase Ia clinical trial of SCIO-469 evaluating single doses in healthy volunteers. In April 2001, we completed a Phase Ib clinical trial in 20 healthy volunteers in which we evaluated the safety and tolerability of multiple doses of SCIO-469 over a two-week period. 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 Phase IIa trial in rheumatoid arthritis patients began in February 2002. This multi-center, randomized, placebo-controlled clinical study will enroll 120 patients who have active RA and are receiving methotrexate. The main objective of the study is to evaluate the safety and tolerability of six escalating doses of SCIO-469 in RA patients. The company expects to announce results from this study in the first quarter of 2003.

### NATRECOR

#### CONGESTIVE HEART FAILURE

According to the American Heart Association's 2001 HEART AND STROKE STATISTICAL UPDATE, approximately 4.7 million Americans currently suffer from chronic CHF and 550,000 new cases of CHF will be diagnosed in the United States this year. Annual expenditures for CHF are estimated to be \$21.0 billion, including \$15.8 billion for inpatient care.

Chronic CHF is characterized by a progressive loss in the heart's ability to pump blood. It is attributable to weakening of the contractile cells of the heart and accumulation of scar tissue. Different diseases can cause CHF, including coronary artery disease, heart attacks, inflammation of the heart tissue and diseases of the heart valves. Weakened heart muscle often results in poor cardiac output because the heart is unable to empty blood adequately from the ventricles to the circulation with each beat. Blood pools in the ventricles, and the heart changes from its normal shape and becomes enlarged. Subsequently, blood begins to back up into the blood vessels of the lungs, causing marked increases in pulmonary vascular pressures. As pressure increases, fluid moves from the pulmonary blood vessels into the air spaces, causing pulmonary congestion. One frequently used measurement of pulmonary vascular pressure is pulmonary capillary wedge pressure, or PCWP.

CHF symptoms that result from the pooling of blood include shortness of breath, edema, or fluid retention, and swelling of the legs and feet. CHF symptoms that result from the inefficiency of the heart to distribute or adequately pump oxygen-rich blood to body tissues include fatigue and weakness as well as a loss of appetite. As the disease progresses, these symptoms can severely impact the patient's quality of life, such that even the ability to perform simple tasks, such as walking across the room, becomes limited.

In the early stages of CHF, the body activates several hormonal pathways that

## Edgar Filing: SCIOS INC - Form 10-K

help the heart compensate in the short-term but have adverse long-term effects. These hormones, which include adrenalin, angiotensin II, aldosterone and endothelin, stimulate the heart to beat faster and stronger, thicken the wall of the heart and maintain blood pressure by constricting blood vessels and stimulating the kidney to retain sodium. If these pathways remain activated over a sustained period of time, the beneficial effects are lost and injurious effects develop, contributing to an eventual deterioration of heart function. Current medications and medications under development generally focus on one or more of these hormonal pathways.

Many CHF patients will eventually experience a rapid deterioration, or decompensation, and require urgent treatment in the hospital. This condition is called acute CHF. Acute CHF accounts for approximately one million hospital admissions each year in the United States. Acute CHF is the most frequent cause of hospitalization among Medicare patients. In addition, patients suffering from chronic CHF have a five-year mortality rate of approximately 50%. For more than a decade, there were no new FDA-approved drugs to treat acute CHF.

### NATRECOR: OUR SOLUTION FOR THE TREATMENT OF ACUTE CONGESTIVE HEART FAILURE

Natrecor is a recombinant form of human B-type natriuretic peptide, or BNP, a naturally occurring hormone in the body that aids in the healthy functioning of the heart. BNP is secreted by the ventricles of the heart as a response to CHF. We believe that the advantage of Natrecor, compared to other forms of therapy for acute CHF, is that it works on multiple components of the acute CHF disease pathway. In particular, based upon pre-clinical studies and clinical trials, we believe that Natrecor:

- .. dilates veins, which decreases elevated pulmonary pressures, or prelude;
- .. dilates arteries, which decreases the resistance against which the heart has to pump, or afterload;
- .. stimulates the kidney to excrete excess sodium, or natriuresis;

4

- .. stimulates the kidney to excrete excess fluid, or diuresis; and
- .. opposes many of the injurious consequences caused by the long-term elevation of hormones such as adrenalin, angiotension II, aldosterone and endothelin.

In clinical trials, Natrecor has also been shown to significantly improve blood circulation and patient symptoms compared to IV nitroglycerin without the need for labor-intensive monitoring, and its method of administration does not require frequent dosing adjustments. In addition, in clinical trials, Natrecor has not been associated with an increase in the incidence of cardiac arrhythmias and has demonstrated no evidence of drug interactions with other agents used concurrently in the treatment of acute CHF.

We have made significant progress since FDA approval of Natrecor. We launched Natrecor immediately after approval with 168-person cardiovascular sales force coupled with 2 Area Business Directors and 18 Area Business Managers. As of February 7, 2002, we stocked Natrecor in approximately 60% of the 2000-targeted academic and community hospitals. To enhance our hospital and physician access, we aggressively pursued contracts with GPOs. These GPOs contract for hundreds of their member hospitals and, as a group, assist us in gaining access for Natrecor and our cardiovascular specialists in thousands of hospitals. Currently, we have signed GPO arrangements with Owen, Consorta, and Amerinet, and Premier. In addition to GPO agreements, Kaiser Hospital has put Natrecor on

## Edgar Filing: SCIOS INC - Form 10-K

its formulary for Northern and Southern California hospitals. We also recently finalized a purchasing agreement with the Veteran's Administration, which allowed Natrecor to be placed on the Federal Supply Schedule.

### OTHER/COMPETING TREATMENTS FOR CONGESTIVE HEART FAILURE

While some cardiac risk factors such as smoking, high cholesterol, high blood pressure, diabetes and obesity can be controlled with lifestyle changes, the majority of patients with CHF require additional treatments to help manage their disease. Competing medications for the treatment of CHF, including diuretics, inotropes, vasodilators and beta-blockers, only focus on single components of the diverse pathways contributing to CHF. For example, diuretics help the kidneys rid the body of excess fluid, thereby reducing blood volume and the heart's workload. Inotropes strengthen the heart's pumping action. Vasodilators, such as ACE inhibitors, cause the peripheral arteries to dilate, making it easier for blood to flow. Beta-blockers slow the heart rate and reduce blood pressure by blocking the effects of adrenalin.

Upon arrival at the emergency department, patients who experience acute episodes of CHF are typically treated with a combination of oxygen, morphine and intravenous diuretics. A small percentage of patients respond to this initial therapy and do not require admission to the hospital; however, the majority of acute CHF patients require additional medical intervention and are admitted. Additional acute CHF treatments may include intravenous administration of inotropes, such as dobutamine, and vasodilators, such as nitroglycerin. While each of these therapies assist in managing acute CHF, each also has inherent limitations. Inotropes strengthen the contractility of the heart but increase the incidence of cardiac arrhythmias, or irregular heartbeats, and are associated with increased mortality. Intravenously administered nitroglycerin requires careful monitoring and slow dosage increases in small increments, resulting in delays in attaining positive responses in acutely ill patients. Moreover, therapeutically effective doses of IV nitroglycerin are:

- .. unpredictable from patient to patient;
- .. very close to toxic degrees of hypotension; and
- .. associated with increased tolerance or loss of effectiveness.

These complications of IV nitroglycerin often require the transfer of acute CHF patients to more costly treatment units within the hospital, such as the cardiac and intensive care units, in order to provide careful patient monitoring.

### NATRECOR CLINICAL TRIALS

We have conducted numerous clinical trials evaluating Natrecor over the past eight years. Approximately 1,000 patients have been treated with Natrecor in 12 trials, including four pivotal efficacy and safety trials. In all of these trials, Natrecor administration has been associated with improved blood circulation and vascular filling pressures in the heart and lungs. Two of the efficacy trials further demonstrated statistically significant improvement of symptoms in acute CHF patients.

### AMENDED NDA SUBMISSION TRIALS

We have completed two trials since the submission of our original NDA, the VMAC

## Edgar Filing: SCIOS INC - Form 10-K

trial, or Vasodilation in the Management of Acute CHF, and the PRECEDENT trial, or Prospective Randomized Evaluation of Cardiac Ectopy with Dobutamine or Nesiritide Therapy. These trials formed the basis of our amended NDA.

THE VMAC TRIAL. We began enrollment in our VMAC trial in October 1999 and, in July 2000, completed enrollment of 498 patients hospitalized for acute CHF in the United States. This trial compared the effects of Natrecor, IV nitroglycerin and placebo, when individually added to standard therapy, such as diuretics and inotropes. The primary endpoints were a reduction in pulmonary capillary wedge pressure, or PCWP--a measure of the pulmonary vascular pressure of the heart, reflecting its workload--and improvement of the symptom of shortness of breath. The VMAC trial achieved both of its primary endpoints. Key results of the VMAC trial that were presented in November 2000 at the annual scientific meeting of the American Heart Association include:

- .. Natrecor produced a 20% decrease in PCWP at three hours, most of which occurred in the first 15 minutes, which was significantly better than the 7% decrease in PCWP at three hours for the placebo group;
- .. Natrecor improved shortness of breath significantly better than placebo;
- .. Natrecor decreased PCWP significantly faster and to a greater extent than IV nitroglycerin;
- .. Natrecor significantly improved breathing in patients receiving standard active therapy; in contrast, IV nitroglycerin did not significantly improve breathing in these patients;
- .. Natrecor-treated patients had significantly fewer adverse events than either placebo or IV nitroglycerin patients;
- .. acute CHF patients experiencing active ischemia, which is impaired blood flow to the heart, showed no significant difference in adverse side effects in respect to Natrecor, compared to placebo or nitroglycerin; and
- .. patients receiving Natrecor did not develop tolerance to the drug over time, and consequently, unlike IV nitroglycerin, the effects of Natrecor were sustained through 24 hours at the same dosage.

THE PRECEDENT TRIAL. The PRECEDENT trial compared the safety of Natrecor and dobutamine, the most commonly used inotrope treatment for acute CHF. Key results of the PRECEDENT trial indicated that:

- .. Natrecor produced fewer cardiac arrhythmias than dobutamine; and
- .. use of Natrecor was associated with fewer deaths than the use of dobutamine.

### CURRENT CLINICAL TRIALS

In March 2001, we initiated the PROACTION, or Prospective Randomized Outcomes Study of Acutely Decompensated Congestive Heart Failure Treated Initially in an Outpatient setting with Natrecor, trial, a pilot study designed to compare the clinical effects, safety profile and economic impact of standard therapy plus Natrecor to standard therapy plus placebo. The PROACTION trial completed enrollment of 250 acute CHF patients in December 2001. We expect to complete the study period follow-up and data analysis in the first half of 2002. These patients were treated in the emergency department or observation unit of a hospital, where the majority of the approximately one million hospitalizations each year for acute CHF begin. A preliminary review of the blinded data should confirm the ease of use and beneficial safety profile of Natrecor when administered in a less monitored clinical setting. Review of the blinded data is also expected to demonstrate that the rate of admissions from the emergency



## Edgar Filing: SCIOS INC - Form 10-K

department is much lower than assumed when the study was designed. Although useful clinical, safety, and economic data pertaining to the emergency department may result from this trial, the probability of finding statistically significant and pharmoeconomic differences between Natrecor and placebo on in-hospital costs is unlikely.

In January 2002, we initiated the FUSION, or Management of Patients with CHF After Hospitalization with Follow Up Serial Infusions Of Natrecor, study, a multi-center, randomized, open-label pilot study that will be conducted at approximately 40 U.S. sites and will enroll over 200 patients. Patients will be randomized to receive either their usual long-term cardiac medications, with or without IV inotropes, or serial infusions of Natrecor in addition to their usual long-term cardiac medications, excluding IV inotropes. All treatment groups will have weekly outpatient visits, and Natrecor patients will receive infusions for 4 to 6 hours at each weekly visit. Patients will receive study treatment for 12 weeks, followed by a one-month follow up period. Data from the FUSION study are expected to be available in the first quarter of 2003. As of February 28, 2002, 15 patients have been enrolled in the study.

6

### RESEARCH COLLABORATION WITH MEDTRONIC

In April 2000, we entered into a research collaboration agreement with Medtronic to study the feasibility of infusing patients with Natrecor via Medtronic's infusion products. This agreement requires Medtronic to collaborate with us on the infusion of vasodilators using Medtronic's products until the first patient is implanted with a Medtronic infusion product administering Natrecor. In May 2001, we expanded this research collaboration by entering into an agreement to conduct a clinical study to evaluate the hemodynamic, endocrine and clinical effects of Natrecor using information collected by Medtronic's Chronicle Implantable Hemodynamic Monitor, or IHM, both during and after infusions of Natrecor. A pilot feasibility study began in July 2001 at the Karolinska Hospital in Stockholm and is ongoing. 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 approved for sale in the United States or Europe. In November 2001, Medtronic and Scios determined the feasibility studies of infusing Natrecor with Medtronic's implantable delivery devices to be completed. Medtronic and Scios decided not to pursue feasibility studies concerning infusion of Natrecor with Medtronic's implantable delivery devices.

### P38 KINASE INHIBITOR PROGRAM

#### THE IMMUNE SYSTEM AND INFLAMMATION

The immune system is composed of multiple cell types, including white blood cells, each with a specific functional role. This system is regulated by cytokines, which are proteins produced by immune system cells. When the body encounters foreign material, or when tissue injury occurs, numerous enzymes in the immune system are activated, causing the production of various inflammatory cytokines such as interleukin-1, or IL-1, and tumor necrosis factor-alpha, or TNF.

One class of the immune system's family of enzymes is the mitogen-activated protein kinases, or MAP kinases. The MAP kinases are a family of intracellular signaling enzymes that are activated when cells are either stimulated or stressed and mediate many beneficial and injurious cellular responses. One of the MAP kinases, p38 kinase, is responsible for increased production of IL-1,

## Edgar Filing: SCIOS INC - Form 10-K

TNF and the inflammatory enzyme cyclooxygenase-2, or COX-2.

Autoimmune diseases occur when the immune system is abnormally activated against its own body. In the case of rheumatoid arthritis, the immune system is activated against joint tissues. White blood cells then invade the joint space, and, when activated, produce proteins such as IL-1, TNF and COX-2, which result in pain, swelling and eventual destruction of the affected joints. Other diseases that are worsened by sustained high levels of TNF and IL-1 include inflammatory bowel disease and CHF. We believe that patients treated with an oral p38 kinase inhibitor could experience a reduction in both the symptoms and the progression of inflammatory diseases since it could inhibit the production of IL-1, TNF and COX-2.

### CURRENT THERAPY FOR AUTOIMMUNE AND INFLAMMATORY DISEASES

Currently, there is no cure or prevention for autoimmune disease. Optimal medical management requires the early introduction of therapies in order to prevent the long-term effects of the disease. In the case of rheumatoid arthritis, long-term effects include irreversible joint damage and hypertrophy of joint tissues limiting a patient's ability to move the affected joints.

Traditionally, initial drug treatment of inflammatory diseases involves the use of non-steroidal anti-inflammatory agents. Steroids, such as glucocorticoids, are often added as the disease or symptoms progress. Although these agents help patients increase function and improve symptoms, they do not stop progression of the disease. Moreover, these drugs have been demonstrated to cause both stomach and kidney problems. In addition, persistent steroid treatment may result in excess suppression of the immune system, which can lead to infection, decreased bone marrow function and osteoporosis. Recently, more selective anti-inflammatory agents, or COX-2 inhibitors, such as Celebrex and Vioxx, have been introduced for symptom relief; however, they do not alter the progression of inflammatory disease. Sales of COX-2 inhibitors for the treatment of inflammatory disease were approximately \$4.8 billion in 2000.

More powerful drugs exist for patients that do not respond to initial drug therapy. In the case of rheumatoid arthritis, drugs such as methotrexate, hydroxychloroquine and sulfasalazine can have individual side effects, which must be monitored closely, and a delay of one to six months for a clinical response is common.

7

Within the past four years, inhibition of inflammatory cytokines has become an established treatment for autoimmune disease. In the case of rheumatoid arthritis, two new protein therapeutics, Enbrel and Remicade, were introduced to inhibit the effects of TNF. Combined U.S. sales of these agents totaled approximately \$956.0 million in 2000. These treatments have been shown to be effective at arresting the progression of the disease; however, they must be given by injection or infusion on a repeated basis. Resistance to the treatment is also an issue with these new drugs. This is due in part to increasing production by a patient's immune system of antibodies that neutralize administered proteins.

We are focusing our initial drug development efforts on creating an orally available small molecule drug for the treatment of rheumatoid arthritis. The Arthritis Foundation estimates that approximately 2.1 million Americans currently suffer from rheumatoid arthritis. Decision Resources, an independent market research group, suggests that the global market for rheumatoid arthritis therapies will be approximately \$6.6 billion by 2009, up from almost \$1.5 billion in 1999. Rheumatoid arthritis patients generate more than nine million

## Edgar Filing: SCIOS INC - Form 10-K

physician office visits and more than 250,000 hospitalizations each year. It is estimated that, in aggregate, the average yearly earnings deficit for all working individuals with rheumatoid arthritis is approximately \$6.5 billion.

### SCIO-469: OUR P38 KINASE INHIBITOR FOR THE TREATMENT OF INFLAMMATORY DISEASES

SCIO-469 is a novel oral, small molecule compound designed to inhibit p38 kinase. Oral administration allows for careful dosage adjustment, which may permit the physician to inhibit TNF sufficiently to obtain a useful therapeutic effect without subjecting the patient to the risk of infection associated with complete TNF inhibition.

**PRE-CLINICAL STUDIES.** In pre-clinical studies of acute and chronic inflammatory arthritis, orally administered doses of SCIO-469 reduced cellular production of COX-2 in a dose-dependent manner and reduced COX-2 and TNF levels in whole blood assays. Statistically significant reductions in inflammation also were observed in animal models of arthritis. In October 2000, we presented pre-clinical data involving our p38 kinase inhibitors at the annual scientific meeting of the American College of Rheumatology. The study demonstrated that our p38 kinase inhibitors had statistically significant anti-inflammatory effects in both acute and chronic animal models of inflammation.

**CLINICAL TRIALS.** In January 2001, we completed a Phase Ia clinical trial of SCIO-469 evaluating single oral doses in healthy volunteers. This Phase Ia clinical trial enrolled 30 volunteers. In April 2001, we completed a Phase Ib clinical trial with 20 healthy volunteers in which we evaluated the safety and tolerability of multiple doses of SCIO-469 over a two-week period. Based on the results of these trials, we initiated a Phase IIa clinical trial with rheumatoid arthritis patients in February 2002. This multi-center, randomized, placebo-controlled clinical study will enroll 120 patients who have active RA and are receiving methotrexate. The main objective of the study is to evaluate the safety and tolerability of six escalating doses of SCIO-469 in RA patients. The company expects to announce results from this study in the first quarter of 2003.

### TGF-BETA PROGRAM

In March 2002, we announced the addition of a new drug candidate that could become the first oral inhibitor of transforming growth factor (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 with driving 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.

Scios has developed novel and potent small molecule inhibitors that are designed to block activation of the TGF-beta receptor. They have been shown to be effective in reducing scar formation or fibrosis when given orally to animals. Scios expects to advance two lead molecules representing different chemical classes through pre-clinical development and is planning to announce the first medical indication for this new therapeutic class in 2003.

### STRATEGY

## Edgar Filing: SCIOS INC - Form 10-K

We are focused on developing and commercializing novel pharmaceutical products that address large market opportunities with unmet medical needs, initially in the areas of cardiovascular and inflammatory disease. Key elements of our strategy include:

- .. MAXIMIZING THE NEAR-TERM COMMERCIAL OPPORTUNITIES FOR NATRECOR. Natrecor is the first drug to be approved by the FDA for the treatment of acute CHF in over a decade. We have a focused 168-persons sale force dedicated to establishing Natrecor as the standard of care. We believe that this sales force is the largest in the United States exclusively dedicated to the acute CHF market. We also intend to expand the near-term commercial opportunities for Natrecor in the area of acute CHF by obtaining approvals to market Natrecor in European nations through a licensing agreement with GSK, and through collaborators outside of the European markets.
- .. EXPANDING THE COMMERCIAL OPPORTUNITIES FOR NATRECOR. We plan to expand the market opportunities for Natrecor including its use in additional clinical settings. We plan to pursue additional clinical settings for Natrecor including its use in serial outpatient infusions.
- .. ADVANCING THE DEVELOPMENT OF OUR SMALL MOLECULE THERAPEUTICS PROGRAM. We plan to continue to add state-of-the-art technologies to enhance our ability to develop small molecule therapeutics in addition to our traditional strengths in developing protein therapeutics. The major advantages of small molecule therapeutics are the potential for oral administration, the ability to adjust dosing to maximize efficacy and minimize toxicity and the ease and cost of manufacturing. Currently, we are developing SCIO-469, an oral, small molecule inhibitor of p38 kinase for the treatment of rheumatoid arthritis. In addition, we are focusing on the development of small molecule inhibitors of the TGF-beta receptor, which we hope will prove to be useful for a broad range of diseases characterized by unregulated scarring and eventual organ failure.
- .. BROADENING OUR PRODUCT PORTFOLIO THROUGH LICENSE OR ACQUISITION. We believe that we can leverage our Natrecor-dedicated sales force by marketing additional products to the acute care market. We are evaluating the licensing or acquisition of additional product candidates, several of which are in the areas of cardiovascular and inflammatory disease. We may also acquire additional technologies or businesses that we believe will enhance our research and development capabilities.
- .. COLLABORATING SELECTIVELY WITH BIOTECHNOLOGY AND PHARMACEUTICAL COMPANIES. As we expand certain aspects of our development pipeline, we intend to partner with biotechnology and pharmaceutical companies in order to gain access to additional research and development or marketing expertise. Our approach to partnership will be on a selective basis, seeking to maintain the highest possible value of our product candidates. In order to accomplish this task, we intend to delay partnering of any product until its clinical utility has been established.

