

SCIOS INC
Form S-3/A
November 15, 2002
Table of Contents

As filed with the Securities and Exchange Commission on November 14, 2002

Registration No. 333-99641

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

AMENDMENT NO. 2
TO
FORM S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

SCIOS INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of Incorporation or Organization)

95-3701481
(I.R.S. Employer Identification Number)

820 West Maude Avenue
Sunnyvale, CA 94085 (408) 616-8200
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

MATTHEW R. HOOPER, ESQ.
Vice President, General Counsel and Secretary
820 West Maude Avenue
Sunnyvale, CA 94085
(408) 616-8200
(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent For Service)

Copy To:

KIMBERLY WILKINSON, ESQ.
Latham & Watkins
505 Montgomery Street, Suite 1900
San Francisco, California 94111
(415) 391-0600

Approximate date of commencement of proposed sale to the public: From time to time after this registration statement becomes effective.

Edgar Filing: SCIOS INC - Form S-3/A

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. _____

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

Table of Contents

The information in this prospectus is incomplete and may be changed. The selling securityholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED NOVEMBER 14, 2002

PROSPECTUS

\$150,000,000

Scios Inc.

**5.50% Convertible Subordinated Notes Due 2009
Shares of Common Stock Issuable Upon Conversion of the Notes**

In August 2002, we issued and sold \$150,000,000 aggregate principal amount of our 5.50% Convertible Subordinated Notes due 2009 in a private offering. This prospectus will be used by selling securityholders to resell the notes and the common stock issuable upon conversion of the notes. Holders may convert the notes into our common stock at any time through maturity, at a conversion price of \$39.30 per share, subject to adjustment in specified events. We will pay interest on the notes each February 15 and August 15 to the holders of record on each February 1 and August 1. The first interest payment will be made on February 15, 2003.

We may redeem some or all of the notes on or after August 19, 2005 at the redemption prices listed in this prospectus, plus accrued interest. You may require us to repurchase your notes upon a change in control, at our option, in cash, common stock or a combination thereof, at 100% of the principal amount of the notes to be purchased, plus accrued and unpaid interest to, but excluding, the purchase date.

We have pledged a portfolio of U.S. government securities as security for the first six scheduled interest payments due on the notes.

The notes will not be listed on any national securities exchange. Our common stock is quoted on the Nasdaq National Market under the symbol SCIO. On November 13, 2002, the last reported sale price of our common stock on the Nasdaq National Market was \$29.88 per share.

We will not receive any proceeds from the sale by the selling securityholders of the notes or the common stock issuable upon conversion of the notes. Other than selling commissions and fees and stock transfer taxes, we will pay all expenses of the registration and sale of the notes and the common stock.

Investing in the notes involves risk. See Risk Factors beginning on page 4 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is _____, 2002

Table of Contents**TABLE OF CONTENTS**

	Page
<u>PROSPECTUS SUMMARY</u>	1
<u>RISK FACTORS</u>	4
<u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	15
<u>USE OF PROCEEDS</u>	16
<u>PRICE RANGE OF COMMON STOCK AND DIVIDEND POLICY</u>	16
<u>RATIO OF EARNINGS TO FIXED CHARGES</u>	16
<u>BUSINESS</u>	17
<u>MANAGEMENT</u>	35
<u>DESCRIPTION OF NOTES</u>	39
<u>DESCRIPTION OF CAPITAL STOCK</u>	54
<u>SELLING SECURITYHOLDERS</u>	57
<u>PLAN OF DISTRIBUTION</u>	60
<u>MATERIAL UNITED STATES FEDERAL INCOME TAX CONSEQUENCES</u>	62
<u>LEGAL MATTERS</u>	68
<u>EXPERTS</u>	68
<u>INCORPORATION BY REFERENCE</u>	68
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	68

You should rely only on the information contained or incorporated by reference in this prospectus. We have not authorized anyone to provide you with different information. You should not assume that the information contained or incorporated by reference in this prospectus is accurate as of any date other than the date of this prospectus. We are not making an offer of these securities in any state where the offer is not permitted.

Table of Contents

PROSPECTUS SUMMARY

This summary highlights some information contained or incorporated by reference in this prospectus. It may not contain all of the information that is important to you. Important information is incorporated by reference into this prospectus. To understand this offering fully, you should read the entire prospectus carefully, including the Risk factors section and the documents we have referred you to. References in this prospectus to us, we, the Company or Scios refer to Scios Inc., the issuer of the notes, and its subsidiaries.

Scios Inc.

