SCIOS INC
Form 10-K
March 15, 2002

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark One)

[X] 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 [X] 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

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

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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. 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

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

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

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 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 May 2001, we expanded our existing research collaboration with Medtronic to initiate a clinical study to evaluate the hemodynamic, endrocrine and clinical effects of Natrecor using information collected by Medtronic's Chronicle Implantable Hemodynamic Monitor both during and after infusions of Natrecor. 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 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 plan to launch Natrecor 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 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.

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

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;

.. 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

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

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 arrythmias 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

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.

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,

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.

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

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

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.

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

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

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

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

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

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

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 Biodel 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 Biodel 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

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

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

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 Natrecor, 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 Natrecor, human BNP. Our U.S. patents on Natrecor are subject to possible extension due to time taken up in the regulatory approval process. We believe our key patent on Natrecor, 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.

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

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. Natrecor, 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. Natrecor has been priced above the cost of these existing drugs, which may harm

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.

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 injectible 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.

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.

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

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.

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.

Natrecor 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 Natrecor and its potential advantages over other treatments. The degree of market acceptance of Natrecor will also depend on a number of factors, including:

.. the degree of clinical efficacy and safety;

.. cost-effectiveness of Natrecor;

.. its advantage over alternative treatment methods; and

.. reimbursement policies of government and third party payers.

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

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

Periodically, the FDA is likely to inspect each of the facilities involved in manufacturing Natrecor. Natrecor is manufactured for us by BioChemie GmbH, a subsidiary of Novartis, in Austria and is shipped 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.

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

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

ability to effectively market and sell Natrecor.

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.

OUR OPERATING RESULTS ARE SUBJECT TO FLUCTUATIONS THAT MAY CAUSE OUR STOCK PRICE TO DECLINE.

Our revenues and expenses have fluctuated significantly in the past. This fluctuation has in turn caused our operating results to vary significantly from quarter to quarter and year to year. We expect the fluctuations in our revenues and expenses to continue, and thus, our operating results should also continue to vary significantly. These fluctuations may be due to a variety of factors including:

.. our success in selling Natrecor;

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

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

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

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

WE DEPEND ON OUR KEY PERSONNEL AND WE MUST CONTINUE TO ATTRACT AND RETAIN KEY EMPLOYEES AND CONSULTANTS.

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

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.

OUR PRODUCTS USE NOVEL ALTERNATIVE TECHNOLOGIES AND THERAPEUTIC APPROACHES, WHICH HAVE NOT BEEN WIDELY STUDIED.

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

RAPID CHANGES IN TECHNOLOGY AND INDUSTRY STANDARDS COULD RENDER OUR POTENTIAL PRODUCTS UNMARKETABLE.

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

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

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

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

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

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

.. devote greater resources to market or sell their products;

.. adapt more quickly to new technologies and scientific advances;

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

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

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

.. take advantage of acquisition or other opportunities more readily than we can.

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

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

IF WE ARE UNABLE TO PROTECT OUR INTELLECTUAL PROPERTY RIGHTS ADEQUATELY, THE VALUE OF OUR POTENTIAL PRODUCTS COULD BE DIMINISHED.

Our success is dependent in part on obtaining, maintaining and enforcing our patents and other proprietary rights. Patent law relating to the scope of claims in the biotechnology field in which we operate is still evolving and surrounded by a great deal of uncertainty. Accordingly, we cannot assure you that our pending patent applications will result in issued patents. Because certain U.S. patent applications may be maintained in secrecy until a patent issues, we cannot assure you that others have not filed patent applications for technology covered by our pending applications or that we were the first to invent the technology.

Other companies, universities and research institutions have or may obtain patents and patent applications that could limit our ability to use, manufacture, market or sell our product candidates or impair our competitive position. As a result, we may have to obtain licenses from other parties before we could continue using, manufacturing, marketing or selling our potential products. Any such licenses may not be available on commercially acceptable terms, if at all. If we do not obtain required licenses, we may not be able to market our potential products at all or we may encounter significant delays in product development while we redesign potentially infringing products or methods.

In addition, although we own a number of patents, including issued patents and patent applications relating to 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

relationship with us. However, these agreements may not provide effective protection of our technology or information or, in the event of unauthorized use or disclosure, they may not provide adequate remedies.

IF WE FAIL TO NEGOTIATE OR MAINTAIN SUCCESSFUL ARRANGEMENTS WITH THIRD PARTIES, OUR DEVELOPMENT AND MARKETING ACTIVITIES MAY BE DELAYED OR REDUCED.

We have entered into, and we expect to enter into in the future, arrangements with third parties to perform research, development, regulatory compliance, manufacturing or marketing activities relating to some or all of our product candidates. If we fail to secure or maintain successful collaborative arrangements, our development and marketing activities may be delayed or reduced. We may be unable to negotiate favorable collaborative arrangements that, if necessary, modify our existing arrangements on acceptable terms. Most of our agreements can be terminated under certain conditions by our partners. In addition, our partners may separately pursue competing products, therapeutic approaches or technologies to develop treatments for the diseases targeted by us or our efforts. Even if our partners continue their contributions to the collaborative arrangements, they may nevertheless determine not to actively pursue the development or commercialization of any resulting products. Also, our partners may fail to perform their obligations under the collaborative arrangements or may be slow in performing their obligations. In these circumstances, our ability to develop and market potential products could be severely limited.

RISKS RELATED TO OUR INDUSTRY

WE FACE UNCERTAINTIES OVER REIMBURSEMENT AND HEALTHCARE REFORM.

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

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

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

available to us on acceptable terms.

WE USE HAZARDOUS MATERIALS IN OUR BUSINESS, AND ANY CLAIMS RELATING TO IMPROPER HANDLING STORAGE OR DISPOSAL OF THESE MATERIALS COULD HARM OUR BUSINESS.

Our research and development activities involve the controlled use of hazardous materials, chemicals, biological agents and radioactive compounds. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by such laws and regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any resulting damages, and any such liability could exceed our resources. We may be required to incur significant costs to comply with these laws in the future. Failure to comply with these laws could result in fines and the revocation of permits, which could prevent us from conducting our business.

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

.. 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

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.

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 Of
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

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, Cardiorenal 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

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

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,

STATEMENT OF OPERATIONS DATA:	2001	2000	1999	1998	1997
	(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,				
BALANCE SHEET DATA:	2001	2000	1999	1998	1997
	(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

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(1)as reclassified for EITF 99-19

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

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

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