### MARKETING AND SALES--NATRECOR

#### NATRECOR EDUCATION

We continue to build awareness for Natrecor among key target audiences through a variety of tactical programs, including medical seminars, continuing medical education programs, advisory boards and publications. At December 31, 2001, we had hired 12 Scientific Affairs Managers and a Director of Scientific Affairs who are focused in educating physicians on diseases of the cardiovascular system and building relationships with opinion-leading cardiologists. We continue to identify and develop relationships with physicians and nurses who play a leading role in the diagnosis and treatment of CHF.

## Edgar Filing: SCIOS INC - Form 10-K

In addition, we launched a nationwide registry to collect and analyze demographic and treatment data about patients hospitalized due to acutely decompensated heart failure. ADHERE, the Acute Decompensated HEArt failure national Registry, is expected to have a unique database of information of tens of thousands of patients gathered from approximately 300 U.S. hospitals over the next several years. We believe ADHERE will help clinicians better determine factors associated with improved clinical outcomes in acute decompensated heart failure, the primary cause of more than one million hospital admissions in the U.S. each year. ADHERE should also provide comprehensive demographic and treatment data on a wide range of hospitalized heart failure patients. By tracking how these chronically ill patients are treated over time, we can use this information to identify optimal treatment strategies for them and develop comprehensive acute heart failure guidelines.

### SALES FORCE TEAM

In early 2001, in connection with Innovex, we built our sales force team in anticipation of the FDA approval of Natrecor. We initially hired two Area Business Directors, 18 Area Business Managers to manage our sales force, and a 168-person

9

cardiovascular sales force. Our management team and sales force have extensive experience in and have been involved in the successful commercialization of hospital based products. Our team of 188-persons is the largest sales force solely dedicated to the acute heart failure market.

### GROUP PURCHASING ORGANIZATIONS (GPO)

To enhance our hospital and physician access, we have aggressively pursued contracts with GPOs. These GPOs contract for hundreds of their member hospitals and, as a group can assist Scios in gaining access for Natrecor and our cardiovascular specialists in thousands of hospitals. We currently have signed GPO arrangements with Owen, Consorta, Amerinet, and Premier. In addition to GPO agreements, Kaiser Hospital has put Natrecor on its formulary for its Northern and Southern California hospitals, and we have entered into a purchasing agreement with the Veteran's Administration, which allowed Natrecor to be placed on the Federal Supply Schedule.

### GLAXOSMITHKLINE AGREEMENT (GSK)

In December 2001, we entered into a binding summary of terms with Glaxo Group Ltd., an affiliate of GlaxoSmithKline, or GSK, in which we will license Natrecor to GSK in all European markets. Under the terms of the agreement, GSK will have the rights to sell and distribute the product for which we will receive an up-front fee and milestone payments totaling (Pounds)15.0 million British Pounds (which at December 31, 2001 equaled approximately \$22 million U.S. Dollars), in addition to future royalties in the identified countries. We will manufacture and supply the bulk product to GSK. Both companies will work together to continue clinical development of Natrecor in Europe. In order to obtain European approval for Natrecor, GSK expects to use the extensive clinical data we submitted to obtain approval from the FDA in August 2001. The companies expect to launch Natrecor in Europe in the first half of 2004. No revenue has been recognized related to this agreement through December 31, 2001.

### OUR AGREEMENT WITH INNOVEX

In January 2001, we entered into a sales and marketing alliance with Innovex, a

## Edgar Filing: SCIOS INC - Form 10-K

subsidiary of Quintiles Transnational Corp. As part of the three and one half year agreement, PharmaBio Development, Inc., an affiliate of Innovex, agreed to fund \$30.0 million of our costs to launch Natrecor over the first 24 months of the commercialization of Natrecor and to loan us up to \$5.0 million. Under the agreement, Innovex identified, hired, trained and deployed a dedicated cardiology and emergency medicine sales force of 168 persons at our cost to launch Natrecor. In December 2001, Scios, Innovex and PharmaBio, amended the January 2001 agreement in relation to the Natrecor sales force and the infrastructure supporting it. The amendment will enable Scios, at its option, to assume control of the Natrecor sales force in June 2003, one year earlier. Of the \$30.0 million in funding to be provided by PharmaBio, we received \$10.0 million in the fourth quarter of 2001, and will receive the remaining \$20.0 million over the following 17 months. Under the amendment, we eliminated the \$5.0 million line of credit provided by PharmaBio to Scios. As part of the funding agreement, we will pay PharmaBio a declining royalty rate on net sales of Natrecor through early 2008. We also granted PharmaBio a warrant to purchase 700,000 shares of our common stock at an exercise price of \$20.00 per share.

### LICENSING ARRANGEMENTS WITH THIRD PARTIES

We have licensed some of our product candidates to third parties, who are now responsible for product development. Under these arrangements, we typically receive a combination of up-front payments, milestone payments upon their achievement of scientific and clinical benchmarks and royalties on commercial sales of products by our partners.

#### BNP

In 1998, we entered into a cross-license agreement with Shionogi under which we granted Shionogi a royalty-free, nonexclusive license to our BNP patent rights for the diagnostic field. In exchange, Shionogi granted us a royalty-bearing, exclusive license under Shionogi's BNP patents to develop therapeutic products. For therapeutic products, we pay royalties on net sales for the life of the patent in countries where Shionogi holds one or more BNP patents. In countries where Shionogi has no issued patent covering BNP, but one or more pending patent applications which cover BNP, we are obligated to pay a reduced royalty on the net sales of our therapeutic products during the pendency of such applications, up to a maximum of four years following commencement of our sales in the country where such applications are pending, after which the royalty obligation shall cease, unless and until the pending applications result in one or more issued claims covering BNP, in which case we would be obligated to pay the full royalty from the date of patent issuance until the expiration or invalidity of the

10

BNP patents in question. Shionogi holds patents relating to BNP in Japan and Europe. We believe that Shionogi may have a patent application pending in the United States.

We have licensed to Biosite Diagnostics and Abbott Laboratories the right to use our patents on BNP for diagnostic purposes. Biosite has developed and is currently marketing a point-of-care diagnostic test for BNP levels in the United States and Europe. This test is used to identify individuals with CHF or to monitor progression of their disease or their response to treatment. We are currently receiving royalties from Biosite on the sales of their diagnostic products. Abbott is continuing to develop its BNP diagnostic product.

#### FIBROBLAST GROWTH FACTOR

## Edgar Filing: SCIOS INC - Form 10-K

In 1982, Biotechnology Research Partners, Ltd., a California limited partnership, or BRP, was formed primarily to conduct research and experimentation in the field of biotechnology and to develop and produce from genetically engineered micro-organisms or cells new products that have potential pharmaceutical and other commercial applications. Out of this research, Fibroblast Growth Factor, or FGF, was discovered. FGF is a naturally occurring protein, which stimulates the growth of new blood vessels. In 1988, we licensed the FGF technology to Kaken Pharmaceutical. In April 2001, Kaken received approval from the Japanese Ministry of Health and Welfare to market an FGF-based product for the treatment of recalcitrant dermal ulcers in Japan. As part of the partnership agreement for BRP, BRP and Scios share in the royalties from product sales of FGF. During 2001, we received royalties on sales of FGF-based products by Kaken in Japan. The distributions of the royalty payments were approximately 63% to Scios and 37% to the limited partners of BRP. Costs and expenses are shared in this same percentage for audit, legal, and general and administrative expenses. Scios R&D, Inc., a wholly owned subsidiary of Scios, owns 100% of BRP, Inc., the general partner of BRP. Scios owns approximately 59% of BRP and consolidates the results of BRP in its financial statements.

In November 1999, we granted a license to Chiron covering rights to FGF in the areas not previously licensed by us. We may receive up to \$12.0 million in milestone payments upon Chiron's completion of certain development objectives. In addition, we will receive royalties based on sales of FGF products in countries where we hold patents. Chiron has completed separate Phase II human clinical trials evaluating FGF as a treatment for coronary artery and peripheral vascular disease.

We have also granted nonexclusive licenses under our FGF patents and technology to Orquest, for the development of products for the treatment of bone fractures.

We are obligated to make payments to Organon International based on amounts received by us upon commercialization of FGF. Approximately \$0.2 million remains to be paid under this obligation, which stems from our 1989 reacquisition of certain FGF rights previously licensed to Organon.

### VASCULAR ENDOTHELIAL GROWTH FACTOR\121\

VEGF\121\ is a naturally occurring protein used to stimulate the growth of new blood vessels. In May 1996, we granted a license to GenVec for the use of the gene encoding VEGF\121\ in gene therapy products. GenVec is currently conducting Phase II clinical trials of its BIOBYPASS angiogen which incorporates the use of our licensed technology. This product is being evaluated to treat coronary artery disease and peripheral vascular disease. We will receive royalties on any future sales of these products.

### GLUCAGON-LIKE PEPTIDE-1

GLP-1 is a potent peptide that stimulates insulin release when blood sugar levels are above normal. In 1988, we licensed from Massachusetts General Hospital the exclusive use of certain patent applications for GLP-1 and certain analogs upon which we will pay a royalty on any future sales. In 1996, we granted Novo Nordisk an exclusive license to our GLP-1 technology and the additional rights we acquired pursuant to the Massachusetts General Hospital license. We will receive royalties on product sales made by Novo Nordisk. Novo Nordisk is responsible for development activities for GLP-1 and has initiated Phase II human clinical trials of a GLP-1 analog that they are developing as a treatment for Type 2 diabetes.

### ALZHEIMER'S DISEASE

We have concluded separate research collaborations with Eli Lilly and with

## Edgar Filing: SCIOS INC - Form 10-K

DuPont Pharmaceuticals to develop new therapies for Alzheimer's Disease. The joint research phase of our collaboration with DuPont ended in November 2000. The

11

joint research phase of our collaboration with Eli Lilly ended December 31, 2001. Under the Eli Lilly agreement, we are entitled to receive potential milestone payments if certain events are achieved, and Eli Lilly is entitled to commercialize any resulting products subject to royalty payments to us. With the termination of the DuPont and Eli Lilly collaborations, the Company has decided to discontinue further substantial research efforts relating to identification and characterization of proteins and biological mechanisms implicated in Alzheimer's disease.

### DRUG DELIVERY SYSTEMS

Prior to our acquisition of Nova Pharmaceuticals in 1992, Nova had been developing several drug delivery systems, including the Gliadel implant to treat primary brain cancer. The Gliadel technology was developed pursuant to a license agreement with the Massachusetts Institute of Technology relating to MIT's Bidel drug delivery technology. We licensed Gliadel to Guilford Pharmaceuticals in 1994. Gliadel was approved for marketing in the United States in 1996. We assigned our Bidel license rights back to MIT, which administers the licensing of this technology, including the license with Guilford. We and MIT are receiving royalty and milestone payments under the license agreement with Guilford. We conducted the Gliadel project on behalf of Nova Technology Limited Partnership, the limited partnership that funded Nova's research and development on these projects. In December 1992, the Company exercised its option to acquire all interests in Nova Technology Limited Partnership for \$20.4 million. The Company also issued contingent payment rights to all limited partners of the partnership, pursuant to which the Company is obligated until January 15, 2008 to pay royalties on the sale or license of certain products that were under development by the partnership. The Company had accrued \$44,000 at December 31, 2001 as a result of royalties associated with the commercialization of Guilford's Gliadel wafer.

### PSYCHIATRIC SALES AND MARKETING DIVISION

Since 1990, our Psychiatric Sales and Marketing Division, or PSMD, had the exclusive right to market certain products in the United States under a licensing agreement with GSK, including Eskalith and Eskalith CR, Thorazine, Stelazine, and Parnate. GSK was responsible for the manufacture and distribution of these products. As part of our agreement with GSK, we paid GSK 40% of our net profits from the sales of these products. We sold the marketing rights back to GSK and terminated the licensing agreement effective March 31, 2001. We received from GSK \$4.0 million in 2001 and \$3.0 million in 2002, and expect to receive a final payment of \$2.4 million in 2003.

### RESEARCH AND DEVELOPMENT

Our technical capabilities now include disease-based gene microarrays, bioinformatics, structural informatics and state-of-the-art medicinal chemistry, including computational chemistry modeling, all of which have added to our traditional technical strengths in protein cloning and expression.

In order to discover new pathways of disease, our research has assembled tissue samples from a broad array of human and experimental diseases of the cardiovascular system. We analyze these tissues for the expression of new genes that may be involved in particular diseases. We do this by a technique known as



## Edgar Filing: SCIOS INC - Form 10-K

microarray gene display, in which fluorescent tags identify which genes may be up regulated or down regulated during the course of a particular disease. We then apply commercial and proprietary software analysis to the sequence of these genes and to the patterns of their expression in order to highlight cellular pathways that may be playing a particular role in a disease process. This process is known as bioinformatics.

Particular attention is paid either to the presence of a known enzyme participating unexpectedly in a disease process or to a novel enzyme. Our molecular biologists then express these candidate target enzymes in an activated state as pure proteins and develop high throughput screening assays to discover inhibitors of those enzymes within our chemical compound library, which we have developed over the last several years. Applying the tools of structural informatics, our protein chemists develop computer-based, three-dimensional structures of these enzymes that guide our chemists in developing lead inhibitory molecules with respect to potency and selectivity. Once we have brought a drug candidate to the optimum level of potency and safety, we test the drug at both the cellular and animal level, again applying gene microarray technology. This allows the rapid evaluation of the drug for efficacy while ensuring that potential toxicities are minimized before testing in the clinic.

We are focused on diseases of the cardiovascular system, with a particular emphasis on inflammation in both its acute and chronic forms and scarring as a cause of chronic organ failure. Our research has emphasized an emerging family of protein therapeutic targets known as protein kinases. Kinases are naturally occurring intracellular signaling "switches" that work by

12

attaching phosphate groups to other proteins, thereby activating cellular processes controlled by those proteins, including the transcription of new proteins. While the vast majority of protein kinases are engaged in beneficial work on behalf of the cells of the body, medical research over the last decade has clearly demonstrated that cellular pathways abnormally activated by certain kinases contribute to both the symptoms and progression of many diseases. By applying the most advanced technologies available with proprietary methodology, including the development of gene analysis software, we have dedicated ourselves to the identification of kinases participating in diseases within our strategic focus and developing and testing inhibitors of those enzymes for potential therapeutic value. The rapid pre-clinical and clinical development of our p38 kinase inhibitor, SCIO-469, and our preliminary advances in our TGF-beta program represents the initial success of this innovative approach.

Our aggregate research and development expense totaled \$48.1 million in 2001, \$39.3 million in 2000, and \$34.3 in 1999.

### MANUFACTURING

Our products are manufactured for us by third parties. In 1995, we entered into an agreement with BioChemie GmbH in Austria for the manufacture of Natrecor. We expect the agreement to run through 2009. BioChemie ships Natrecor in powder form to Abbott Laboratories in McPherson, Kansas, where it is blended, filled and packaged for shipment. We also maintain arrangements with several companies to manufacture our p38 kinase inhibitor compounds and intend to enter into a long-term supply relationship if our compounds continue to proceed through development.

### PATENTS AND PROPRIETARY RIGHTS

## Edgar Filing: SCIOS INC - Form 10-K

We seek patent protection for proprietary technology and products in the United States and abroad to prevent others from unfairly capitalizing on our investment in research. Other companies engaged in research and development of new healthcare products also actively pursue patents for their technologies. We also rely upon trade secrets and know-how to reinforce our competitive position. However, trade secret protection will not preclude others from independently developing technology similar to ours, nor can there be any assurance that third parties that have signed confidentiality agreements with us will honor those agreements.

We currently own or hold exclusive rights to 82 issued U.S. patents and 50 U.S. pending patent applications covering our proprietary technology and products. We also own or hold exclusive rights to foreign patents and patent applications corresponding to most of the U.S. patents and patent applications in our portfolio. Our issued patents include patents on Natreacor, certain of our p38 kinase inhibitors, FGF, VEGF\121\ and GLP-1. Our proprietary position with respect to certain principal products under development is described below. If a patent issues prior to marketing approval, as has been the case with all of our issued patents to date, we can apply for extension of the patent term for a limited period of time to make up for a portion of the patent term lost to the regulatory approval period. The absence of a patent covering products, which we have licensed to third parties, could reduce the royalties due to us under the agreements with those parties.

### NATRECOR

We have been issued United States, Canadian and European patents covering the endogenous form of Natreacor, human BNP. Our U.S. patents on Natreacor are subject to possible extension due to time taken up in the regulatory approval process. We believe our key patent on Natreacor, which currently expires in May 2009, may be extended to late 2013 or early 2014. Pursuant to a royalty-bearing, exclusive license granted to us by Shionogi, we also have the exclusive right to develop therapeutic products using BNP under certain patents and applications on BNP originally filed by Daiichi Pharmaceutical and subsequently acquired by Shionogi. Shionogi holds patents in Japan and Europe. We believe that Shionogi may have a patent application pending in the United States. Although we were granted a Japanese patent on BNP, the patent was revoked in 1998 in an opposition filed against the patent by an unidentified party. The opposition did not challenge the originality of our BNP discovery but based its challenge solely on an interpretation of utility requirements for patentability peculiar to Japanese patent law. We appealed the revocation to the Tokyo High Court. On March 13, 2001, the Tokyo high court affirmed the revocation. Because we believe the decision is contrary to both Japanese precedent and patentability requirements in the United States and Europe, we have appealed the revocation to the Japanese Supreme Court. The decision does not affect our patent rights outside of Japan, nor does the revocation impact our ability to exclusively market BNP in Japan insofar as our exclusive license under the patent rights of Daiichi includes several Japanese patents of Daiichi directed to BNP.

13

### P38 KINASE INHIBITORS

We have filed a series of patent applications in the United States covering the classes of p38 kinase inhibitors that we have identified. To date, we have been issued three U.S. patents directed to certain of these p38 inhibitors. These patents will expire in 2018, subject to possible extension for FDA regulatory delays. While the classes of small molecule compounds identified by our researchers appear to be unique, we are aware that other companies are also

## Edgar Filing: SCIOS INC - Form 10-K

working to develop p38 kinase inhibitor compounds, and have filed patent applications on and received patents covering certain classes of compounds that these competing companies have identified and covering various aspects of identifying such compounds.

### FGF

After an interference with The Salk Institute for Biological Studies, we were awarded a U.S. patent on DNA sequences, expression vectors, and microorganisms used in the recombinant production of human basic FGF. Our basic FGF U.S. patent will expire in 2012, and it may be extended for FDA regulatory delays. We also hold European and Japanese patents on human basic FGF. Synergen, now owned by Amgen, has obtained patents directed to a form of FGF that we believe is different from the form of FGF produced by us. A U.S. patent issued to Salk contains claims directed to substantially pure mammalian basic FGF containing the 146 amino acid sequence of bovine basic FGF or a naturally occurring homologous sequence of another mammalian species. Although we have been advised by counsel that the Salk patent would be invalid if read broadly enough to cover our form of FGF, there is still risk that an assertion of this patent could block our partners' ability to develop and market human basic FGF in the absence of a license, or if such a license is granted, could reduce the royalty income to us. We opposed Salk's European patent, which resulted in revocation of the patent. Salk appealed the revocation. In February 2002, the Technical Board of Appeal agreed with the grounds of appeal and entered its decision to maintain the patent as granted. Our European patent was opposed by Chiron and Pharmacia. Our patent was upheld and both opponents appealed. As a result of our license to Chiron, Chiron, who is also a licensee of Salk, withdrew from the opposition against our European patent, and we have withdrawn from our opposition against the Salk patent.

In March 1994, we obtained a non-exclusive license to make, use and sell FGF under a U.S. patent issued to Harvard University containing claims to purified cationic (basic) FGF. The Harvard patent is based on a patent application having a filing date earlier than the application, which formed the basis for the Salk patent. Sublicense rights under this patent are included in the rights granted by us to our FGF licensees, Kaken and Chiron.

### VEGF\121\

Seven isoforms of human VEGF (hVEGF) are known, having 121, 145, 148, 165, 183, 189 and 206 amino acids, respectively. We believe that our researchers were the first to identify, clone and produce by recombinant DNA technology the 121 amino acid form of hVEGF (hVEGF\121\). hVEGF\121\ is the only human VEGF isoform known not to bind to heparin. We own two U.S. patents issued in 1993 covering hVEGF\121\, and in 1996 received a European patent covering this VEGF isoform. Our U.S. patents on VEGF\121\ will expire 2010 but may be extended for FDA regulatory delays. We have patent applications pending in Canada and Japan. Other companies and institutions, including Genentech, Pharmacia and the Regents of the University of California, hold patents and pending patent applications claiming various isoforms of hVEGF and certain VEGF variants.