We are a biopharmaceutical company that discovers, develops and markets novel treatments for cardiovascular and inflammatory diseases. On August 13, 2001, we launched Natrecor following FDA approval of Natrecor for the treatment of acutely decompensated congestive heart failure. In addition to Natrecor, we have two focused product programs, p38 kinase and TGF-beta. Our first program is directed to the development of inhibitors of p38 kinase, an enzyme responsible for increased production of various proteins that cause inflammation. SCIO-469, our first compound designed to inhibit this enzyme, is targeted for the treatment of rheumatoid arthritis and is currently in clinical development. Our second product program is directed to the development of inhibitors of TGF-beta, a signaling protein that is implicated in a broad range of diseases characterized by unregulated scarring and eventual organ failure. We are currently in preclinical development for compounds designed to inhibit this protein. In July 2002, we announced that the lead indication for these compounds will be chronic obstructive pulmonary disease.

We operate in an industry that is characterized by long product development cycles, which require substantial amount of capital to be invested in research and development. We had net losses of \$69.6 million for the nine months ended September 30, 2002, and as of September 30, 2002, we had an accumulated deficit of approximately \$543.5 million.

You should read the Risk Factors section beginning on page 4 of this prospectus to ensure that you understand the risks associated with an investment in the notes or the common stock issuable upon conversion of the notes.

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. Our principal executive offices are located at 820 West Maude Avenue, Sunnyvale, California 94085. Our telephone number is (408) 616-8200.

Our website is located at www.sciosinc.com. Information contained on our website does not constitute part of this prospectus.

We own various copyrights, trademarks and trade names used in our business including the following: Natrecor[®] and Fibblast[®]. This prospectus also includes trademarks, service marks and trade names of other companies, including the following: Veletri, BIOYPASS[®], Gliadel[®], Bidel[®], Enbrel[®], Remicade[®], Celebrex[®], Vioxx[®], Simdax[®], Eskalith[®], Eskalith CR[®], Stelazine[®], Thorazine[®], Parnate[®] and Kineret[®].

Table of Contents

THE NOTES

Issuer	Scios Inc.
Securities offered	\$150,000,000 aggregate principal amount of 5.50% Convertible Subordinated Notes due 2009.
Interest	5.50% per annum on the principal amount, payable semiannually in arrears in cash on February 15 and August 15 of each year, commencing February 15, 2003. The first interest payment will include interest from August 5, 2002, the closing date.
Maturity date	August 15, 2009.
Conversion rights	The notes are convertible into common stock at the option of the holder at any time prior to redemption, repurchase or maturity at a conversion price of \$39.30 per share, subject to adjustments in specified events. See Description of notes Conversion of the notes.
Security	We have purchased and pledged to the trustee under the indenture, as security for the benefit of the trustee under the indenture and the ratable benefit of the holders of the notes, approximately \$24.0 million of U.S. government securities, which will be sufficient upon receipt of scheduled principal and interest payments thereon, to provide for the payment in full of the first six scheduled interest payments due on the notes. The notes are not otherwise secured. See Description of notes Security.
Ranking	The notes (other than with respect to payments made toward the first six scheduled interest payments due on the notes, as described above under Security) are subordinated in right of payment to all existing and future senior indebtedness of Scios Inc. and are structurally subordinated to any indebtedness and other liabilities (including trade and other payables) of our subsidiaries. As of September 30, 2002, we had approximately \$28.3 million of indebtedness that constituted senior indebtedness, no indebtedness that ranked equal in right of payment to the notes and no indebtedness at our subsidiaries that would have been structurally senior to the notes. The indenture governing the notes does not limit the amount of indebtedness, including senior indebtedness, that we or our subsidiaries may incur. See Description of notes Subordination of the notes.
Optional redemption	At any time on or after August 19, 2005, we may redeem some or all of the notes at the declining redemption prices listed herein, plus accrued interest. See Description of notes Optional redemption by Scios.
Repurchase at holder's option	You may require us to repurchase your notes upon a change in control in cash, or at our option in shares of common stock, or a combination

Table of Contents

thereof, at 100% of the principal amount of the notes plus accrued and unpaid interest to, but excluding, the repurchase date. The number of shares of common stock will be equal to the repurchase price (to the extent not paid in cash) divided by 95% of the average closing sales prices of our common stock for the five trading day period immediately preceding and including the third trading day preceding the repurchase date. We may not have sufficient funds to pay the purchase price for all duly tendered notes upon a change in control.

Sinking fund

None.

Use of proceeds

The selling securityholders will receive all of the proceeds from the sale under this prospectus of the notes and the common stock issuable upon conversion of the notes. We will not receive any proceeds from these sales.

Nasdaq National Market symbol for common stock

SCIO

Trading

The notes are not listed on any national securities exchange.