### COMPETITION

For patients treated with acute CHF, many therapeutic options are available. Competing drugs fall into three main categories: vasodilators, inotropes and diuretics. Natreacor, approved for marketing in August of 2001, competes against both vasodilators and inotropes in the acute CHF market. Many of the currently marketed drugs are available in generic formulation and have an associated low cost. In addition, milrinone, an inotrope, is currently promoted by Sanofi-Synthelabo and is expected to lose patent protection in May 2002. Natreacor has been priced above the cost of these existing drugs, which may harm

## Edgar Filing: SCIOS INC - Form 10-K

our competitive position relative to these drugs. While early acceptance is encouraging, the higher cost of Natrecor may prevent us from being able to compete effectively with these long-standing existing forms of therapy.

New drugs in development for the treatment of acute CHF would compete with Natrecor if approved by the FDA or other regulatory agencies. Veletri (tezosentan), a non-selective endothelin receptor antagonist, is being developed by Actelion but the drug did not meet its primary endpoints for heart failure. It is not clear whether Actelion will continue the development of this product. Abbott had previously submitted an NDA for Simdax, a calcium sensitizer described as an inotrope, but withdrew the application in 2000. Abbott appears to be moving forward with development of this product.

14

We are aware of several pharmaceutical and biotechnology companies that are actively developing or have commercialized products addressing the same disease indication as the p38 MAP kinase inhibitor. Current commercial competition for rheumatoid arthritis treatments include generic methotrexate, the injectable TNF inhibitors such as Centecor's Remicade and Immunex's Enbrel and the recent launch of Amgen's (formally Immunex) interleukin-1 inhibitor, Anakinra. In addition competition will result from the most often prescribed drugs to treat rheumatoid arthritis, the non-steroidal anti-inflammatory drugs such as ibuprofen and the COX-2 inhibitors such as Pharmacia's Celebrex and Merck's Vioxx. These drugs are palliative and do not reverse or prevent the progression of the disease.

In addition, we are aware of a few pharmaceutical and biotechnology companies that are specifically developing a p38 MAP kinase inhibitors for treating rheumatoid arthritis. In 2001, Vertex Pharmaceuticals (which recently merged with Aurora Biosciences) suspended the development of its lead oral p38 compound indicated for rheumatoid arthritis. Vertex intends to initiate clinical trials with two-second generation compounds in the first half of 2002. These companies, including Beringer Ingleheim and Vertex may possess both greater access to capital and research and development resources. We may be unable to compete effectively with any of these development projects. If we are successful in developing our own p38 kinase inhibitor compound we may face intense competition.

We expect that competition for our products, when approved for sale, will be based, among other things, on efficacy, reliability, product safety, price and patent position. Our ability to compete effectively and develop products that can be manufactured cost-effectively and marketed successfully will depend on our ability to:

- .. advance our technology platforms;
- .. license additional technology;
- .. maintain a proprietary position in our technologies and products;
- .. obtain required government and other public and private approvals on a timely basis;
- .. attract and retain key personnel; and
- .. enter into corporate partnerships.

Our failure to achieve any of the above goals could impair our business.

## Edgar Filing: SCIOS INC - Form 10-K

### GOVERNMENT REGULATION

Pharmaceutical drugs are subject to extensive pre- and post-market regulation by the FDA, including regulations that govern the testing, manufacturing, safety, efficacy, labeling, storage, record keeping, advertising, and promotion of the products. The process required by the FDA before a new drug may be marketed in the United States generally involves the following: completion of pre-clinical laboratory and animal testing; submission of an investigational new drug application, which must become effective before clinical trials may begin; performance of adequate and well controlled human clinical trials to establish the safety and efficacy of the proposed drug products intended use; and approval by the FDA of an NDA.

Human clinical trials are typically conducted in three sequential phases that may overlap. These phases generally include the following: Phase I during which the drug is introduced into healthy human subjects or, on occasion patients, and is tested for safety, dose tolerance and metabolism; Phase II during which the drug is introduced into a limited patient population to determine the efficacy of the product of specific targeted diseases, to determine dosage tolerance and optimal dosage and to identify possible adverse effects and safety risks; and, Phase III during which the clinical trial is expanded to a more diverse patient group in geographically dispersed clinical trial sites to further evaluate clinical efficacy, optimal dosage and safety. The FDA, and the Institutional Review Board at each institution at which a clinical trial is being performed, may suspend a clinical trial at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable health risk.

The results of product development, pre-clinical animal studies and human studies are submitted to the FDA as part of the NDA. The NDA also must contain extensive manufacturing information. FDA does allow under certain circumstances for the joint manufacturing of drug products. The FDA may approve or disapprove the NDA if applicable FDA regulatory criteria are not satisfied or it may require additional clinical data. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-market regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require post-marketing studies, referred to as Phase IV studies, to monitor the effect of approved products, and may limit further marketing of the product based on the results of these post-market studies.

15

The FDA has broad post-market regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals.

With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals, which include, among others, off-label promotion, industry sponsored scientific and educational activities, standards and regulations for direct-to-consumer advertising, and promotional activities involving the Internet. The FDA has very broad enforcement authority under the Federal Food Drug and Cosmetic Act, and failure to abide by these regulations can result in penalties including the issuance of a warning letter directing a company to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and state and federal civil and criminal investigations and prosecutions.

We are also subject to various laws and regulations regarding laboratory

## Edgar Filing: SCIOS INC - Form 10-K

practices, product manufacturing, including FDA's current Good Manufacturing Practice requirements, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, the FDA has broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could harm our business. Additionally, before any of our products may be marketed in foreign countries, they are subject to pre- and post-market regulation similar to that required in the United States.

### EMPLOYEES

We had 425 full-time employees as of December 31, 2001 as follows:

Sales Representatives and Management deployed in the field.....	188
Sales Operations and Marketing.....	11
Research and Development.....	178
General and Administrative.....	48
	---
Total.....	425
	===

We believe our employee relations are good. None of our employees is subject to a collective bargaining agreement.

16

### RISK FACTORS

YOU SHOULD CAREFULLY CONSIDER THE RISKS DESCRIBED BELOW BEFORE MAKING AN INVESTMENT DECISION. OUR BUSINESS, FINANCIAL CONDITION OR RESULTS OF OPERATIONS COULD BE HARMED BY ANY OF THESE RISKS. THE RISKS DESCRIBED BELOW ARE NOT THE ONLY ONES FACING OUR COMPANY. ADDITIONAL RISKS NOT PRESENTLY KNOWN TO US OR THAT WE CURRENTLY DEEM IMMATERIAL MAY ALSO IMPAIR OUR BUSINESS OPERATIONS. THIS DOCUMENT ALSO CONTAINS FORWARD-LOOKING STATEMENTS THAT INVOLVE RISKS AND UNCERTAINTIES. OUR ACTUAL RESULTS COULD DIFFER MATERIALLY FROM THOSE ANTICIPATED IN THESE FORWARD-LOOKING STATEMENTS AS A RESULT OF THE RISKS FACED BY US, INCLUDING THOSE DESCRIBED BELOW AND ELSEWHERE IN THIS DOCUMENT.

#### RISKS RELATED TO NATRECOR

IF NATRECOR DOES NOT GAIN MARKET ACCEPTANCE, OUR BUSINESS WILL SUFFER.

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

- .. the degree of clinical efficacy and safety;
- .. cost-effectiveness of Natreacor;
- .. its advantage over alternative treatment methods; and
- .. reimbursement policies of government and third party payers.

## Edgar Filing: SCIOS INC - Form 10-K

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

IF THE FDA DETERMINES THAT OUR THIRD-PARTY MANUFACTURING FACILITIES ARE NOT ADEQUATE, WE MAY LOSE THE ABILITY TO MANUFACTURE AND SELL NATRECOR.

Periodically, the FDA is likely to inspect each of the facilities involved in manufacturing Natrecor. Natrecor is manufactured for us by BioChemie GmbH, a subsidiary of Novartis, in Austria and is shipped 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. If deficiencies are identified, we may lose the ability to supply and sell Natrecor for an 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. BioChemie GmbH is responsible for manufacturing Natrecor in bulk quantities and Abbott Laboratories is responsible for blending, filling and packaging Natrecor, and if they encounter problems in these processes, our revenues from future sales of Natrecor could decrease. Natrecor is manufactured using industry-accepted recombinant manufacturing techniques, which must be conducted under strict controls and tight timelines. Natrecor is subject to strict quality control testing during all phases of production and prior to its release to the market. Any quality control testing failures could lead to a reduction in the available supply of Natrecor. BioChemie depends on outside vendors for the timely supply of raw materials used to produce Natrecor. Once a supplier's materials have been selected for use in BioChemie's manufacturing process, the supplier in effect becomes a sole or limited source of that raw material due to regulatory compliance procedures. We depend on these third parties to perform their obligations effectively and on a timely basis. If these third parties fail to perform as required, our ability to deliver Natrecor on a timely basis would be impaired. In addition, in the event of a natural disaster, equipment failure, power failure, strike or other difficulty, we may be unable to replace our third party manufacturers in a timely manner and would be unable to manufacture Natrecor to meet market needs.

17

IN THE AREA OF ACUTE CHF, WE FACE COMPETITION FROM COMPANIES WITH SUBSTANTIAL FINANCIAL, TECHNICAL AND MARKETING RESOURCES, WHICH COULD LIMIT OUR FUTURE REVENUES FROM NATRECOR.

Many therapeutic options are available for patients with acute CHF. Competing drugs fall into three main categories: vasodilators, inotropes and diuretics. Natrecor 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 costs more than many of these existing drugs, which may harm our competitive position relative to these drugs.

New drugs in development for the treatment of acute CHF would also compete with Natrecor if approved by the FDA or other regulatory agencies. Tezosentan, a

## Edgar Filing: SCIOS INC - Form 10-K

non-selective endothelin receptor antagonist, is being developed by Actelion Ltd. and has been evaluated in Phase II clinical trials as a vasodilator for the treatment of acute CHF.

In addition, Abbott had previously submitted an NDA for Simdax, a calcium sensitizer described as an inotrope, but withdrew the application in 2000. However, Abbott appears to be moving forward with development of this product. If any such new drug in development is approved by the FDA or other regulatory agencies, we may not be able to compete effectively with these new forms of therapy.

IF WE FAIL TO GAIN APPROVAL FOR NATRECOR AND OUR OTHER PRODUCT CANDIDATES IN INTERNATIONAL MARKETS, OUR MARKET OPPORTUNITIES WILL BE LIMITED.

We have not yet filed for marketing clearance 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.

WE WILL REQUIRE A PARTNER TO MARKET AND COMMERCIALIZE NATRECOR AND OUR OTHER PRODUCT CANDIDATES IN MARKETS OTHER THAN EUROPE.

We plan to partner with other companies for the sale of Natrecor and our other product candidates outside of the United States. In December 2001, we entered into an agreement with GSK in all European markets. Under the terms of the agreement, GSK will have the rights to sell and distribute Natrecor for which Scios will receive an up-front fee and milestone payments, in addition to future royalties on European sales. Scios will manufacture and supply the bulk product (active pharmaceutical ingredient) to GSK.

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

THE SUCCESS OF NATRECOR IN THE EUROPEAN MARKET IS HIGHLY DEPENDENT ON OBTAINING EUROPEAN APPROVAL AND OUR LICENSING AGREEMENT WITH GSK FOR MARKETING, PROMOTION AND SALES ACTIVITIES.

In order to obtain European Approval for Natrecor, GSK expects to use the extensive clinical data we submitted to obtain approval from the FDA in August 2001. If we receive the necessary approvals, we expect to launch Natrecor in Europe in the first half of 2004. However, while the clinical data used to support the FDA submission is 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 for Scios.

Under the terms of the agreement, GSK will have the rights to sell and distribute Natrecor for which Scios will receive an up-front fee and milestones payments, in addition to future royalties on European sales. Accordingly, our revenue from sales of Natrecor in Europe will be highly dependent on GSK's



## Edgar Filing: SCIOS INC - Form 10-K

ability to effectively market and sell Natrecor.

18

The companies intend to conduct a health outcomes trial, commencing in 2002, which the companies will use to assess market acceptance of Natrecor in major European countries. The health outcomes trial could affect the price at which Natrecor will be sold. We cannot be assured that a preferred price for Natrecor will be obtainable and that market acceptance of Natrecor will be achieved.

IF WE FAIL TO OBTAIN ADDITIONAL MARKETING APPROVALS FROM THE FDA FOR THE USE OF NATRECOR FOR ADDITIONAL THERAPEUTIC INDICATIONS OR IF 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, 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 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, we cannot exclude the possibility that serious adverse events related to the use of Natrecor might occur in the future, which could either limit its use or cause the FDA to revoke our approval to market Natrecor.

### OTHER RISKS RELATED TO SCIOS

WE HAVE A HISTORY OF LOSSES, EXPECT TO OPERATE AT A LOSS FOR THE FORESEEABLE FUTURE AND MAY NEVER BE PROFITABLE.

We may not be able to achieve or earn a profit in the future. We began operations in December 1981, and since that time, with the sole exception of 1983, we have not earned a profit on a full-year basis. Our losses have historically resulted primarily from our investments in research and development. As of December 31, 2001, we had an accumulated deficit of approximately \$473.9 million.

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

- .. sales of Natrecor beginning in August 2001;
- .. one-time sales of bulk FGF product and royalties from Fiblast Spray sales by Kaken in Japan;
- .. one-time signing fees from our corporate partners under agreements supporting the research, development and commercialization of our product candidates;
- .. one-time payments from our corporate partners when we achieved regulatory or development milestones;
- .. research funding from our corporate partners; and
- .. our psychiatric sales and marketing division.

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

## Edgar Filing: SCIOS INC - Form 10-K

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.

19

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 personnel or to attract additional highly qualified personnel could delay the development of our product candidates and harm our business.

The success of our present and future operations will also depend to a significant extent on the experience, abilities and continued services of certain executive officers of Scios. In this regard, Dick Brewer, our President and Chief Executive Officer, was diagnosed in mid-2001 with early-stage Multiple Myeloma, a form of blood cancer. He continues to undergo treatment and in February 2002 moved into the next phase of his treatment program. During this phase, which is expected to last approximately two months, the Company has expanded the role of Dr. Donald Rice, the Chairman of the Board, and established an Office of the Chairman, composed of Dr. Rice and our senior management team. A loss of the services of Mr. Brewer or other key management personnel could have a material adverse effect on the Company.

## Edgar Filing: SCIOS INC - Form 10-K

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 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 PRE-CLINICAL 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 pre-clinical 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 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 pre-clinical studies and early clinical trials are often not accurate indicators of results of later-stage clinical trials that involve larger human populations.

20

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.

## Edgar Filing: SCIOS INC - Form 10-K

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

MANY OTHER COMPANIES ARE TARGETING THE SAME DISEASES AND CONDITIONS AS WE ARE. COMPETITIVE PRODUCTS FROM OTHER COMPANIES COULD SIGNIFICANTLY REDUCE THE MARKET ACCEPTANCE OF OUR PRODUCTS.

The markets in which we compete are well established and intensely competitive. We may be unable to compete successfully against our current and future competitors. Our failure to compete successfully may result in pricing reductions, reduced gross margins and failure to achieve market acceptance for our potential products. Our competitors include pharmaceutical companies, biotechnology companies, chemical companies, academic and research institutions and government agencies.

For example, many pharmaceutical and biotechnology companies have initiated research programs similar to ours. Many of these organizations have substantially more experience and more capital, research and development, regulatory, manufacturing, sales, marketing, human and other resources than we do. As a result, they may:

- .. develop products that are safer or more effective than our product candidates;
- .. obtain FDA and other regulatory approvals or reach the market with their products more rapidly than we can, reducing the potential sales of our product candidates;
- .. devote greater resources to market or sell their products;
- .. adapt more quickly to new technologies and scientific advances;
- .. initiate or withstand substantial price competition more successfully than we can;
- .. have greater success in recruiting skilled scientific workers from the limited pool of available talent;
- .. more effectively negotiate third-party licensing and collaboration arrangements; and
- .. take advantage of acquisition or other opportunities more readily than we can.

In addition, our product candidates, if approved and commercialized, will compete against well-established existing therapeutic products that are currently reimbursed by government health administration authorities, private health insurers and health maintenance organizations. We face and will continue to face intense competition from other companies for collaborative arrangements with pharmaceutical and biotechnology companies, for relationships with academic and research institutions and for licenses to proprietary technology. In addition, we anticipate that we will face increased competition in the future as new companies enter our markets and as scientific developments continue to expand the understanding of various diseases. While we will seek to expand our technological capabilities to remain competitive, research and development by others may render our technology or product candidates obsolete

## Edgar Filing: SCIOS INC - Form 10-K

or noncompetitive or result in treatments or cures superior to any therapy developed by us.

21

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 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

## Edgar Filing: SCIOS INC - Form 10-K

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.

22

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

WE MAY BE REQUIRED TO DEFEND LAWSUITS OR PAY DAMAGES IN CONNECTION WITH THE ALLEGED OR ACTUAL HARM CAUSED BY OUR PRODUCT CANDIDATES.

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

## Edgar Filing: SCIOS INC - Form 10-K

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:

- .. variations in our quarterly operating results;
- .. changes in securities analysts' estimates of our financial performance;
- .. changes in market valuations of similar companies;
- .. announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;
- .. additions or departures of key personnel;
- .. future sales of common stock;
- .. announcements by us or our competitors of technological innovations of new therapeutic products, clinical trial results and developments in patent or other proprietary rights;
- .. announcements regarding government regulations, public concern as to the safety of drugs developed by us or others or changes in reimbursement policies; and

23

- .. 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 subjects of a securities class action lawsuit, which was eventually

## Edgar Filing: SCIOS INC - Form 10-K

dismissed with a determination that the plaintiffs had no basis for their claim. If we face such litigation in the future, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

WE HAVE IMPLEMENTED PROVISIONS IN OUR CHARTER DOCUMENTS THAT MAY ULTIMATELY DELAY, DISCOURAGE OR PREVENT A CHANGE IN OUR MANAGEMENT OR CONTROL OF US.

Our certificate of incorporation and bylaws contain provisions that could make it more difficult for our stockholders to replace or remove our directors or to effect any other corporate action. These provisions include those which:

- .. prohibit holders of less than ten percent of our outstanding capital stock from calling special meetings of stockholders;
- .. prohibit stockholder action by written consent, thereby requiring stockholder actions to be taken at a meeting of our stockholders; and
- .. establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon by stockholders at stockholder meetings.

Moreover, our certificate of incorporation does not provide for cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates.

Some of the above provisions may also have possible anti-takeover effects, which may make an acquisition of us by a third party more difficult, even if such an acquisition could be beneficial to our stockholders. In addition, our certificate of incorporation also authorizes us to issue up to 20,000,000 shares of preferred stock in one or more different series with terms to be determined by our board of directors at time of issuance. As of December 31, 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.

24

### EXECUTIVE OFFICERS OF THE COMPANY

Our executive officers and their ages at February 28, 2002 are as follows:

NAME	AGE	POSITION
Richard B. Brewer.....	50	President, Chief Executive Officer and Director
George F. Schreiner, M.D., Ph.D.....	52	Chief Scientific Officer
David W. Gryska.....	45	Senior Vice President, Finance and Chief Financial Officer
Patricia A. Baldwin, Ph.D.....	46	Vice President, Quality and Product Development
Thomas L. Feldman.....	51	Vice President, Sales and Marketing
M. Allison Herd.....	41	Vice President, Human Resources
Matthew R. Hooper.....	44	Vice President and General Counsel
Darlene P. Horton, M.D.....	40	Vice President, Medical Affairs
Jane A. Moffitt.....	49	Vice President, Regulatory Affairs



## Edgar Filing: SCIOS INC - Form 10-K

RICHARD B. BREWER joined us in September 1998 as President, Chief Executive Officer and Director. From February 1996 to June 1998, he served as the Executive Vice President of Operations and then as Chief Operating Officer of Heartport, Inc., a medical device company. From 1984 to 1995, Mr. Brewer served in various capacities for Genentech Europe Ltd., Genentech Canada, Inc. and Genentech, Inc., most recently as Senior Vice President, U.S. Sales and Marketing. Mr. Brewer received a B.S. from Virginia Polytechnic Institute and an M.B.A. from Northwestern University.

GEORGE F. SCHREINER, M.D., PH.D., joined us in January 1997 as Vice President, Cardioresenal Research. He became our Chief Scientific Officer in August 2000, responsible for leading our research group. From 1992 until January 1997, Dr. Schreiner was with CV Therapeutics, Inc., a biopharmaceutical company, as Vice President, Medical Science and Pre-clinical Research. From 1980 to 1992, Dr. Schreiner served on the faculties of Harvard Medical School and Washington University School of Medicine. Dr. Schreiner received an A.B. in Psychology/Sociology from Harvard College, an M.D. from Harvard Medical School and a Ph.D. in Immunology from Harvard University.

DAVID W. GRYSKA joined us in December 1998 as Vice President of Finance and Chief Financial Officer and became our Senior Vice President of Finance in November 2000. From 1993 to December 1998, Mr. Gryska was Vice President, Finance and Chief Financial Officer of Cardiac Pathways Corporation, a medical device company. Mr. Gryska was with Ernst & Young LLP from 1982 to 1993 and served as a partner from 1989 to 1993. Mr. Gryska received a B.A. in Accounting and a B.A. in Finance from Loyola University of Chicago and an M.B.A. from Golden Gate University.

PATRICIA A. BALDWIN, PH.D., joined us in 1986 as a Scientist in the Novel Drug Delivery Department. In 1990, she moved to the Pharmaceutical Research and Development Department and in 1995, Dr. Baldwin became our Director of Analytical Chemistry. In September 1999, she became our Senior Director of Analytical Methods and Quality Control and in March 2000, Dr. Baldwin was promoted to our Vice President, Quality and Product Development. Dr. Baldwin received a B.S. in Chemistry from Stanford University and a Ph.D. in Chemistry from the University of California, Berkeley.

THOMAS L. FELDMAN joined us in 1995 as Vice President of Commercial Operations and in November 1999, became our Vice President, Sales and Marketing. From 1973 to 1995, Mr. Feldman held various sales and marketing positions at pharmaceutical companies affiliated with Johnson & Johnson, including National Sales Manager at Ortho Pharmaceutical Corporation (1993 to 1994) and National Sales Manager at McNeil Pharmaceutical (1990 to 1993). Mr. Feldman received a B.A. in Business and Speech from North Dakota State University.

M. ALLISON HERD joined us in March 2001 as Vice President of Human Resources. From February 2000 to March 2001, she was Director of Human Resources with Network ICE Corporation, a software company. From March 1998 to February 2000, Ms. Herd was Director of Human Resources with Cardiac Pathways, a medical device company. From November 1996 to March 1998, she was Human Resources Manager with Progressive Angioplasty Systems, a medical device company. From April 1996 to November 1996, Ms. Herd was Senior Human Resources Generalist with CLONTECH Laboratories, Inc., a biotechnology company. Ms. Herd holds a B.A. in Sociology from San Jose State University and an M.A. in Human Resources from Golden Gate University.

MATTHEW R. HOOPER joined us in October 2000 as Senior Patent Counsel in which he handled all intellectual property matters for the Company. In October 2001, Mr. Hooper became Vice President, General Counsel of Scios and currently oversees all

legal aspects of the Company's operations. From November 1999 to September 2000, Mr. Hooper was senior counsel in the litigation group of Jones Day Reavis and Pogue in Chicago. From 1994 to 1999, he held the position of counsel at Abbott Laboratories in its patent and trademark department. Before joining Abbott, Mr. Hooper served as a patent attorney at Amoco Corporation from 1985 through 1994, and an associate attorney in private practice in Chicago from 1982 through 1985. He received his J.D. from Northwestern University Law School and his B.S. degree in Chemistry from LaSalle University.

DARLENE P. HORTON, M.D., joined us in July 1996 and is responsible for directing and managing our clinical research programs. In August 2000, Dr. Horton was appointed our Vice President, Medical Affairs. Prior to joining Scios, she was a Pediatric Cardiology Fellow at UCSF's Cardiovascular Research Institute, and she remains on the clinical faculty at the University of California, San Francisco. Dr. Horton received a B.S. in Microbiology and an M.D. from the University of Florida in Gainesville.

JANE A. MOFFITT joined Scios in August, 2001 as Vice President of Regulatory Affairs and is responsible for overseeing all aspects of the Company's regulatory operations. In her previous position with Cygnus, Inc., a medical device company, she served as Vice President, Regulatory Affairs and Quality Assurance. Prior to Cygnus, Ms. Moffitt ran her own consulting business, advising numerous medical device and biotechnology companies on regulatory affairs and quality assurance. Before that, she served as Vice President, Worldwide Regulatory Affairs, at Collagen Corporation and as Vice President, Regulatory Affairs/Quality Assurance at Amsco International, Inc. in Pittsburgh. She came to Amsco from Allergan, Inc., where she was Assistant General Counsel and Director of Regulatory Affairs. She received her B.S. degree from Dickinson College in Carlisle, Pa., and her J.D. from the Dickinson School of Law. She earned her LL.M. in Trade Regulation from the New York University School of Law through the Food & Drug Law Institute Fellowship Program.

#### ITEM 2. PROPERTIES

We lease a 52,000 square foot office building in Sunnyvale, California pursuant to two leases which both expire on August 31, 2008. We also lease two neighboring 33,600 and 7,200 square foot office buildings, which both expire on December 31, 2003. Our annual lease payments for the Sunnyvale facilities are approximately \$1.9 million. In addition, we lease a warehouse in Mountain View, California that expires on December 31, 2003. We believe our facilities are sufficient for the foreseeable future.

#### ITEM 3. LEGAL PROCEEDINGS

On November 29, 1995, we were notified by the United States Environmental Protection Agency, or EPA, that we may have a liability in connection with the clean-up of a toxic waste site arising out of the alleged disposal of hazardous substances by a subcontractor of Nova Pharmaceutical Corporation, the Company acquired in 1992. We are one of many potentially responsible parties that have been identified as associated with this specific site. We held discussions with the EPA and expected a settlement agreement pursuant to which we agreed to contribute to site clean-up costs. We reserved \$90,000 at December 31, 2000 as provision for the settlement thereof. During 2001, we settled the liability with a final settlement payment of \$81,264.

#### ITEM 4. SUBMISSION OF MATTERS TO VOTE OF SECURITY HOLDERS

## Edgar Filing: SCIOS INC - Form 10-K

No matters were submitted to a vote of security holders during the fourth quarter of the fiscal year covered by this report.

26

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTER

#### PRICE RANGE OF COMMON STOCK

Since our initial public offering in 1983, our Common Stock has traded on the NASDAQ National Market under the symbol "SCIO". The table below sets forth the high and low sales prices (converted to decimals and rounded to the nearest whole cent) as reported by NASDAQ for the Common Stock during the last eight quarters. The prices appearing in the tables below reflect over the counter market quotations, which reflect inter-dealer prices, without retail markups, markdowns or commissions, and may not represent actual transactions.

	----- COMMON STOCK -----			
	FY 2001		FY 2000	
	HIGH	LOW	HIGH	LOW
	-----			
Q1.....	\$23.81	\$15.31	\$ 8.63	\$4.84
Q2.....	29.33	20.25	5.88	4.00
Q3.....	23.01	14.94	11.00	5.44
Q4.....	\$28.70	\$16.58	\$23.06	\$9.13

#### DIVIDEND POLICY

We have not paid any cash and do not anticipate paying cash dividends in the foreseeable future.

#### HOLDERS OF COMMON STOCK

As of December 31, 2001, there were 3,835 record owners of our common stock.

### ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated historical information has been derived from the audited consolidated financial statements of the Company. The financial information as of December 31, 2001, 2000, 1999, 1998, and 1997 and for each of the five years in the period ended December 31, 2001 are derived from audited consolidated financial statements and are included elsewhere in this Annual Report on Form 10-K. The following Selected Consolidated Financial Data should be read in conjunction with "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Item 8. Consolidated Financial Statements and Supplementary Data" included elsewhere in this Annual Report on Form 10-K. The historical results are not necessarily indicative of the results of operations to be expected in the future.

-----  
YEAR ENDED DECEMBER 31,

Edgar Filing: SCIOS INC - Form 10-K

	2001	2000	1999	1998	1997
STATEMENT OF OPERATIONS DATA:					
(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)					
Revenues (1).....	\$ 47,345	\$ 12,624	\$ 28,355	\$ 44,668	\$ 14,459
Loss from operations.....	(65,176)	(42,372)	(24,333)	(11,991)	(39,737)
Other income (expense) net.....	3,006	(147)	4,283	11,102	2,254
Net loss.....	(62,497)	(42,522)	(20,064)	(2,363)	(38,667)
Net loss per common share and per common share assuming dilution.....	\$ (1.47)	\$ (1.12)	\$ (0.53)	\$ (0.06)	\$ (1.07)
Pro forma effect of adopting SAB 101:					
Net loss.....	N/A	N/A	\$ (916)	\$ (21,511)	\$ (38,667)
Basic and diluted loss per share.....	N/A	N/A	\$ (0.02)	\$ (0.57)	\$ (1.07)
DECEMBER 31,					
	2001	2000	1999	1998	1997
BALANCE SHEET DATA:					
(IN THOUSANDS)					
Cash and securities.....	\$129,316	\$ 71,531	\$100,712	\$ 97,311	\$ 64,700
Working capital.....	18,411	13,057	1,706	8,083	4,524
Total assets.....	156,178	88,669	118,272	138,829	116,871
Long term obligations.....	15,479	39,095	42,866	34,573	31,919
Stockholders' equity.....	\$ 81,148	\$ 18,045	\$ 42,787	\$ 74,926	\$ 60,142

-----  
(1) as reclassified for EITF 99-19

27

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

THE FOLLOWING DISCUSSION SHOULD BE READ IN CONJUNCTION WITH OUR CONSOLIDATED FINANCIAL STATEMENTS, INCLUDING THE RELATED NOTES, CONTAINED ELSEWHERE IN THIS REPORT ON FORM 10-K. 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, BUT ARE LIMITED TO THOSE SET FORTH UNDER "RISK FACTORS" IN THIS REPORT ON FORM 10-K.

OVERVIEW

We are a biopharmaceutical company developing novel treatments for cardiovascular and inflammatory diseases. Our disease-based technology platform integrates expertise in protein biology with computational and medicinal chemistry to identify novel targets and rationally design small molecule compounds for large markets with unmet medical needs. We launched Natrecor following U.S. Food and Drug Administration, or FDA, approval of Natrecor for the treatment of acute congestive heart failure, or CHF, on August 13, 2001, and recorded sales of \$14.1 million for the year ended December 31, 2001.

We are focused on the development of three product candidates, Natrecor for the treatment of acute congestive heart failure; SCIO-469, an oral, small molecule inhibitor of p38 kinase for the treatment of rheumatoid arthritis (RA); and novel small molecule inhibitors of the receptor for TGF-beta, a cytokine that

## Edgar Filing: SCIOS INC - Form 10-K

has been implicated in diseases characterized by chronic scar formation, or fibrosis.

### RESULTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 2001, 2000, AND 1999

#### REVENUES

**PRODUCT SALES.** Total product sales were \$30.0 million for the year ended December 31, 2001, and none for the years ended December 31, 2000 and 1999. In 2001, \$15.9 million of product sales were derived from one-time sales of bulk FGF to Kaken following the product approval of Fiblast Spray in Japan. These sales are not expected to recur. The remaining product sales resulted from the launch of Natrecor following FDA approval in August 2001 and recorded \$14.1 million of product sales in 2001.

**RESEARCH AND DEVELOPMENT CONTRACT REVENUES AND ROYALTIES.** Research and development contract revenues and royalties were \$4.8 million, \$5.7 million, and \$18.4 million for the years ended December 31, 2001, 2000, and 1999, respectively. In 2001, contract revenues primarily reflect our research collaboration agreements with Eli Lilly & Company of \$3.0 million. In addition, we received royalty payments totaling \$1.8 million from sales of Fiblast Spray in Japan by Kaken, and from sales of diagnostic BNP testing by Biosite and Abbott Laboratories. The decrease from 2000 to 2001 of \$0.9 million was primarily due to the end of our research collaboration agreement with DuPont Pharmaceutical Company, effective November 2000. The \$12.7 million decrease from 1999 to 2000 was primarily attributable to \$9.0 million in one-time milestone payments received in 1999 from corporate partners Chiron Corporation and Novo Nordisk A/S, \$2.3 million in clinical research funding from Bayer AG and \$1.4 million in royalty payments from GenVec, Guilford Pharmaceuticals and other research collaboration agreements. Research and development contract revenues tend to fluctuate based on the amount of research services performed, the status of projects under collaboration and the achievement of milestones. Due to the nature of the Company's collaborative agreement revenues, results in any one-year are not necessarily indicative of results to be achieved in the future. The Company's ability to generate additional collaborative agreement revenues may depend, in part, on its ability to initiate and maintain relationships with potential and current collaborative partners. There can be no assurance that such relationships will be established or that current research and development contract revenues will not decline.

**PSYCHIATRIC PRODUCT SALES AND CO-PROMOTION COMMISSIONS.** Psychiatric product sales and co-promotion commissions for the years ended December 31, 2001, 2000, and 1999 were \$3.1 million, \$6.9 million, and \$10.0 million. The decrease of \$3.8 million from 2000 to 2001 was primarily due to the sale of marketing rights for certain psychiatric products to GSK and the termination of the license agreement in March 2001. At the same time, the Company dissolved its Psychiatric Sales and Marketing Division, and deployment of the PSMD sales force. The decline in product sales from 1999 to 2000 of \$3.0 million was largely the result of reduced distributor inventories caused by manufacturing and product shelf life issues of Eskalith CR (one of five products manufactured by GSK that were sold by the Company), coupled with the erosion of sales as a result of new market entrants and generic drugs.

**GAIN ON SALE OF MARKETING RIGHTS.** Commencing in the fourth quarter of 2000, we solicited and received bids regarding the sale of our exclusive marketing rights for certain GSK psychiatric products sold by us. The marketing rights

## Edgar Filing: SCIOS INC - Form 10-K

were eventually sold to GSK. The marketing rights were originally licensed from GSK under a 1990 licensing agreement. In order to effect the sale, the licensing agreement was terminated effective March 31, 2001, and we received from GSK \$4.0 million in 2001 and \$3.0 million in 2002 and expect to receive a final payment of \$2.4 million in 2003. We recognized a gain on the sale of the marketing rights of \$9.4 million related to the sale in 2001.

### COSTS AND EXPENSES

**COST OF PRODUCT SALES.** Cost of product sales were \$1.9 million for the year ended December 31, 2001 and none for the years ended December 31, 2000 and 1999. The expenses were mainly due to the cost to manufacture and distribute Natrecor and royalty on a cross license agreement. In addition, we classified in cost of product sales royalty payments to the limited partners of Biotechnology Research Partners, Ltd. on revenues generated from the one-time sales of bulk FGF shipments to Kaken, and the cost of shipping bulk FGF to Kaken in Japan. All costs associated with the manufacture of Natrecor bulk drug product and finished products to which title transferred to us prior to FDA approval, on August 13, 2001, was expensed as research and development.

**RESEARCH AND DEVELOPMENT.** Research and development expenses were \$48.1 million, \$39.3 million, and \$34.3 million for the years ended December 31, 2001, 2000 and 1999, respectively. The \$8.8 million increase from 2000 to 2001 was primarily due to increased expenses related to our p38 kinase inhibitor, TGF-beta, and Natrecor programs. The \$5.0 million increase from 1999 to 2000 was primarily attributable to the increased clinical expenses related to Natrecor and increased research expenses related to our p38 kinase inhibitor program.

During 2001, 2000, and 1999, we spent \$48.1 million, \$39.3 million, and \$34.3 million, respectively on research and development. Below is a summary of these costs by major project (in millions).

	-----	2001	2000	1999
	-----	-----	-----	-----
Natrecor.....	\$22.5	\$19.2	\$14.1	
SCIO-469.....	17.5	11.8	3.8	
TGF-beta.....	3.7	2.8	1.6	
Alzheimer's.....	1.9	2.3	2.4	
FGF.....	--	0.2	2.9	
Other research.....	2.5	3.0	9.5	
	-----	-----	-----	
Total Research and Development.....	\$48.1	\$39.3	\$34.3	
	=====	=====	=====	

We spent \$22.5 million on Natrecor in 2001. The cost in 2001 was primarily for the development of Natrecor for the treatment of CHF for new indications and costs to approve the drug with the FDA. Future costs are unknown, as we will continuously develop other therapeutic uses of Natrecor for CHF and FDA approval of clinical study programs is difficult to estimate. If we are not successful we will not be able to expand the market potential for Natrecor. We have spent approximately \$130 million in research and development expenses on the development of Natrecor since the program began in 1988.

We spent \$17.5 million on the SCIO-469 program in 2001. The cost to complete the research for SCIO-469 is unknown because it is a new clinical candidate. This program is highly dependent on FDA approval of the clinical study programs

## Edgar Filing: SCIOS INC - Form 10-K

and ultimate FDA approval to market the drug. We recently started Phase IIa trials and have spent approximately \$33.9 million in research and development expenses since the program began in 1998. If we are not successful we will not be able to expand into the rheumatoid arthritis market.

We spent \$3.7 million in the TGF-beta program in 2001. The cost to complete the research for TGF-beta is unknown because it is a new clinical candidate and we have spent approximately \$8.8 million in research and development expenses since the program began in 1998. We have not commenced human clinical trials and this program is highly dependent on FDA approval for clinical studies and ultimate FDA approval to market the drug.

We spent \$1.9 million on the Alzheimer's program in 2001. The Alzheimer's program, which included a research collaboration with Eli Lilly, ended on December 31, 2001. There were severance costs of approximately \$295,000 related to the termination of certain scientific personnel, which were incurred in fiscal year 2002. We expect no other future expenses in this program.

29

We spent \$2.5 million in 2001 in other research expenses. Other research expenses represent costs associated with general research that is not directly chargeable to a project. We expect these costs to continue as we identify new candidates to enter clinical trials.

We expect substantial expenses in the Research and Development area during the next several years. We are unable to predict the level of spending until near the end of the various programs because of the uncertainty of FDA approval of clinical study programs.

**SELLING, GENERAL AND ADMINISTRATIVE.** Selling, general and administrative expenses were \$62.5 million, \$16.7 million, and \$12.0 million for the years ended December 31, 2001, 2000, and 1999, respectively. The increase of \$45.8 million from 2000 to 2001 was primarily due to sales and marketing expenses to launch Natrecor and the addition of general and administrative staff to support the increase in overall headcount. These sales and marketing expenses include the building of a marketing infrastructure, the cost of a 188-person sales force and management team, the commissions to the sales force on Natrecor sales, and the expenses of promotional and marketing programs. The \$4.7 million increase from 1999 to 2000 was primarily the result of Natrecor pre-launch activities, a proxy contest in early 2000, outside consulting expenses relating to strategic planning, increased headcount and bonuses paid during the period.

**RESTRUCTURING CHARGES.** We incurred a restructuring charge in 1999 of \$6.4 million resulting from a corporate reorganization, which included the closure of our Mountain View manufacturing facility and a 30% reduction in our workforce. All restructuring activities were complete by the end of the second quarter of 2000, leaving a remaining balance of \$1.0 million in the restructuring reserve. This unused reserve primarily resulted from changes in the estimates of the cost of workforce reductions and the gain on the sale of excess capital assets that were unanticipated. The reserve was credited to restructure expense in the second quarter of 2000.

**OTHER INCOME (EXPENSE).** Net other income (expense) was \$3.0 million, \$(0.1) million, and \$4.3 million for the years ended December 31, 2001, 2000 and 1999, respectively. The \$3.1 million increase from 2000 to 2001 was largely due to lower interest expense of \$1.0 million, realized gains on securities of \$1.0 million and a decrease in other expense of \$1.1 million. Interest expense was lower in 2001 due to a lower debt balance and lower interest rates on the Genentech debt. The decrease in other expense was largely due to the write off

## Edgar Filing: SCIOS INC - Form 10-K

and investment value adjustments for securities in Neurocine and GenVec in 2000. The \$4.4 million decrease from 1999 to 2000 was primarily attributable to the 1999 net gain on the sales of securities in Guilford.

### LIQUIDITY AND CAPITAL RESOURCES

To date, our operations and capital requirements have been financed primarily with the proceeds of public and private sales of common stock and preferred stock, research and development partnerships, collaborative agreements with pharmaceutical firms, product sales and investment income. At December 31, 2001, our combined cash, cash equivalents and marketable securities (both current and non-current) totaled \$129.3 million.

In January 2001, we entered into a sale and marketing alliance with Innovex, a subsidiary of Quintiles Transnational Corp. As part of the original three and one half year agreement, PharmaBio Development, Inc., an affiliate of Innovex, agreed to fund \$30.0 million of our costs to launch Natrecor over the first 24 months of the commercialization of Natrecor and to loan us up to \$5.0 million. In December 2001, Scios, Innovex and PharmaBio amended the January 2001 agreement. The amendment will enable Scios, at its option, to assume control of the Natrecor sales force in June 2003, one year ahead of schedule, and we eliminated the \$5.0 million line of credit provided by PharmaBio to Scios. Of the \$30.0 million funding from PharmaBio, we received \$10.0 million in the fourth quarter of 2001, and will receive the remaining \$20.0 million over the next 17 months. As part of the funding agreement, we will pay PharmaBio a declining royalty rate on net sales of Natrecor through early 2008. We also granted PharmaBio a fully vested warrant to purchase 700,000 shares of our common stock at an exercise price of \$20.00 per share. These warrants are exercisable over the next 17 months beginning December 2001 through May 2003.

In December 2001, we entered into a binding summary of terms with Glaxo Group Ltd., an affiliate of GlaxoSmithKline, or GSK, in which we will license Natrecor to GSK in all European markets. Under the terms of the agreement, GSK will have the rights to sell and distribute the product for which we will receive an up-front fee and milestone payments totaling (Pounds)15.0 million British Pounds (which at December 31, 2001 equaled approximately \$22 million U.S. Dollars), in addition to future royalties in the identified countries. We will manufacture and supply the bulk product to GSK. Both companies will work together to continue clinical development of Natrecor in Europe. In order to obtain European approval for Natrecor, GSK expects to use the extensive clinical data we submitted to obtain approval from the FDA in August 2001. The companies expect to launch Natrecor in Europe in the first half of 2004. No revenue has been recognized related to this agreement through December 31, 2001.

30

We have \$33.0 million due to Genentech at December 31, 2002 of which \$20.0 million can be repayable in the Company's Series B preferred stock at anytime through December 31, 2002. In addition, if the Company should decide to convert the loan to preferred stock, a portion of the loan that is not convertible will become due and payable before December 31, 2002. The amount of the loan that is due before the maturity date is based on a formula that considers the amount of loan converted to stock and the outstanding loan balance.

Net cash used in operating activities of \$68.5 million in 2001 was primarily attributable to the loss of \$62.5 million and decreases in net operating assets and liabilities of \$13.1 million, partially offset by non-cash expenses of \$7.1 million. For 2000, net cash used by operating activities amounted to \$34.8 million. This was primarily attributable to the net loss for the year of \$42.5 million, partially offset by non-cash charges related to depreciation, and



## Edgar Filing: SCIOS INC - Form 10-K

amortization of deferred compensation totaling \$8.0 million, and \$0.3 million of cash used by changes in operating assets and liabilities. For 1999, net cash used in operating activities of \$8.5 million was primarily attributable to funding net operating losses, partially offset by non-cash expenses and increases in operating assets and liabilities. Cash provided by changes in operating assets and liabilities is primarily a function of an increase in accounts payable and accrued liabilities.

Net cash used in investing activities of \$8.4 million in 2001 consisted of purchases of property and equipment of \$5.4 million, and net purchases of marketable securities of \$3.0 million. Net cash provided in investing activities was \$20.8 million in 2000 and consisted of net sales of marketable securities of \$22.1 million, partially offset by purchases of fixed assets of \$1.3 million. Net cash provided by investing activities of \$5.7 million in 1999 consisted of net purchases of marketable securities of \$11.1 million and purchases of fixed assets of \$5.0 million, offset by proceeds from the sales of facilities and equipment of \$21.8 million.

Net cash provided by financing activities of \$131.9 million in 2001 was due to the proceeds from the issuance of common stock of \$122.0 million, a payment from PharmBio of \$10.0 million under the Innovex agreement, the collection of stockholders notes receivable of \$0.4 million, partially offset by repurchase of Scios stock of \$0.4 million. Net cash provided by financing activities of \$5.7 million for 2000 was mainly due to the proceeds from the issuance of common stock and collection of notes receivables from stockholders of \$10.3 million, partially offset by the payment of notes payable of \$4.6 million. Net cash provided by financing activities of \$7.7 million in 1999 was largely due to proceeds from notes payable of \$7.5 million and proceeds from the issuance of common stock of \$1.2 million, partially offset by the purchase of treasury stock of \$1.0 million.

We expect that the net proceeds from the issuance of common stock in June 2001, together with our existing cash, cash equivalents and marketable securities, proceeds from existing collaborations, including our agreement with PharmaBio, and revenues from the sales of Natreacor will enable us to maintain our current and planned operations for at least the next twelve months. In the event we will 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.

### INCOME TAXES

At December 31, 2001, we had federal and state net operating loss carryforwards of approximately \$436.2 million and \$61.0 million, respectively. We also had federal and state research tax credit carry-forwards of approximately \$13.2 million and \$7.4 million, respectively. The federal net operating loss and other tax credit carry-forwards will expire at various dates beginning in the year 2002 through 2021, if not used. Our state net operating loss and other tax credit carry-forwards will expire at various dates beginning in the year 2002 through 2006, if not used. These net operating loss and other tax credit carry-forwards provide an additional source of liquidity only to the extent that profitable operations are achieved prior to the expiration of the carry-forward periods. The use of losses generated through the date of our 1992 merger with Nova Pharmaceuticals Corporation may be subject to substantial annual limitations due to the "ownership change" provisions of the Internal Revenue Code of 1986.

### CRITICAL ACCOUNTING POLICIES

## Edgar Filing: SCIOS INC - Form 10-K

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities, revenue and expenses and disclosures at the date of the financial statements. On

31

an on-going basis, we evaluate our estimates, including those related to accounts receivable, inventories and income taxes. We use authoritative pronouncements, historical experience and other assumptions as the basis for making estimates. Actual results could differ from those estimates.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements. We recognize revenue from product sales when there is pervasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable, and collection is reasonably assured. Provisions for discounts and rebates to customers, and returns and other adjustments are provided for in the same period that the related product sales are recorded based upon analyses of historical discounts, rebates and returns. We maintain an accounts receivable allowance for an estimated amount of losses that may result from customer's inability to pay for product purchased. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required. We have established a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized. We account for income taxes under the provisions of Statement of Financial Accounting Standards, or SFAS, No. 109, "Accounting for Income Taxes." Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using the enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

### NEW ACCOUNTING PRONOUNCEMENTS

In July 2001, the FASB issued Statement of Financial Accounting Standards No. 141 (SFAS 141), "Business Combinations." SFAS 141 requires the purchase method of accounting for business combinations initiated after June 30, 2001 and eliminates the pooling-of-interests method. Scios did not have any business combination transactions in the year ended December 31, 2001.

In July 2001, the FASB issued Statement of Financial Accounting Standards No. 142 (SFAS 142), "Goodwill and Other Intangible Assets," which in Scios' case is effective for fiscal years beginning after December 15, 2001. SFAS 142 requires, among other things, the discontinuance of goodwill amortization. In addition, the standard includes provisions upon adoption for the reclassification of certain existing recognized intangibles as goodwill, reassessment of the useful lives of existing recognized intangibles, reclassification of certain intangibles out of previously reported goodwill and the testing for impairment of existing goodwill and other intangibles. The Company does not currently have any goodwill or intangible assets, and does not believe that the implementation of SFAS 142 will have any significant impact on its financial position or results of operations.

In October 2001, the FASB issued Statement of Financial Accounting Standards No. 144 (SFAS 144), "Accounting for the Impairment or Disposal of Long-Lived

## Edgar Filing: SCIOS INC - Form 10-K

Assets to be Disposed Of." SFAS 144 addresses financial accounting and reporting of impairment of long-lived assets to be disposed of. However, SFAS 144 retains the fundamental provisions of SFAS 121 for: (1) recognition and measurement of the impairment of long-lived assets to be held and used; and (2) measurement of long-lived assets to be disposed of by sale. SFAS 144 is effective for fiscal year beginning after December 15, 2001. We believe SFAS 144 has no impact on Scios' financial position and results of operations.

### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to a variety of risks, including changes in interest rates affecting the return on our investments and foreign currency fluctuations. In the normal course of our business, we employ established policies and procedures to manage our exposure to fluctuations in interest rates and foreign currency values.

Our exposure to market rate risk for changes in interest rates relates primarily to our investment portfolio. We attempt to place our investments with high quality issuers and, by policy, limit the amount of credit exposure to any one issuer and do not use derivative financial instruments in our investment portfolio. We maintain an investment portfolio of various issuers, types and maturities, which consist of both fixed and variable rate financial instruments. These securities are classified as available-for-sale, and consequently, are recorded on the balance sheet at fair value with unrealized gains or losses reported as a separate component in stockholders' equity, net of applicable taxes. At any time, sharp changes in interest rates can affect the value of our investment portfolio and its interest earnings. Currently, we do not hedge these interest rate exposures. However, through our money manager, we maintain management control systems to monitor interest rate risk. The risk management control systems use analytical techniques as well as other procedures to review interest rate risk. Assuming a

32

hypothetical interest rate increase of 10%, the fair value of our total investment portfolio as of December 31, 2001 would have potentially incurred a loss of \$248,000.

Our exposure to foreign currency fluctuations is limited to our supply contract for Natrecor, which is denominated in the Euro, and license and milestone payments from GSK, which are denominated in the British Pound. Changes in the exchange rate between the Euro and the U.S. dollar payments could adversely affect our manufacturing costs. Changes in the exchange rate between the British Pound and U.S. dollar could adversely affect our earnings performance. 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.

Our long-term debt with Genentech of \$33.0 million has a variable interest rate at the prime interest rate. Our exposure is the fluctuation in the prime interest rate over the next 12 months. An increase in prime interest rate will increase our interest expense on the debt.

### ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See Index to Consolidated Financial Statements appearing on page 34 of this Form 10-K.

## Edgar Filing: SCIOS INC - Form 10-K

### ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

### PART III

#### ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

IDENTIFICATION OF DIRECTORS. The information required by Item 10 of Form 10-K with respect to identification of directors is incorporated by reference to the information contained in the sections captioned "Election of Directors" and "Compliance with Section 16(a) of the Exchange Act" of our definitive Proxy Statement for the 2002 Annual Meeting of Stockholders.

IDENTIFICATION OF EXECUTIVE OFFICERS. See "Executive Officers of the Company" above under Item 1.

#### ITEM 11. EXECUTIVE COMPENSATION

The information required by Item 11 of Form 10-K is incorporated by reference to the information contained in the sections captioned "Executive Compensation," "Stock Option Grants and Exercises," "Employment and Severance Agreements," Information About the Board of Directors and Committees of the Board: Compensation of Directors--Standard Arrangements" and "Compensation Committee Interlocks and Insider Participation" of our definitive Proxy Statement for the 2002 Annual Meeting of Stockholders.

#### ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information required by Item 12 of Form 10-K is incorporated by reference to the information contained in the section captioned "Security Ownership of Management and Principal Stockholders" of our definitive Proxy Statement for the 2002 Annual Meeting of Stockholders.

#### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by Item 13 of Form 10-K is incorporated by reference to the information contained in the section captioned "Certain Relationships and Transactions" of the our definitive Proxy Statement for the 2002 Annual Meeting of the Stockholders.

33

### PART IV

#### ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

(a) (1) Consolidated Financial Statements.

	PAGE
	----
Report of Independent Accountants.....	F-1
Consolidated Balance Sheets, December 31, 2001 and 2000.....	F-2
Consolidated Statements of Operations and Comprehensive Loss, years ended December 31, 2001, 2000, and 1999.....	F-3
Consolidated Statements of Cash Flows, years ended December 31, 2001, 2000, and 1999.....	F-4

Edgar Filing: SCIOS INC - Form 10-K

Consolidated Statements of Stockholders' Equity, years ended December 31, 2001, 2000, and 1999..... F-5
Notes to Consolidated Financial Statements..... F-6

(2) Financial Statement Schedules.

Omitted because they are not required, are not applicable, or the information is included in the consolidated financial statements or notes thereto.

(3) Exhibits.

See Exhibit Index at page 36 of this Form 10-K.

(b) Reports on Form 8-K.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

Date: March 12, 2002

/S/ RICHARD B. BREWER

By: Richard B. Brewer
PRESIDENT AND CHIEF EXECUTIVE OFFICER

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Richard B. Brewer and Donald B. Rice, or either of them, his attorney-in-fact, each with the power of substitution, for him in any and all capacities, to sign any amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that the said attorney-in-fact, or his substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Table with 3 columns: SIGNATURE, TITLE, DATE. Row 1: /S/ RICHARD B. BREWER, President, Chief Executive Officer and Director (Principal Executive Officer), March 12, 2002. Row 2: /S/ DAVID W. GRYSKA, Chief Financial Officer (Principal Financial and Accounting Officer), March 12, 2002.

Edgar Filing: SCIOS INC - Form 10-K

David W. Gryska

/S/ DONALD B. RICE, PH.D.	Chairman of the Board	March 12, 2002
-----		
Donald B. Rice, Ph.D.		
/S/ SAMUEL H. ARMACOST	Director	March 12, 2002
-----		
Samuel H. Armacost		
/S/ RANDAL J. KIRK	Director	March 12, 2002
-----		
Randal J. Kirk		
/S/ CHARLES A. SANDERS, M.D.	Director	March 12, 2002
-----		
Charles A. Sanders, M.D.		
/S/ SOLOMON H. SNYDER, M.D.	Director	March 12, 2002
-----		
Solomon H. Snyder, M.D.		
/s/ Burton E. Sobel, M.D.	Director	March 12, 2002
-----		
Burton E. Sobel, M.D.		
/S/ EUGENE L. STEP	Director	March 12, 2002
-----		
Eugene L. Step		

EXHIBIT INDEX

EXHIBIT  
NUMBER

-----

3.1	Certificate of Incorporation.....
3.1(a)	Certificate of Amendment of Certificate of Incorporation.....
3.2	Bylaws.....
4.1	Certificate of Designation of Series B Preferred Stock of Scios Inc.....
4.2	For a discussion of certain registration rights in favor of Genetech, Inc., see Exhibit and 10.41.....
10.1	Biotechnology Research Partners, Ltd. Agreement of Limited Partnership dated October 29, 1982; Development Contract, Technology License Agreement and Joint Venture Agreement between Biotechnology Research Partners, Ltd. and the Registrant dated December 29, 1982; Promissory Note dated December 29, 1982; and Memorandum of Understanding between Battery Park Credit Company and Biotechnology Research Partners, Ltd. dated December 28, 1982.....
10.2*	1983 Incentive Stock Option Plan, as amended, and form of Stock Option Agreement, Promissory Note and Pledge Agreement.....

Edgar Filing: SCIOS INC - Form 10-K

- 10.3 Common Stock Purchase Agreement dated April 15, 1985 between the Registrant and American Home Products Corporation.....
- 10.5\* 1986 Supplemental Stock Option Plan, as amended, and form of Stock Option Agreement, Promissory Note and Pledge Agreement.....
- 10.6 Rights Exercise Agreement between the Registrant and American Home Products Corporation February 28, 1986 and Letter of March 26 and May 16, 1986.....
- 10.11\* 1992 Equity Incentive Plan.....
- 10.18 Form of Purchase Option Agreement between each of the limited partners of Nova Technology Limited Partnership and Nova.....
- 10.19\* Non employee Director Stock Option Plan.....
- 10.29 CNS Psychiatric Products Agreement dated June 30, 1990 between SmithKline Beecham Corporation and Nova.....
- 10.33 Preferred Stock Purchase Agreement dated December 30, 1994 between the Registrant and Genentech, Inc.....
- 10.34 Note Agreement dated December 30, 1994 between the Registrant and Genentech, Inc. (See Number 10.41 below amending the Note Agreement).....
- 10.35 Assignment of Lease dated March 22, 1995 for premises located at 820 West Maude Avenue, Sunnyvale, California.....
- 10.38\* Employment Letter dated September 8, 1998 between the Registrant and Richard B. Brewer.....
- 10.39 Purchase and Sale Agreement and Joint Escrow Instructions (Mountain View Real Estate Sale) dated May 24, 1999 between Alexandria Real Estate Equities, Inc. and Registrant's wholly owned Subsidiary Bio-Shore Holdings, Ltd. Portions of the exhibit have been omitted pursuant to 10.35 for confidential treatment.....
- 10.41 First Amendment to Note Agreement and Preferred Stock dated November 3, 1999 between the Registrant and Genentech, Inc. (See Exhibit 10.34 above).....
- 10.42 Promissory Note dated December 27, 1999 by the Registrant to Chiron Corporation.....
- 10.43\* Change of Control Severance Plans with Employees, Officers and Chief Executive Officer.....
- 10.44 Alliance Agreement dated January 10, 2001 between the Registrant, Innovex L.P. and PharmaBio Development Inc. (including a Warrant Agreement between the Registrant and PharmaBio Development Inc. attached thereto as Exhibit B). Portions of the exhibit have been granted confidential treatment.....

EXHIBIT  
NUMBER  
-----

- 10.45 Amendment No. 4 to Lease dated January 22, 1993 for the premises located at 820 West Maude Avenue, Sunnyvale, California (See Exhibit 10.35 above).....

Edgar Filing: SCIOS INC - Form 10-K

- 10.46 Lease Agreement dated November 17, 1995 for premises located at 820 West Maude Avenue, Sunnyvale, California.....
- 10.47 Sublease Agreement dated March 24, 1999 for premises located at 749 North Mary Avenue, Sunnyvale, California.....
- 10.48 First Amendment dated May 28, 2001 to Sublease dated May 24, 1999 for premises located at 749 North Mary Avenue, 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 West Maude Avenue Sunnyvale, California.....
- 10.51 Amended and Restated Alliance Agreement dated November 1, 2001 between the Registrant, Innovex L.P., Innovex Support Services Limited Partnership and PharmaBio Development Inc. (including a Warrant Agreement between the Registrant and Pharmabio Development Inc. attached thereto as Exhibit B). Portions of the exhibit have been omitted pursuant to a request for confidential treatment.....
- 10.52 Binding Summary of Terms between the Registrant and Glaxo Group Ltd. dated December 20, 2000. Portions of the exhibit have been omitted pursuant to a request for confidential treatment.....
- 21.2 Subsidiaries of the Registrant.....
- 23.1 Consent of PricewaterhouseCoopers LLP.....
- 24.1 Powers of Attorney. Reference is made to page 35.....

- 
- \* Management contract or compensatory plan or arrangement.
  - A Filed as an exhibit to Form S-1 Registration Statement (File No. 2-86086), as amended, and incorporated herein by reference.
  - B Filed as an exhibit to Form S-1 Registration Statement (File No. 33-3186), as amended, and incorporated herein by reference.
  - E Filed as an exhibit to Annual Report on Form 10-K for fiscal year 1988 and incorporated herein by reference.
  - G Filed as an exhibit to Form S-8 Registration Statement (File No. 33-39878) filed on April 8, 1991 and incorporated herein by reference.
  - H Filed as an exhibit to Annual Report on Form 10-K for fiscal year 1991 and incorporated herein by reference.
  - I Filed as an exhibit to Form S-1 Registration Statement (File No. 33-14937) filed on behalf of Nova Technology Limited Partnership and incorporated herein by reference.
  - J Filed as an exhibit to Form S-4 Registration Statement (File No. 33-49846) filed on July 22, 1992 and incorporated herein by reference.
  - N Filed as an exhibit to Nova's Annual Report on Form 10-K for fiscal year 1990 and incorporated herein by reference.
  - Q Filed as an exhibit to Annual Report on Form 10-K for fiscal year 1994 and incorporated herein by reference.
  - R Filed as an exhibit to Quarterly Report on Form 10-Q for quarter ended March 31, 1995 and incorporated herein by reference.
  - T Filed as an exhibit to Annual Report on Form 10-K for fiscal year 1998 and incorporated herein by reference.
  - U Filed as an exhibit to Quarterly Report on Form 10-Q for the quarter ended September 30, 1999 and incorporated herein by reference.
  - V Filed as an exhibit to Annual Report on Form 10-K for fiscal year 1999 and incorporated herein by reference.
  - W Filed as an exhibit to Report on Form 8-K dated January 24, 2000 and incorporated herein by reference.



## Edgar Filing: SCIOS INC - Form 10-K

- Y Filed as an exhibit to Annual Report on Form 10-K for fiscal year 2000 and incorporated herein by reference.
- Z Filed as an exhibit to Annual Report on Form 10-K/A (Amendment No. 2) for fiscal year 2000 and incorporated herein by reference.
- aa Filed as an exhibit to Quarterly Report on Form 10-Q for the quarter ended September 30, 2001 and incorporated herein by reference.

37

### REPORT OF INDEPENDENT ACCOUNTANTS

To the Board of Directors and Stockholders of Scios Inc.

In our opinion, the consolidated financial statements listed in the index appearing under Item 14(a) on page 34 present fairly, in all material respects, the financial position of Scios Inc. and its subsidiaries at December 31, 2001 and 2000, and the results of their operations and comprehensive loss and their cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PRICEWATERHOUSECOOPERS LLP

San Jose, California  
February 8, 2002

F-1

### SCIOS INC.

#### CONSOLIDATED BALANCE SHEETS

DECEMBER 31,	
2001	2000

(IN THOUSANDS, EXCEPT SHARE DATA AND PER SHARE DATA)

#### ASSETS

##### Current assets:

Cash and cash equivalents.....	\$ 58,296	\$ 3,291	
Marketable securities.....	7,351	35,356	
Accounts receivable, net of allowance for doubtful accounts of \$146 at December 31, 2001, and none at December 31, 2000, respectively.....	6,943	5,217	

Edgar Filing: SCIOS INC - Form 10-K

Inventory.....	1,158	--
Prepaid expenses and other assets.....	4,214	722
	-----	-----
Total current assets.....	77,962	44,586
Marketable securities, non-current.....	63,669	32,884
Property and equipment, net.....	10,424	8,910
Other assets.....	4,123	2,289
	-----	-----
Total assets.....	\$ 156,178	\$ 88,669
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable.....	\$ 9,625	\$ 4,587
Accrued employee compensation.....	9,685	4,021
Other accrued liabilities.....	7,206	6,728
Deferred contract revenue.....	--	16,193
Current portion of long-term debt.....	33,035	--
	-----	-----
Total current liabilities.....	59,551	31,529
Long-term debt.....	15,479	39,095
	-----	-----
Total liabilities.....	75,030	70,624
	-----	-----
Commitments and contingencies (Notes 10, 11, and 12)		
Stockholders' equity:		
Preferred stock; \$.001 par value; 20,000,000 shares authorized; 4,991 issued and outstanding.....	--	--
Common stock; \$.001 par value; 150,000,000 shares authorized; issued and outstanding 46,015,167 and 39,166,373 shares, respectively.....	46	39
Additional paid-in capital.....	561,352	428,987
Treasury stock; 30,000 and none shares, respectively.....	(445)	--
Deferred warrant costs.....	(6,794)	--
Notes receivable from stockholders.....	--	(352)
Deferred compensation.....	(106)	(417)
Accumulated other comprehensive income.....	999	1,195
Accumulated deficit.....	(473,904)	(411,407)
	-----	-----
Total stockholders' equity.....	81,148	18,045
	-----	-----
Total liabilities and stockholders' equity.....	\$ 156,178	\$ 88,669
	=====	=====

THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE CONSOLIDATED FINANCIAL STATEMENTS.

F-2

SCIOS INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

-----  
YEAR ENDED DECEMBER 31,

Edgar Filing: SCIOS INC - Form 10-K

	2001	2000	1999
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)			
Revenues:			
Product sales.....	\$ 30,052	\$ --	\$ --
Research and development contracts and royalties.....	4,788	5,710	18,402
Psychiatric product sales and co-promotion commissions, net of expenses.....	3,142	6,914	9,953
Gain on sale of marketing rights.....	9,363	--	--
	47,345	12,624	28,355
Costs and expenses:			
Cost of product sales.....	1,916	--	--
Research and development.....	48,130	39,278	34,305
Selling, general and administration.....	62,475	16,711	11,983
Restructuring charges (credits).....	--	(993)	6,400
	112,521	54,996	52,688
Loss from operations.....	(65,176)	(42,372)	(24,333)
Other income (expense):			
Interest income.....	4,869	4,774	4,828
Interest expense.....	(2,818)	(3,796)	(2,793)
Realized gains (losses) on securities.....	849	(152)	4,933
Other income (expense).....	106	(973)	(2,685)
	3,006	(147)	4,283
Loss before provision for income taxes.....	(62,170)	(42,519)	(20,050)
Provision for income taxes.....	(327)	(3)	(14)
Net loss.....	(62,497)	(42,522)	(20,064)
Other comprehensive income (loss):			
Change in unrealized gains (losses) on securities....	(196)	2,255	(12,472)
Comprehensive loss.....	\$ (62,693)	\$ (40,267)	\$ (32,536)
Loss per common share:			
Basic and diluted.....	\$ (1.47)	\$ (1.12)	\$ (0.53)
Weighted average number of common shares outstanding used in calculation of:			
Basic and diluted.....	42,623,093	37,997,872	37,730,048
Pro forma effect of adopting SAB 101:			
Net loss.....	N/A	N/A	\$ (916)
Basic and diluted loss per share.....	N/A	N/A	\$ (0.02)

THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE CONSOLIDATED FINANCIAL STATEMENTS.

Edgar Filing: SCIOS INC - Form 10-K

CONSOLIDATED STATEMENTS OF CASH FLOWS

	YEAR ENDED DECEMBER 31,		
	2001	2000	1999
(IN THOUSANDS)			
Cash flows from operating activities:			
Net loss.....	\$ (62,497)	\$ (42,522)	\$ (20,064)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization.....	3,580	3,717	3,473
Accrued interest payable.....	2,818	3,791	2,793
Loss on disposal of property and equipment.....	365	253	429
Amortization of deferred compensation.....	311	234	317
Allowance for bad debt.....	(146)	--	--
Valuation of stock option issued to non-employee for services rendered.....	176	--	--
Change in assets and liabilities:			
Accounts receivable.....	(1,580)	(2,149)	3,700
Inventory.....	(1,158)	--	--
Prepaid expenses and other assets.....	(5,326)	963	(422)
Accounts payable.....	5,038	3,015	(754)
Accrued employee compensation.....	5,664	1,402	(947)
Other accrued liabilities.....	478	(755)	945
Deferred contract revenue.....	(16,193)	(1,697)	994
Restructuring charges (credits).....	--	(1,052)	1,052
Net cash used in operating activities.....	(68,470)	(34,800)	(8,484)
Cash flows from investing activities:			
Purchases of property and equipment.....	(5,459)	(1,346)	(4,975)
Proceeds from sale of facilities and equipment.....	--	--	21,754
Sales/maturities of marketable securities.....	398,180	63,971	105,240
Purchases of marketable securities.....	(401,158)	(41,845)	(116,368)
Net cash provided by (used in) investing activities.....	(8,437)	20,780	5,651
Cash flows from financing activities:			
Issuance of common stock.....	122,005	10,535	1,243
Purchase of treasury stock.....	(445)	--	(1,048)
Proceeds/payments from stockholders notes receivable....	352	(244)	37
Payment of note payable.....	--	(4,562)	--
Proceeds from commercialization agreement.....	10,000	--	7,500
Net cash provided by financing activities.....	131,912	5,729	7,732
Net increase (decrease) in cash and cash equivalents.....	55,005	(8,291)	4,899
Cash and cash equivalents at beginning of year.....	3,291	11,582	6,683
Cash and cash equivalents at end of year.....	\$ 58,296	\$ 3,291	\$ 11,582
Supplemental cash flow data:			
Cash paid during the period for interest.....	--	\$ 4,562	--
Converted Genetech notes payable into preferred stock....	--	\$ 5,000	--
Change in net unrealized gains (losses) on securities....	\$ (196)	\$ 2,255	\$ (12,472)

Edgar Filing: SCIOS INC - Form 10-K

Write off of fully depreciated assets.....	--	\$	904	\$	13,407
Notes receivable from stockholders.....	--	\$	423		--
Deferred compensation.....	--	\$	311	\$	152
Discount on commercialization obligation.....	\$	3,397	--		--
Deferred warrant costs.....	\$	6,794	--		--

THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE CONSOLIDATED FINANCIAL STATEMENTS.

F-4

SCIOS INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

		COMMON STOCK		ADDITIONAL
	PREFERRED SHARES	SHARES	PAR VALUE	PAID-IN CAPITAL
(IN THOUSANDS, EXCEPT SHARE DATA).....				
BALANCES AT JANUARY 1, 1999.....	--	38,468,652	\$38	\$416,420
Purchase of treasury stock.....				
Options exercised.....		185,163		1,240
Treasury stock reissued.....		(225,163)		(1,220)
Notes receivable from stockholders.....				
Deferred compensation.....		40,000		150
Amortization of deferred compensation.....				
Changes in unrealized gains on available-for-sale securities				
Net loss.....				
BALANCES AT DECEMBER 31, 1999.....	--	38,468,652	38	416,600
Preferred stock issued to retire debt.....	4,991			5,000
Options exercised.....		1,432,757	1	10,530
Treasury stock reissued.....		(735,036)		(3,450)
Notes receivable from stockholders.....				
Deferred compensation.....				310
Amortization of deferred compensation.....				
Changes in unrealized gains on available-for-sale securities				
Unrealized gain on GenVec common stock.....				
Net loss.....				
BALANCES AT DECEMBER 31, 2000.....	4,991	39,166,373	39	428,980
Common stock issued.....		5,750,000	6	112,750
Purchase of treasury stock.....				
Options exercised.....		1,061,590	1	8,370
Employee stock purchase plan shares issued.....		37,204		860
Valuation of stock option issued to non-employee for services rendered.....				170
Warrants issued in connection with commercialization agreement.....				10,190
Notes receivable from stockholders.....				
Amortization of deferred compensation.....				
Changes in unrealized gains on available-for-sale securities				
Net loss.....				



# Edgar Filing: SCIOS INC - Form 10-K

SCIOS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

### 1. BUSINESS OF THE COMPANY

Scios Inc. (the "Company", "we" or "our") is a biopharmaceutical company developing novel treatments for cardiovascular and inflammatory diseases. The Company is distinguished by its disease-based technology platform, which integrates expertise in protein biology with computational and medicinal chemistry to identify novel targets, and rationally design small molecule compounds.

On August 13, 2001, we received final approval from the U.S. Food and Drug Administration, or FDA, to market Natrecor for the intravenous treatment of patients with acutely decompensated congestive heart failure. We launched Natrecor in that same month and recorded \$14.1 in revenue for the year ended December 31, 2001.

During 2001, we recorded \$15.9 million of one-time sales of bulk FGF to Kaken Pharmaceutical Co, Ltd. of Japan or Kaken (see Note 4e). Kaken will manufacture future needs of FGF to meet their requirements and accordingly sales of FGF will not repeat in future years.

Our psychiatric sales and marketing division marketed seven products in the United States in cooperation with the Company's partners (see Note 4c). In March 2001, GSK and the Company agreed to sell the marketing rights to those products to GSK and terminate the license agreement relating to certain GSK psychiatric products effective March 31, 2001. In addition, the Company ended the deployment of the Psychiatric Sales and Marketing Division sales force. Effective March 31, 2001, we discontinued the sale of these products.

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.

In the course of its development activities, the Company has sustained operating losses and expects such losses to continue at least through fiscal year 2003.

### 2. RESTRUCTURING CHARGES AND EXPENSES

In 1999, the Company recorded a restructuring charge of approximately \$6.4 million for the disposal of certain excess assets and severance costs. All restructuring activities were complete by the end of the second quarter of 2000, leaving a remaining balance of \$1.0 million in the reserve. The remaining reserve was credited to restructure expense in the second quarter of 2000.

### 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### PRINCIPLES OF CONSOLIDATION

The consolidated financial statements include the accounts of the Company and its wholly owned and majority-owned subsidiaries. Intercompany transactions and balances are eliminated on consolidation.

#### RECLASSIFICATIONS

Certain previously reported amounts have been reclassified to conform with the current period presentation. These reclassifications had no impact on previously reported results of operations.

## Edgar Filing: SCIOS INC - Form 10-K

### USE OF ESTIMATES

The preparation of financial statements in conformity with generally accepted accounting principals requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

F-6

SCIOS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

### CASH EQUIVALENTS

The Company considers all highly liquid investments with maturities of less than 90 days, at the time acquired, to be cash equivalents. Cash equivalents are stated at cost, which approximates market value.

### MARKETABLE SECURITIES

All marketable securities at December 31, 2001 and December 31, 2000 were deemed by management to be available-for-sale and are carried at fair value with the resulting net unrealized gains or losses, reported as a component of accumulated other comprehensive income (loss). Premium and discount on debt securities recorded at the date of purchase are amortized and accreted, respectively, to interest income using the effective interest method. Short-term marketable securities are those with remaining maturities at the balance sheet date of one year or less. Long-term marketable securities have remaining maturities at the balance sheet date of greater than one year. Realized gains and losses on sales of all such securities are reported in earnings and computed using the specific identification cost method.

The Company assesses the value of its available-for-sale marketable securities on a regular basis to assess whether an other-than-temporary decline in the fair value has occurred. Factors which the Company uses to assess whether an other than temporary decline has occurred include, but are not limited to, the period of time which the fair value is below original cost, significant changes in the operating performance, financial condition or business model, and changes in market conditions. Any "other than temporary decline" in value is reported in earnings and a new cost basis for the marketable security established.

### 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. All costs associated with the manufacture of Natrecor bulk drug product and finished products to which title transferred to us prior to FDA approval was expensed as research and development. On August 13, 2001, we received FDA approval for Natrecor and any Natrecor bulk drug product and finished goods to which we took title after that date was recorded as inventory.

### BUSINESS RISK AND CREDIT CONCENTRATION

Approximately 63% of our total revenues in 2001 were derived from product sales. These product sales consisted of one-time sales of bulk FGF to Kaken in



## Edgar Filing: SCIOS INC - Form 10-K

Japan of \$15.9 million, and Natreacor sales of \$14.1 million. Bulk sales of FGF are not expected to repeat in future years. About 10% or \$4.8 million of our total revenues were from our research and development collaborations, licenses, royalties, and milestone payments. The majority of this revenue was from Eli Lilly and Company ("Eli Lilly") which accounted for \$3.0 million of the total \$4.8 million for the development of drugs to prevent or retard the progression of Alzheimer's disease. At the end of December 31, 2001, Eli Lilly and we jointly terminated the collaboration. The remaining balance of \$1.8 million was from royalties from Biosite and Kaken and licensing payments from Abbot Laboratories. In addition, 7% or \$3.1 million of our total revenues in 2001 came from psychiatric product sales and co-promotion commissions, net of expenses. As explained in Note 4c, we sold the marketing rights to GSK and discontinued the sales of these products effective March 31, 2001.

Our revenues from Natreacor are all sold through wholesalers. The Company's top four wholesalers typically represent approximately 90% of net revenue. These four wholesalers accounted for approximately \$12.8 million or 91% of our net revenue of Natreacor for the year ended December 31, 2001. As a percent of net revenue, the four wholesalers accounted for 28%, 26%, 24% and 13%, respectively.

At December 31, 2001 wholesalers accounted for \$4.2 million of the \$6.9 million in accounts receivable. As a percent of the \$4.2 million, four wholesalers accounted for 32.7%, 23.3%, 23.3% and 13.3%, respectively.

Approximately 40% of our total revenues in 2000 were derived from psychiatric product sales, which consists entirely of sales in the United States under a license agreement with GSK.

F-7

SCIOS INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

In 1999 license revenues from Chiron Corporation ("Chiron") accounted for 27%, milestone payments from Novo Nordisk accounted for 22%, and Alzheimer's research reimbursement with Eli Lilly accounted for 22% of total research and development contract revenues. Approximately 11% of 1999 research and development contract revenues were from the agreement with Bayer AG ("Bayer") for commercialization of Natreacor (nesiritide). The agreement with Bayer was terminated in May 1999.

At December 31, 2001, the \$6.9 million in accounts receivable included approximately \$4.2 million from product sales of Natreacor, and \$3.0 million from GSK, and \$0.1 million of other receivable, less reserves of \$0.4 million.

At December 31, 2000, the \$5.2 million in accounts receivable included \$3.5 million from GSK, and \$1.0 million from Janssen Pharmaceutica Inc. ("Janssen").

The Company's excess cash is invested in a diversified portfolio of securities consisting of United States Treasury Notes, deposits with major banks and financial institutions, and investment-grade interest-bearing corporate securities issued by companies in a variety of industries. In addition, the Company owned 100,871 shares of GenVec Corporation (NASDAQ--GNVC) common stock, with a fair market value of \$499,311, at the end of December 31, 2001.

The Company relies on a third party to manufacture its product. Reliance on third-party manufacturers involves a number of risks, including the lack of control over the manufacturing process and the potential absence or

## Edgar Filing: SCIOS INC - Form 10-K

unavailability of adequate capacity. If the Company's third party manufacturer cannot or will not manufacture its products in required volumes, on a cost-effective basis, in a timely manner, or at all, the Company will have to secure additional manufacturing capacity. Even if this additional capacity is available at commercially acceptable terms, the qualification process could be lengthy and could cause interruptions in product shipments.

Certain Company products require approval from the FDA and foreign regulatory agencies prior to commercialized sales and are subject to continued regulations once approved. There can be no assurances that the Company's new products will receive any of these required approvals. If the Company was denied such approvals or such approvals were delayed, it could have a materially adverse impact on the Company.

### DEPRECIATION AND AMORTIZATION

Leasehold improvements and equipment are stated at cost and are depreciated using the straight-line method over the estimated useful lives of the assets (3 to 7 years for equipment). Leasehold improvements are amortized on a straight-line basis over the shorter of the asset life or fixed-lease term. Upon sale or retirement of assets, the cost and related accumulated depreciation or amortization is removed from the balance sheet, and the resulting gain or loss is reflected in operations. Repairs and maintenance are charged to expenses when incurred.

### IMPAIRMENT OF LONG-LIVED ASSETS

The Company assesses the impairment of identifiable intangibles and fixed assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors considered important which could trigger an impairment review include, but are not limited to, significant underperformance relative to expected historical or projected future operating results, significant changes in the manner of use of the acquired assets or the strategy for the Company's overall business, significant negative industry or economic trends, significant decline in the Company's stock price for a sustained period, and the Company's market capitalization relative to net book value. When the Company determines that the carrying value of long-lived assets may not be recoverable based upon the existence of one or more of the above indicators of impairment, the Company measures any impairment based on a projected discounted cash flow method using a discount rate commensurate with the risk inherent in the Company's current business model.

### TREASURY STOCK

Treasury stock of 30,000 shares at December 31, 2001 was stated at cost and was considered issued and outstanding. During September 2001, the Board of Directors authorized the repurchase of up to \$10 million of Scios common stock. The

F-8

SCIOS INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

repurchases are to be made through open-market transactions at the discretion of management as market conditions warrant. As of December 31, 2001, we had repurchased 30,000 shares of our common stock at an average purchase price of \$14.83 per share.

## Edgar Filing: SCIOS INC - Form 10-K

### REVENUE RECOGNITION

We recognize revenue from product sales when there is pervasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable, and collection is reasonably assured. Provisions for discounts and rebates to customers, and returns and other adjustments are provided for in the same period that the related product sales are recorded based upon analyses of historical discounts, rebates and returns. Shipping and distribution costs are expensed to cost of product sales.

### RESEARCH AND DEVELOPMENT CONTRACTS AND ROYALTIES

Research and development contract revenue from cost-reimbursement agreements with collaboration partners is recorded as the related expenses are incurred, up to contractual limits. Payments received that are related to future performance are deferred and recorded as revenue as they are earned over specified future performance periods. Charges to these collaboration partners are based upon negotiated rates for full time equivalent employees of the Company and such rates are intended to approximate the Company's anticipated costs. All revenues recognized to date are not refundable if the relevant research effort is not successful. Research and development expenses in 2001, 2000, and 1999 include approximately \$1.9 million, \$2.3 million, and \$2.4 million respectively, incurred in connection with programs subject to cost reimbursement, collaborative or other performance agreements.

Royalty income from licensing agreements is recognized when the royalty payments are received and earned.

### RESEARCH AND DEVELOPMENT

Research and development costs are charged to operations as incurred. Certain research and development projects are funded under agreement with collaboration partners, and the costs related to these activities are included in research and development expense. The charges to collaboration partners are based upon negotiated rates for full-time equivalent employees of the Company, and such rates are intended to approximate the Company's anticipated costs.

### FAIR VALUE OF FINANCIAL INSTRUMENTS

Carrying amounts of certain of the Company's financial instruments including cash and cash equivalents, accounts receivable, accounts payable and other accrued liabilities approximate fair value due to their short maturities. Based on borrowing rates currently available to the Company for loans with similar terms, the carrying value of notes payable approximates fair value. Estimated fair values for marketable securities, which are separately disclosed elsewhere, are based on quoted market prices for the same or similar instruments.

F-9

SCIOS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

### COMPUTATION OF NET LOSS PER SHARE

Basic net loss per share is calculated using the weighted average number of vested common shares outstanding for the period. Diluted net loss is calculated using the weighted average number of common and dilutive common equivalent

## Edgar Filing: SCIOS INC - Form 10-K

shares outstanding during the period. The outstanding options to purchase common stock and the affect of converting preferred stock to common stock were excluded from diluted earnings calculations because the effect would be anti-dilutive.

For the year ended December 31, 2001, the following items were not included in the calculation of diluted net loss per share because to do so would be anti-dilutive for the period:

	2001	2000	1999
PharmaBio warrants, 700,000 total warrants with an exercise price of \$20.00. Warrants are exercisable pro rata over the next 17 months and will expire in ten years.....	175,000	--	--
Option to issue preferred stock to repay debt for a maximum of \$20 million. Shares are computed based on the year end stock price. Actual number of preferred shares will depend upon the price and dollar value used toward payment of Genentech debt (see Note 4f) (*).....	841,396	499,100	--
Company stock option plans.....	6,872,775	4,517,328	5,571,861
	7,889,171	5,016,428	5,571,861
	7,889,171	5,016,428	5,571,861

(\*)None of the shares shall be exercised, sold, assigned or transferred prior to December 30, 2002, except with the prior written approval of the Company.

### COMPREHENSIVE INCOME (LOSS)

The Company's unrealized gains (losses) on marketable securities represent the only component of comprehensive income (loss) that is excluded from the Company's net loss. The Company's comprehensive income (loss) has been presented in the consolidated financial statements. As the Company is in a loss position, tax effects have not been allocated to the components of other comprehensive income (loss).

### PATENT COSTS

Costs related to patent prosecution are expensed as incurred, as recoverability of such expenditures is uncertain.

### SEGMENT REPORTING

Management has determined that the Company operates in one business segment. We currently sell and market Natrecor in the United States for the treatment of patients with acutely decompensated congestive heart failure.

### ADVERTISING COSTS

We expense advertising costs as incurred. Advertising costs for Natrecor were approximately \$0.9 million for the year ended December 31, 2001 and none in prior years.

### INCOME TAXES

## Edgar Filing: SCIOS INC - Form 10-K

The Company accounts for income taxes under Statement of Financial Accounting Standard No. 109, "Accounting for Income Taxes," which prescribes the use of the liability method whereby deferred tax asset or liability account balances are calculated at the balance sheet date using current tax laws and rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

F-10

SCIOS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

### RECENT ACCOUNTING PRONOUNCEMENTS

In July 2001, the FASB issued Statement of Financial Accounting Standards No. 141 (SFAS 141), "Business Combinations." SFAS 141 requires the purchase method of accounting for business combinations initiated after June 30, 2001 and eliminates the pooling-of-interests method. Scios did not have any business combination transactions in the year ended December 31, 2001.

In July 2001, the FASB issued Statement of Financial Accounting Standards No. 142 (SFAS 142), "Goodwill and Other Intangible Assets," which in Scios' case is effective for fiscal years beginning after December 15, 2001. SFAS 142 requires, among other things, the discontinuance of goodwill amortization. In addition, the standard includes provisions upon adoption for the reclassification of certain existing recognized intangibles as goodwill, reassessment of the useful lives of existing recognized intangibles, reclassification of certain intangibles out of previously reported goodwill and the testing for impairment of existing goodwill and other intangibles. The Company does not currently have any goodwill or intangible assets, and does not believe that the implementation of SFAS 142 will have any significant impact on its financial position or results of operations.

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 to be Disposed Of." SFAS 144 addresses financial accounting and reporting of impairment of long-lived assets to be disposed of. However, SFAS 144 retains the fundamental provisions of SFAS 121 for: (1) recognition and measurement of the impairment of long-lived assets to be held and used; and (2) measurement of long-lived assets to be disposed of by sale. SFAS 144 is effective for fiscal years beginning after December 15, 2001. We believe SFAS 144 will have no impact on Scios' financial position and results of operations.

### SAB 101

Effective January 1, 2001, the Company adopted Staff Accounting Bulletin No. 101 (SAB 101) "Revenue Recognition in Financial Statements." SAB 101 requires that license and other up front fees received from research collaborators be recognized as earned over the term of the agreement unless the fee is in exchange for products delivered or services performed that represent the culmination of a separate earnings process.

The cumulative effect of adoption as of January 1, 2000 was immaterial to the results of the Company's operations and financial position. However, certain revenue recognized in periods prior to January 1, 2000 would have been recognized in different periods in accordance with the provisions of SAB 101. In the year ended December 31, 1998, the Company recorded a \$20.0 million

## Edgar Filing: SCIOS INC - Form 10-K

license fee in connection with the Natrecor commercialization agreement with Bayer AG. Under SAB 101, \$19.1 million of this license fee would have been reallocated from 1998 to the year ended December 31, 1999, the year in which the Bayer commercialization agreement was terminated. As a result, the loss for the year ended December 31, 1998 would have increased by \$19.1 million and the loss for the year ended December 31, 1999 decreased by \$19.1 million. In accordance with the implementation provisions of SAB 101, the accompanying financial data for periods prior to January 1, 2000, the date of adoption, have not been restated.

The pro forma effects of implementing SAB 101 on the results previously reported for the year ended December 31, 1999 are presented below:

	YEAR ENDED DECEMBER 31, 1999		
			BASIC AND DILUTED LOSS PER SHARE
	REVENUES	NET LOSS	SHARE
(IN THOUSANDS, EXCEPT PER SHARE DATA)			
As Reported.....	\$28,355	\$(20,064)	\$(0.53)
Pro-forma.....	\$47,503	\$ (916)	\$(0.02)

Concurrent with the implementation of SAB 101, the Company implemented the consensus reached in EITF 99-19 "Reporting Revenue Gross as a Principal Versus Net as an Agent." The effect of this EITF results in netting the revenues

F-11

SCIOS INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

received from the Psychiatric Sales and Marketing Division (PSMD) with related direct costs, as such it had no effect on previously reported operating results. All periods presented reflect retroactive application of this EITF consensus.

#### 4. JOINT BUSINESS ARRANGEMENTS

##### A. AGREEMENT WITH CHIRON CORPORATION

In November 1999, the Company signed a license agreement with Chiron for the rights to Fiblast (trafermin) ("Fiblast"). Fiblast is a human basic fibroblast growth factor. The Company received \$5.0 million in license and technology transfer fees and \$7.5 million from a Promissory Note due on December 31, 2006. The note and related interest will be forgiven if Fiblast is approved in the United States before December 31, 2006. The Company will also receive royalties based on future sales of Fiblast products.

##### B. AGREEMENT WITH JANSSEN PHARMACEUTICA INC.

The Company entered into a three-year agreement, effective April 1998, with Janssen to jointly promote the anti-psychotic drug, Risperdal, in the United

## Edgar Filing: SCIOS INC - Form 10-K

States. Under the agreement, the Company receives base payments plus incentive compensation on achieving specified sales levels over a contract year beginning in April and ending in March. Janssen manufactures and distributes the product. This agreement ended on March 31, 2001.

### C. AGREEMENTS WITH GLAXOSMITHKLINE CORPORATION

Under the terms of an agreement with GSK, the Company has the exclusive rights to market certain GSK psychiatric products in the United States. GSK is fully responsible for ancillary matters relating to product sales, including various administrative tasks and maintenance of all New Drug Applications with respect to the GSK Products, and certain product liability insurance. The Company pays GSK 40% of net profits, as defined in the agreement, from sales of the GSK Products.

In September 1998, the Company entered into an agreement with GSK to co-promote Paxil in the United States. Under the agreement, the Company receives base payments plus incentive compensation on achieving specified sales levels during a specified term. Although the agreement ended in December 2000, the companies had agreed to extend the agreement through March 31, 2001.

Commencing in the fourth quarter of 2000, the Company solicited and received bids in connection with selling its marketing rights for certain psychiatric products sold by the Company. The marketing rights were sold to GSK. In order to effect the sale, the licensing agreement was terminated effective March 31, 2001, and the Company received from GSK \$4.0 million in 2001, and will receive \$3.0 million in 2002, and will receive \$2.4 million in 2003.

The Company 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, the Company ended the deployment of the Psychiatric Sales Marketing Division sales force and terminated certain full-time support personnel. Severance payments for these personnel amounted to approximately \$0.8 million.

In December 2001, we entered into a binding summary of terms with Glaxo Group Ltd., an affiliate of GlaxoSmithKline, or GSK, in which we will license Natrecor to GSK in all European markets. Under the terms of the agreement, GSK will have the rights to sell and distribute the product for which we will receive an up-front fee and milestone payments totaling (Pounds)15.0 million British Pounds (which at December 31, 2001 equaled approximately \$22 million U.S. Dollars) in addition to future royalties in the identified countries. We will manufacture and supply the bulk product to GSK. Both companies will work together to continue clinical development of Natrecor in Europe. In order to obtain European approval for Natrecor, GSK expects to use the extensive clinical data we submitted to obtain approval from the FDA in August 2001. The companies expect to launch Natrecor in Europe in the first half of 2004. No revenue has been recognized related to this agreement through December 31, 2001.

F-12

SCIOS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

### D. AGREEMENT WITH ELI LILLY AND COMPANY

In April 1997, the Company entered into a research collaboration with Eli Lilly and Company ("Eli Lilly") for the development of drugs to prevent or retard the

## Edgar Filing: SCIOS INC - Form 10-K

progression of Alzheimer's disease. Under the terms of the agreement, Eli Lilly will fund research and will have the first opportunity to develop products from the collaboration. The Company may elect to develop other products from the collaboration. The commercialization partner will make milestone and royalty payments to the other partner. In 2000, the existing agreement was amended to decrease the number of dedicated and non-dedicated employees that work on the project, and at that time the program was further extended to December 31, 2001. At the end of December 31, 2001, we and Eli Lilly terminated the collaboration.

### E. AGREEMENTS WITH KAKEN PHARMACEUTICAL CO., LTD.

In September 1994, the Company entered into a series of agreements with Kaken Pharmaceutical Co., Ltd. ("Kaken"), to expand a previous agreement signed in 1988 for Fiblast. Under the 1994 agreements, the Company will collaborate with Kaken to further develop the Fiblast manufacturing process, provide Kaken a license to the Company's Fiblast manufacturing technology and supply a specified amount of Fiblast product. In return, the Company has received milestone payments, which are contingent on Kaken's continuing development of the product. At December 31, 2000, \$15.9 million of the Company's deferred revenue consisted of payments received for the supply of Fiblast material. Prior to closing its Mountain View manufacturing facility in May 1999, the Company produced the amount of Fiblast due to Kaken and the Company held it for delivery to Kaken upon regulatory approval of the product in Japan. 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 Spray as a treatment for dermal ulcers. During 2001, we shipped all of the bulk FGF to Kaken in Japan and recognized \$15.9 million of previously deferred revenue. We also received royalty payments from the sale of Fiblast of \$0.2 million during 2001.

### F. AGREEMENT WITH GENENTECH, INC.

In December 1994, the Company entered into a collaboration agreement with Genentech, Inc. ("Genentech") for the development and commercialization of Auriculin (anaritide) ("Auriculin") for the treatment of acute renal failure. Concurrent with the collaboration agreement, Genentech purchased \$20.0 million of the Company's preferred stock and provided a \$30.0 million loan to the Company in the form of a letter of credit (see Note 10), which the Company drew down in March of 1997. As of December 31, 1997, Genentech had converted all shares of preferred stock into 2.1 million shares of common stock. In 1997, the Company and Genentech discontinued development of Auriculin based upon the negative results of an interim study. In 1999 the terms of the loan were amended. The loan is repayable in the Company's preferred stock up to a maximum of \$25.0 million at the Company's option at any time through December 31, 2002. In the event the Company converts the loan to preferred stock, the stock cannot be sold or registered until December 30, 2002 without the Company's approval.

In addition, if the Company should decide to convert the loan to preferred stock, a portion of the loan that is not convertible will become due and payable before December 31, 2002. The amount of the loan that is due before the maturity date is based on a formula that considers the amount of loan converted to stock and the outstanding loan balance.

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 Series B preferred stock. The preferred shares convert to 499,100 shares of common stock.

### G. AGREEMENT WITH QUINTILES INTERNATIONAL CORP.



## Edgar Filing: SCIOS INC - Form 10-K

In January 2001, we entered into a sale and marketing alliance with Innovex, a subsidiary of Quintiles Transnational Corp. Innovex supported Scios with a wide range of sales and marketing solutions. This included the hiring and training of a dedicated sales force to launch Natrecor. As part of the original three and one half year agreement, Quintiles, through its corporate venture group PharmaBio Development agreed to fund \$30.0 million of our costs to launch Natrecor over the first 24 months of the commercialization of Natrecor and to loan us up to \$5.0 million. In December 2001, Scios, Innovex and

F-13

SCIOS INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

PharmaBio, amended the January 2001 agreement. The amendment allowed Scios, at its option, to assume control of the Natrecor sales force in June 2003, one year ahead of schedule, and eliminated the \$5.0 million line of credit provided by PharmaBio to Scios. Of the \$30.0 million funding agreement, we received \$10.0 million in the fourth quarter of 2001, and will receive the remaining \$20.0 million in six payments over the following 17 months. As part of the funding agreement, we will pay PharmaBio a declining royalty rate on net sales of Natrecor through early 2008. We also granted PharmaBio a fully vested warrant to purchase 700,000 shares of our common stock at an exercise price of \$20.00 per share. These warrants are exercisable over 17 months beginning December 2001 through May 2003 (see Note 10).

#### 5. MARKETABLE SECURITIES

Unrealized gains and losses on marketable securities at December 31, 2001 by classification were as follows:

	UNREALIZED	UNREALIZED	
COST BASIS	GAINS	LOSSES	FAIR VALUE
(IN THOUSANDS)			
Debt securities:			
U.S. Government & Government Agency	\$20,878	\$193	\$ (85)
Corporate Bonds.....	49,623	469	(58)
	-----	-----	-----
Total.....	\$70,501	\$662	\$(143)
	=====	=====	=====

Unrealized gains and losses on marketable securities at December 31, 2000 by classification were as follows:

	UNREALIZED	UNREALIZED	
COST BASIS	GAINS	LOSSES	FAIR VALUE
(IN THOUSANDS)			
Debt securities:			

Edgar Filing: SCIOS INC - Form 10-K

U.S. Government & Government Agency	\$36,256	\$191	\$ (85)	\$36,362
Corporate Bonds.....	31,808	102	(32)	31,878
	-----	----	-----	-----
Total.....	\$68,064	\$293	\$(117)	\$68,240
	=====	=====	=====	=====

The scheduled maturities for marketable securities at December 31, 2001 by classification were as follows:

-----			-----		
MATURITY		MATURITY			
1 YEAR	MATURITY	MATURITY	4 YEARS		
OR LESS	2 YEAR	3 YEAR	OR MORE	TOTAL	
-----			-----		-----

(IN THOUSANDS)

Debt securities:

U.S. Government & Government Agency Securities.....	\$ --	\$13,943	\$ 5,461	\$1,582	\$20,986
Corporate Bonds.....	7,351	18,418	17,090	7,175	50,034
	-----	-----	-----	-----	-----
Total.....	\$7,351	\$32,361	\$22,551	\$8,757	\$71,020
	=====	=====	=====	=====	=====

The Company realized gains of \$1.1 million and losses of \$0.3 million on the disposal of marketable securities in 2001, gains of \$0.1 million and losses of \$0.3 million on the disposal of marketable securities in 2000, and gains of \$5.2 million and losses of \$0.3 million on the disposal of marketable securities during 1999.

F-14

SCIOS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

6. INVENTORY

	-----	
	DECEMBER 31,	
	-----	
	2001	2000
	-----	-----
(IN THOUSANDS)		
Finished goods.....	\$1,134	\$ --
Work-in-process.....	24	--
	-----	-----
Total.....	\$1,158	\$ --
	=====	=====

7. PROPERTY AND EQUIPMENT

Edgar Filing: SCIOS INC - Form 10-K

	----- DECEMBER 31, -----	
	2001	2000
	-----	-----
(IN THOUSANDS)		
Laboratory equipment.....	\$ 7,901	\$ 6,085
Computer and related equipment.....	5,221	3,256
Furniture and other.....	2,064	1,370
Leasehold improvements.....	10,035	8,977
	-----	-----
	25,221	19,688
Accumulated depreciation and amortization.....	(14,797)	(11,366)
	-----	-----
	10,424	8,322
Construction-in-progress.....	--	588
	-----	-----
Total.....	\$ 10,424	\$ 8,910
	=====	=====

8. OTHER ASSETS

	----- DECEMBER 31, -----	
	2001	2000
	-----	-----
(IN THOUSANDS)		
Deposits.....	\$ 332	\$ 348
Receivable from GSK.....	2,363	--
Other assets.....	499	1,255
Employee notes receivable.....	929	686
	-----	-----
Total.....	\$4,123	\$2,289
	=====	=====

9. OTHER ACCRUED LIABILITIES

	----- DECEMBER 31, -----	
	2001	2000
	-----	-----
(IN THOUSANDS)		
Accrued Medicaid rebates.....	\$ 865	\$1,532
Profit distribution to third parties.....	--	1,139
Accrued clinical trial expenses.....	995	598
Accrued selling and marketing expenses.....	1,498	--
Accrued R&D contract payable.....	737	737
Accrued research partnership distribution.....	689	44

Edgar Filing: SCIOS INC - Form 10-K

Other.....	2,422	2,678
	-----	-----
Total.....	\$7,206	\$6,728
	=====	=====

F-15

SCIOS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

10. LEASE AND DEBT COMMITMENTS

A. OPERATING LEASES

The Company leases three facilities in Sunnyvale, California. The leases for these facilities expire during various periods from December 31, 2003 to August 31, 2008. We also lease a warehouse in Mountain View, California that expires in 2003. In addition, the Company has entered into operating leases covering certain laboratory and computer equipment.

At December 31, 2001, future minimum payments under these leases are as follows:

	-----	
	EQUIPMENT	
	FACILITIES	OPERATING
	LEASES	LEASES
	-----	
(IN THOUSANDS)		
2002.....	\$1,930	\$198
2003.....	2,069	105
2004.....	917	--
2005.....	948	--
2006.....	979	--
Thereafter.....	1,879	--
	-----	-----
Total.....	\$8,722	\$303
	=====	=====

Rent expenses for all facility leases were approximately \$1.9 million, \$1.6 million, and \$2.2 million in 2001, 2000, and 1999, respectively.

B. LONG-TERM DEBT

	-----	
	DECEMBER 31,	
	-----	
	2001	2000
	-----	
(IN THOUSANDS)		
Note payable to Genentech, interest at the prime rate of		

## Edgar Filing: SCIOS INC - Form 10-K

(4.75% at December 31, 2001). The loan is repayable in the Company's preferred stock up to a maximum of \$20 million at anytime through December 31, 2002. If the Company should decide to convert the loan to preferred stock, the portion of the loan that is not convertible (\$13,035 at December 31, 2001) will become due and payable before December 31, 2002.....

Note payable to Chiron, interest at 8.5% and is due December 31, 2006.....	\$ 33,035	\$30,927
Obligation to Quintiles--PharmaBio, amortized based on the royalty payments made on Natrecor sales until 2008.....	8,876	8,168
Discount on Qunitiles--PharmaBio obligation.....	10,000	--
	(3,397)	--
	-----	-----
Total long-term debt.....	48,514	39,095
Less current portion of long-term debt.....	(33,035)	--
	-----	-----
Long-term debt, net of current portion.....	\$ 15,479	\$39,095
	=====	=====

GENENTECH--As part of the Auriculin agreement, 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% at December 31, 2001). In 1999 the terms of the loan were amended. The loan is repayable in the Company's preferred stock up to a maximum of \$25.0 million at the Company's option at any time through December 31, 2002. In the event the Company converts the loan to preferred stock, the stock cannot be sold or registered until December 30, 2002. In addition, if the Company should decide to convert the loan to preferred stock, the portion of the loan that is not converted will become due and payable before December 31, 2002. The amount of the loan that is convertible before the maturity date is based on a formula that considers the amount of the loan converted to stock and the outstanding loan balance.

F-16

SCIOS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

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 Series B preferred stock. (For rights and features of Series B preferred stock see Note 13a). 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.

CHIRON--As part of the Fiblast agreement, Chiron loaned the Company \$7.5 million in December 1999. The Promissory Note bears interest at the rate of 8.5% compounded annually, and is due December 31, 2006. The note and related interest will be forgiven if Fiblast is approved in the United States before December 31, 2006.

QUINTILES--PHARMABIO--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 700,000 warrants to purchase Scios stock at \$20.00 per share. In December 2001,

## Edgar Filing: SCIOS INC - Form 10-K

Scios and PharmaBio amended the January 2001 agreement. The amendment eliminated the \$5.0 million line of credit. All of the 700,000 warrants vested in December 2001 are exercisable over seven installments beginning December 2001 through May 2003. Of the \$30.0 million funding commitment, we received \$10.0 million in the fourth quarter of 2001, and will receive the remaining \$20.0 million in six payments over the following 17 months. As part of the funding agreement, we will pay PharmaBio a declining royalty rate on net sales of Natrecor through early 2008.

The accounting treatment of the commercialization payments of \$30.0 million from PharmaBio falls under the guidance of 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 Task Force reached a consensus on six independent factors that would require reclassification of the proceeds as debt. As the Company meets one of the factors whereby the Company has significant continuing involvement in the generation of the cash flows due to the investor. We have recorded the proceeds from PharmaBio of \$10.0 million in 2001 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.

The accounting treatment for the 700,000 warrants 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 at December 2001, was \$10.2 million. Of this total fair value, \$3.4 million was recognized as a discount related to the debt based on the portion of the cash funding received from PharmaBio in 2001. The remaining balance of \$6.8 million is recorded as Deferred Warrant Costs in the Stockholder's Equity section. The \$6.8 million in Deferred Warrant Costs will be recorded as discount on debt as the remaining \$20.0 million in funding is received from PharmaBio over the next 17 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.

### D. NATRECOR SUPPLY CONTRACT

The Company has entered into a long-term supply agreement with a manufacturer for the supply of bulk Natrecor. The contract 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 (United States equivalent at December 31, 2001, \$21.5 million).

### 11. LITIGATION

On November 29, 1995, the Company was notified by the United States Environmental Protection Agency, or EPA, that it may have a liability in connection with the clean-up of a toxic waste site arising out of the alleged disposal of hazardous substances by a subcontractor of Nova Pharmaceutical Corporation, which the we acquired in 1992. We were one of many potentially responsible parties that were identified as associated with this specific site. We held discussions with the EPA

# Edgar Filing: SCIOS INC - Form 10-K

SCIOS INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

and finalized the amount of potential liability. We reserved \$90,000 at December 31, 2000 as provision for the settlement thereof. During 2001, we settled the liability with a final settlement payment of \$81,264.

### 12. RESEARCH AND DEVELOPMENT COMMITMENTS

#### A. COMMITMENTS TO RESEARCH PARTNERSHIPS

In 1988, the Company purchased the interests of Biotechnology Research Partners, a limited partnership in a joint venture, and made a down payment of \$0.6 million. The balance of the purchase price is to be paid in quarterly installments in accordance with the following formula: (i) until the minority partners have received payments of approximately \$22.8 million, the Company will pay approximately 37% of the royalty income from third-party licenses and approximately 4% of the Company's gross sales of Partnership products; (ii) thereafter, until the minority partners have received aggregate payments of approximately \$34.1 million, the Company will pay approximately 31% of the royalty income and approximately 3% of the Company's gross sales of Partnership products; and (iii) thereafter, until the earlier of 20 years from the date of exercise of the option or the time all patents relating to the Partnership's technology expire and all information relating to that technology becomes part of the public domain, the Company will pay to the minority partners approximately 21% of the royalty income and approximately 2% of the Company's gross sales of Partnership products. Partnership products for which minority partners will receive payments include Fiblast. The Company accrued no amounts at December 31, 2000 and accrued \$0.6 million at December 31, 2001 as the minority partners' share of royalty payments received from Fiblast in 2001.

In December 1992, the Company exercised its option to acquire all interests in Nova Technology Limited Partnership for \$20.4 million. The Company also issued contingent payment rights to all limited partners of the partnership, pursuant to which the Company is obligated until January 15, 2008 to pay royalties on the sale or license of certain products that were under development by the partnership. The Company had accrued \$44,000 at December 31, 2001 as a result of royalties associated with the commercialization of Guilford's Gliadel wafer.

#### B. RESEARCH COLLABORATIONS WITH PARTNERS

As part of the Joint Business Arrangements described in Note 4 above, the Company from time to time agrees to provide and receive resources and support as part of its collaborations with other companies. In the course of such collaborations, issues may arise concerning the ownership of technology that is developed and the fulfillment of each party's obligations to the other. Generally these have been resolved by the parties without resorting to litigation.

### 13. STOCKHOLDERS' EQUITY

#### A. SERIES B PREFERRED STOCK

The Company's preferred stock may be issued in series that have such rights as may be designated by the Board of Directors from time to time. In February 2000, the Company's Board authorized the designation of 50,000 shares of Series B preferred stock. At December 31, 2000 and December 31, 2001 there were 4,991 shares outstanding. As discussed in Note 10b, 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 Series B preferred stock. Each share of Series B

## Edgar Filing: SCIOS INC - Form 10-K

preferred stock converts at a rate of 100:1 of common and will not have voting rights until converted into shares of Scios common stock. In addition, the holders of the Series B preferred stock are entitled to receive dividends as payable on each share of common stock into which such shares could then be converted, when and if declared by the Board of Directors. In the event of any liquidation, dissolution or winding up of the Company, after payment of debts and other liabilities, the holders of the Series B preferred stock (on an as converted basis) and the holders of the common stock shall be entitled to share ratably in the remaining assets of the Company.

### B. DEFERRED COMPENSATION

In August 2000, the Company granted shares of restricted stock to an officer. The shares vest over a six-month period provided that the recipient is still employed by the Company. The market value of these shares was \$0.3 million and has been recorded as a separate component of stockholders' equity. In August 1999, the Company granted shares of restricted stock to an officer.

F-18

SCIOS INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

The shares vest over a three-year period provided that the recipient is still employed by the Company. The market value of the shares awarded was \$0.2 million and has been recorded as a separate component of stockholders' equity. In September 1998, the Company granted shares of restricted stock to an officer and director. The shares vest over a two-year period provided that the recipient is still employed by the Company. The market value of the shares awarded was \$0.6 million and has been recorded as a separate component of stockholders' equity. Deferred compensation for these share grants is being amortized over the applicable period of the vesting. The restricted stock was granted under the 1992 Incentive Stock Plan.

### 14. EMPLOYEE 401(K) BENEFIT PLAN

The Company has a qualified profit sharing plan and trust under Internal Revenue Service Code sections 401(a) and 401(k). Employees are eligible to participate in the plan the first day of the month after hire and can elect to contribute to the plan up to 15% of their salary subject to current statutory limits. In 2001, 2000, and 1999, the Company matched employee contributions at a rate of 100% to a maximum of \$3,000 per employee, except as restricted by statutory limits. The Company contribution is 100% vested at the end of an employee's third year of employment. Company contributions to the plan totaled approximately \$0.7 million in 2001, \$0.6 million in 2000, and \$0.8 million in 1999.

### 15. STOCK OPTION PLANS

Under the Company's stock option plans, the Board of Directors has the authority to determine to whom options will be granted, the number of shares, the vesting period and the exercise price (which cannot be less than fair market value ("FMV") at date of grant for incentive stock options or 85% of FMV for non-statutory options). The options are exercisable at times and in increments as specified by the Board of Directors, generally expire ten years from date of grant and fully vest over periods from three to five years. The following shares are authorized and available for grant as of December 31, 2001:



Edgar Filing: SCIOS INC - Form 10-K

PLAN TITLE	SHARES AUTHORIZED	OPTIONS OUTSTANDING	AVAILABLE FOR GRANT	OPTION PRICE
1983/86.....	2,200,000	18,765	--	Not less than 85% of FMV
1989.....	170,000	10,000	--	FMV
1992.....	6,057,665	1,983,646	1,640,405	Not less than 85% of FMV
1996.....	6,795,000	4,860,168	1,361,267	Not less than 85% of FMV
NQ.....	443,161	--	--	Not less than 85% of FMV
1992 NC.....	442,335	196	--	Not less than 85% of FMV
SA.....	542,000	--	--	Not less than 85% of FMV
Total.....	16,650,161	6,872,775	3,001,672	

Additional information with respect to the activity of outstanding options and restricted common stock is summarized in the following table:

	NUMBER OF SHARES	OPTION PRICE	AGGREGATE PRICE (IN THOUSANDS)
Balances at January 1, 1999.....	4,505,835	\$ 3.69-\$21.13	\$ 35,562
Granted.....	2,119,200	\$ 3.81-\$ 8.75	12,638
Exercised.....	(185,163)	\$ 5.13-\$ 9.63	(1,243)
Canceled.....	(868,011)	\$ 3.81-\$15.06	(6,592)
Balances at December 31, 1999.....	5,571,861	\$ 3.69-\$21.13	40,365
Granted.....	1,190,922	\$0.001-\$15.19	10,912
Exercised.....	(1,432,757)	\$0.001-\$12.00	(10,535)
Canceled.....	(812,698)	\$ 3.81-\$21.13	(7,190)
Balances at December 31, 2000.....	4,517,328	\$0.001-\$21.13	33,552
Granted.....	3,748,500	\$15.18-\$27.60	81,210
Exercised.....	(1,061,590)	\$0.001-\$26.35	(8,379)
Canceled.....	(331,463)	\$ 3.81-\$26.35	(4,378)
Balances at December 31, 2001.....	6,872,775	\$0.001-\$27.60	\$102,005

F-19

SCIOS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

The options outstanding by range of exercise price at December 31, 2001 are as follows:

## Edgar Filing: SCIOS INC - Form 10-K

EXERCISE PRICE	NUMBER OF OPTIONS OUTSTANDING	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE	OUTSTANDING WEIGHTED AVERAGE EXERCISE PRICE	NUMBER OF OPTIONS EXERCISABLE	EXERCISABLE WEIGHTED AVERAGE EXERCISE PRICE
\$ 3.81-\$ 3.94.....	683,617	7.57	\$ 3.67	219,718	\$ 3.86
\$ 3.97-\$ 5.97.....	747,612	6.89	\$ 5.15	582,014	\$ 5.25
\$ 6.06-\$ 8.75.....	800,594	6.04	\$ 7.42	652,825	\$ 7.33
\$ 8.88-\$15.18.....	812,459	6.94	\$10.73	574,398	\$10.23
\$15.19-\$19.10.....	666,534	9.31	\$17.48	70,992	\$15.26
\$19.11-\$20.37.....	809,605	9.15	\$20.28	162,497	\$20.37
\$20.47-\$21.85.....	924,917	9.43	\$21.43	271	\$20.85
\$21.98-\$22.41.....	765,000	9.48	\$22.35	--	\$ 0.00
\$22.54-\$26.90.....	572,437	9.44	\$25.42	48,394	\$26.46
\$27.60-\$27.60.....	60,000	9.32	\$27.60	--	\$ 0.00
\$3.81-\$27.60.....	6,842,775	8.23	\$14.89	2,311,109	\$ 8.76

At December 31, 2001, approximately 2,311,109 options to purchase common stock of the Company were exercisable at an average exercise price of \$8.76. At December 31, 2000, approximately 2,407,480 options to purchase common stock of the Company were exercisable at an average exercise price of \$7.37. In 2000, the Company issued 735,036 shares of treasury stock to fulfill employee option exercises.

On February 5, 2001, the 1996 Equity Incentive Plan was amended to add 1.3 million shares of common stock to this plan. On May 7, 2001, the 1996 Equity Incentive Plan was amended to add 1.8 million shares of common stock to this plan. 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 and approved an Employee Stock Purchase Plan with an initial allocation of 175,000 shares of common stock. On November 5, 2001, the 1996 Equity Incentive Plan was amended to add 1.2 million shares of common stock to this plan.

### RESTRICTED COMMON STOCK

At December 31, 2001 there were 30,000 shares of restricted common stock granted to an officer that were outstanding. The shares vest on August 9, 2002, and at December 31, 2001 none of these shares were vested.

### STOCK BASED COMPENSATION

The Company is required under Statement of Financial Accounting Standards No. 123, "Accounting for Stock Based Compensation" ("SFAS 123"), to disclose pro forma information regarding option grants and the employee stock purchase program made to its employees based on specified valuation techniques that produce estimated compensation charges. These amounts have not been reflected in the Company's Consolidated Statements of Operations because no compensation charge arises when the price of the employees' stock options equals the market value of the underlying stock at the grant date, as in the case of options granted to the Company's employees. Pro forma information under SFAS 123 is as follows:

The following pro forma information has been prepared following the provisions of SFAS No. 123:

Edgar Filing: SCIOS INC - Form 10-K

	YEAR ENDED DECEMBER 31,		
	2001	2000	1999
(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)			
Net loss--as reported.....	\$ (62,497)	\$ (42,522)	\$ (20,064)
Net loss--pro forma.....	\$ (77,646)	\$ (48,148)	\$ (25,449)
Net loss per common share basic and diluted--as reported.....	\$ (1.47)	\$ (1.12)	\$ (0.53)
Net loss per common share basic and diluted--pro forma.....	\$ (1.82)	\$ (1.27)	\$ (0.67)

F-20

SCIOS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

The fair value of each option grant is estimated on the date of grant using the Black-Scholes single option pricing method assuming the following assumptions:

	YEAR ENDED DECEMBER 31,		
	2001	2000	1999
Risk free interest rate.....	4.50%	5.01%	5.50%
Expected life (years).....	5.71	6.1	5.4
Volatility.....	0.8097	0.8573	0.9121
Dividend yield.....	--	--	--
Weighted average per share fair value of options granted.....	\$ 15.34	\$ 7.73	\$ 4.11

The fair value of the employee stock purchase program or ESPP is estimated on the date of the exercise using the Black-Scholes single option pricing method assuming the following assumptions:

	YEAR ENDED DECEMBER 31,		
	2001	2000	1999
Risk free interest rate.....	4.50%	N/A	N/A
Expected life (years).....	0.5	N/A	N/A
Volatility.....	0.8097	N/A	N/A
Dividend yield.....	--	--	--
Weighted average per share fair value of ESPP exercised....	\$ 8.33	N/A	N/A

## Edgar Filing: SCIOS INC - Form 10-K

### TREASURY STOCK

During September 2001, the Board of Directors authorized the repurchase of up to \$10 million of Scios common stock. The repurchases are to be made through open-market transactions at the discretion of management as market conditions warrant. As of December 31, 2001, we purchased 30,000 shares of Scios common stock for an aggregate purchase price of \$445,000. These shares are classified as Treasury Stock on the balance sheet at December 31, 2001.

### 16. INCOME TAXES

The Company's deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

The Company has federal and state income tax net operating loss ("NOL") and research credit carry-forwards at December 31, 2001 for tax purposes available as follows:

Federal NOL.....	\$436,236,000
State NOL.....	\$ 61,041,000
Federal Research Credit.....	\$ 13,204,000
State Research Credit.....	\$ 7,370,000

These federal and state NOL carry-forwards expire in the years 2002 through 2021 and 2002 through 2006, respectively. The federal and state research credit carry-forwards expire in the years 2002 through 2021.

Due to a change in the ownership of the Company, as defined, a portion of the federal and state NOL carryover is subject to an annual utilization limitation. Should another change in ownership occur, future utilization of the Company's NOL carry-forwards may be subject to additional limitations.

F-21

SCIOS INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets are presented below:

	DECEMBER 31,	
	2001	2000
(IN THOUSANDS)		
Net operating loss carryforwards.....	\$ 151,882	\$ 121,069
Credits.....	18,182	16,632

## Edgar Filing: SCIOS INC - Form 10-K

Assets subject to depreciation and amortization.....	12,569	11,700
Deferred revenue.....	--	6,744
Other accrued liabilities.....	5,856	7,685
	-----	-----
Total deferred tax assets.....	188,489	163,830
Valuation allowance.....	(188,489)	(163,830)
	-----	-----
Net deferred tax assets.....	\$ --	\$ --
	=====	=====

Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has placed a valuation allowance against its otherwise recognizable net deferred tax assets.

### 17. INDUSTRY AND GEOGRAPHIC SEGMENT INFORMATION

The Company operates in one business segment, using one measurement of profitability for its business. All long-lived assets are maintained in the United States. The Company receives revenue from product sales and from licensing and development of products. The Company received licensing revenue from partners in the United States, Europe and Asia Pacific.

Revenue by geographic area is as follows:

		----- REVENUES -----
(IN THOUSANDS)		
December 31, 2001:		
United States.....	\$31,241	
International.....	16,104	
	-----	
Total.....	\$47,345	=====
December 31, 2000:		
United States.....	\$12,624	
International.....	--	
	-----	
Total.....	\$12,624	=====
December 31, 1999:		
United States.....	\$22,002	
International.....	6,353	
	-----	
Total.....	\$28,355	=====

### 18. RELATED PARTY TRANSACTIONS

At December 31, 2001, we had notes receivable from three officers. The first note is in the amount of \$280,040 with interest at 5.18% per annum, due and payable on February 28, 2002. The maturity date of the note agreement was amended to February 28, 2003. 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 as Other Assets on the balance sheet at December 31, 2001.

Edgar Filing: SCIOS INC - Form 10-K

F-22

SCIOS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

The second note is in the amount of \$16,666 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 loan is classified as Other Assets on the balance sheet at December 31, 2001.

The third note is in the amount of \$150,000 with interest at 10.0% per annum. This loan will be forgiven in 2006 based on the continued employment of the officer and is collateralized by the officer's residence. The loan was granted in connection with a housing subsidy for the officer to live in California. This loan is classified as Other Assets on the balance sheet at December 31, 2001.

We also have loans to four senior managers in the amount of \$482,698 with interest rates from 4.83% to 10%. These loans were granted in connection with housing subsidies for the individuals to live in California. These loans are classified as Other Assets on the balance sheet at December 31, 2001.

19. QUARTERLY FINANCIAL DATA (UNAUDITED)

The following tables summarize the quarterly financial data for the last two fiscal years:

	FISCAL 2001 QUARTER ENDED			
	MARCH 31,	JUNE 30,	SEPTEMBER 30,	DECEMBER 31,
(IN THOUSANDS, EXCEPT PER SHARE DATA)				
Total revenues.....	\$11,943	\$ 5,241	\$ 19,614	\$ 10,547
Loss from operations.....	(4,017)	(18,121)	(12,869)	(30,169)
Net loss.....	(4,223)	(18,273)	(11,167)	(28,834)
Basic and diluted net loss per share.....	\$ (0.11)	\$ (0.46)	\$ (0.25)	\$ (0.63)
	FISCAL 2000 QUARTER ENDED			
	MARCH 31,	JUNE 30,	SEPTEMBER 30,	DECEMBER 31,
(IN THOUSANDS, EXCEPT PER SHARE DATA)				
Total revenues.....	\$ 3,225	\$ 3,066	\$ 2,816	\$ 3,517
Loss from operations.....	(9,535)	(9,991)	(10,374)	(12,472)
Net loss.....	(9,525)	(10,309)	(10,484)	(12,204)
Basic and diluted net loss per share.....	\$ (0.25)	\$ (0.27)	\$ (0.28)	\$ (0.32)

Edgar Filing: SCIOS INC - Form 10-K

F-23

EXHIBIT INDEX

EXHIBIT  
NUMBER  
-----

3.1	Certificate of Incorporation.....
3.1(a)	Certificate of Amendment of Certificate of Incorporation.....
3.2	Bylaws.....
4.1	Certificate of Designation of Series B Preferred Stock of Scios Inc.....
4.2	For a discussion of certain registration rights in favor of Genetech, Inc., see Exhibit and 10.41.....
10.1	Biotechnology Research Partners, Ltd. Agreement of Limited Partnership dated October 29 Development Contract, Technology License Agreement and Joint Venture Agreement between Biotechnology Research Partners, Ltd. and the Registrant dated December 29, 1982; Promi Note dated December 29, 1982; and Memorandum of Understanding between Battery Park Cred Company and Biotechnology Research Partners, Ltd. dated December 28, 1982.....
10.2*	1983 Incentive Stock Option Plan, as amended, and form of Stock Option Agreement, Promi Note and Pledge Agreement.....
10.3	Common Stock Purchase Agreement dated April 15, 1985 between the Registrant and America Home Products Corporation.....
10.5*	1986 Supplemental Stock Option Plan, as amended, and form of Stock Option Agreement, Promissory Note and Pledge Agreement.....
10.6	Rights Exercise Agreement between the Registrant and American Home Products Corporation February 28, 1986 and Letter of March 26 and May 16, 1986.....
10.11*	1992 Equity Incentive Plan.....
10.18	Form of Purchase Option Agreement between each of the limited partners of Nova Technolo Limited Partnership and Nova.....
10.19*	Non employee Director Stock Option Plan.....
10.29	CNS Psychiatric Products Agreement dated June 30, 1990 between SmithKline Beecham Corporation and Nova.....
10.33	Preferred Stock Purchase Agreement dated December 30, 1994 between the Registrant and Genentech, Inc.....
10.34	Note Agreement dated December 30, 1994 between the Registrant and Genentech, Inc. (See Number 10.41 below amending the Note Agreement).....
10.35	Assignment of Lease dated March 22, 1995 for premises located at 820 West Maude Avenue, Sunnyvale, California.....
10.38*	Employment Letter dated September 8, 1998 between the Registrant and Richard B. Brewer.

Edgar Filing: SCIOS INC - Form 10-K

- 10.39 Purchase and Sale Agreement and Joint Escrow Instructions (Mountain View Real Estate Sale Agreement dated May 24, 1999 between Alexandria Real Estate Equities, Inc. and Registrant's wholly owned subsidiary Bio-Shore Holdings, Ltd. Portions of the exhibit have been omitted pursuant to a request for confidential treatment.....
- 10.41 First Amendment to Note Agreement and Preferred Stock dated November 3, 1999 between the Registrant and Genentech, Inc. (See Exhibit 10.34 above).....
- 10.42 Promissory Note dated December 27, 1999 by the Registrant to Chiron Corporation.....
- 10.43\* Change of Control Severance Plans with Employees, Officers and Chief Executive Officer.....
- 10.44 Alliance Agreement dated January 10, 2001 between the Registrant, Innovex L.P. and PharmaBio Development Inc. (including a Warrant Agreement between the Registrant and PharmaBio Development Inc. attached thereto as Exhibit B). Portions of the exhibit have been granted confidential treatment.....

EXHIBIT  
NUMBER  
-----

- 10.45 Amendment No. 4 to Lease dated January 22, 1993 for the premises located at 820 West Maude Avenue, Sunnyvale, California (See Exhibit 10.35 above).....
- 10.46 Lease Agreement dated November 17, 1995 for premises located at 820 West Maude Avenue, Sunnyvale, California.....
- 10.47 Sublease Agreement dated March 24, 1999 for premises located at 749 North Mary Avenue, Sunnyvale, California.....
- 10.48 First Amendment dated May 28, 2001 to Sublease dated May 24, 1999 for premises located at 749 North Mary Avenue, 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 West Maude Avenue Sunnyvale, California.....
- 10.51 Amended and Restated Alliance Agreement dated November 1, 2001 between the Registrant, Innovex L.P., Innovex Support Services Limited Partnership and PharmaBio Development Inc. (including a Warrant Agreement between the Registrant and PharmaBio Development Inc. attached thereto as Exhibit B). Portions of the exhibit have been omitted pursuant to a request for confidential treatment.....
- 10.52 Binding Summary of Terms between the Registrant and Glaxo Group Ltd. dated December 20, 2000. Portions of the exhibit have been omitted pursuant to a request for confidential treatment.....
- 21.2 Subsidiaries of the Registrant.....
- 23.1 Consent of PricewaterhouseCoopers LLP.....
- 24.1 Powers of Attorney. Reference is made to page 35.....

-----



## Edgar Filing: SCIOS INC - Form 10-K

- \* Management contract or compensatory plan or arrangement.
- A Filed as an exhibit to Form S-1 Registration Statement (File No. 2-86086), as amended, and incorporated herein by reference.
- B Filed as an exhibit to Form S-1 Registration Statement (File No. 33-3186), as amended, and incorporated herein by reference.
- E Filed as an exhibit to Annual Report on Form 10-K for fiscal year 1988 and incorporated herein by reference.
- G Filed as an exhibit to Form S-8 Registration Statement (File No. 33-39878) filed on April 8, 1991 and incorporated herein by reference.
- H Filed as an exhibit to Annual Report on Form 10-K for fiscal year 1991 and incorporated herein by reference.
- I Filed as an exhibit to Form S-1 Registration Statement (File No. 33-14937) filed on behalf of Nova Technology Limited Partnership and incorporated herein by reference.
- J Filed as an exhibit to Form S-4 Registration Statement (File No. 33-49846) filed on July 22, 1992 and incorporated herein by reference.
- N Filed as an exhibit to Nova's Annual Report on Form 10-K for fiscal year 1990 and incorporated herein by reference.
- Q Filed as an exhibit to Annual Report on Form 10-K for fiscal year 1994 and incorporated herein by reference.
- R Filed as an exhibit to Quarterly Report on Form 10-Q for quarter ended March 31, 1995 and incorporated herein by reference.
- T Filed as an exhibit to Annual Report on Form 10-K for fiscal year 1998 and incorporated herein by reference.
- U Filed as an exhibit to Quarterly Report on Form 10-Q for the quarter ended September 30, 1999 and incorporated herein by reference.
- V Filed as an exhibit to Annual Report on Form 10-K for fiscal year 1999 and incorporated herein by reference.
- W Filed as an exhibit to Report on Form 8-K dated January 24, 2000 and incorporated herein by reference.
- Y Filed as an exhibit to Annual Report on Form 10-K for fiscal year 2000 and incorporated herein by reference.
- Z Filed as an exhibit to Annual Report on Form 10-K/A (Amendment No. 2) for fiscal year 2000 and incorporated herein by reference.
- aa Filed as an exhibit to Quarterly Report on Form 10-Q for the quarter ended September 30, 2001 and incorporated herein by reference.