Table of Contents

RISK FACTORS

You should consider the risk factors below as well as the other information set forth or incorporated by reference in this prospectus. If any of the following risks actually occur, our business, financial condition or results of operations could be materially and adversely affected. In such case, our ability to make payments on the notes could be impaired, the trading prices of the notes and our common stock would decline, and you could lose all or part of your investment. Please read Special note regarding forward-looking statements.

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

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

- sales of Natrecor beginning in August 2001;
- one-time sales of bulk FGF product and royalties from Fiblast Spray sales by Kaken in Japan;
- one-time signing fees from our corporate partners under agreements supporting the research, development and commercialization of our product candidates;
- one-time payments from our corporate partners when we achieved regulatory or development milestones;
- research funding from our corporate partners; and
- our psychiatric sales and marketing division, the operations of which we dissolved on March 31, 2001.

We expect that our research, development and clinical trial activities and regulatory approvals, together with future general and administrative activities and the costs associated with launching and commercializing our product candidates and commercializing Natrecor in the United States will result in significant expenses for the foreseeable future.

If we fail to obtain additional capital necessary to fund our operations, we may have to delay or scale back some of our programs or grant rights to third parties to develop and market our products.

We will continue to expend substantial resources developing new and existing product candidates, including costs associated with research and development, acquiring new technologies, conducting preclinical studies and clinical trials, obtaining regulatory approvals and manufacturing products. We believe that our current working capital, revenues from Natrecor sales and future payments, if any, from our collaboration arrangements will be sufficient to meet our operating and capital requirements for at least the next twelve months. Our need for additional funding depends on a number of factors including:

- costs and rate of progress expected in developing product candidates and obtaining regulatory approvals;
- costs of obtaining regulatory approvals or market acceptance for Natrecor in markets other than the United States and for additional indications in the United States;
- acquisition of technologies and other business opportunities that require financial commitments; or
- revenues from the commercialization of Natrecor and any other potential products.

Table of Contents

If Natrecor does not continue to gain market acceptance, our business will suffer.

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

- the degree of clinical efficacy and safety;
- cost-effectiveness of Natrecor;
- its advantage over alternative treatment methods;
- reimbursement policies of government and third party payers; and
- future approval of competitive drugs which work better or are safer.

Sales of Natrecor represented approximately 96% of our revenues for the nine months ended September 30, 2002. Natrecor is the only product that we are currently marketing and our other product candidates are only in early stages of development. If market acceptance of Natrecor is limited, our revenues will suffer and we may not generate sufficient funds to meet our operating and capital requirements.

If the FDA determines that our third-party manufacturing facilities are not adequate, we may lose the ability to manufacture and sell Natrecor.

Periodically, the FDA is likely to inspect each of the facilities involved in manufacturing Natrecor. Natrecor bulk active pharmaceutical ingredient is manufactured for us by BioChemie GmbH, a subsidiary of Novartis, in Austria and is shipped to Abbott Laboratories in McPherson, Kansas where it is blended, filled and packaged for shipment. Although each facility has previously passed FDA inspections, future inspections may result in findings of deficiencies in the facilities or processes that may delay or prevent the manufacture or sale of Natrecor. If deficiencies are identified, we may lose the ability to supply and sell Natrecor for extended periods of time.

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

We rely on third parties for the manufacture of Natrecor bulk drug substance and final drug product for clinical and commercial use. BioChemie GmbH is responsible for manufacturing the bulk active pharmaceutical ingredient of Natrecor and Abbott Laboratories is responsible for blending, filling and packaging Natrecor, and if they encounter problems in these processes, our revenues from future sales of Natrecor could decrease. In addition, we understand that Abbott Laboratories is in late stage clinical trials for Simdax, which if approved, would compete with Natrecor for the treatment of acute congestive heart failure. Natrecor is manufactured using industry-accepted recombinant manufacturing techniques, which uses genetically engineered bacteria to produce a desired protein product. Although the use of genetically engineered bacteria has been approved for production of many other medicines, it must be conducted under strict controls and tight timelines. Natrecor is subject to strict quality control testing during all phases of production and prior to its release to the market. Any quality control testing failures could lead to a reduction in the available supply of Natrecor. BioChemie depends on outside vendors for the timely supply of raw materials used to produce Natrecor. In the event BioChemie needs to change or add an outside vendor, a regulatory filing may be necessary. The filing and approval process for the new vendor may take substantial time. We depend on these third parties to perform their obligations effectively and on a timely basis. If these third parties fail to perform as required, our ability to deliver Natrecor on a timely basis would be impaired. In addition, in the event of a natural disaster, equipment failure, power failure, strike or other difficulty, we may be unable to replace our third-party manufacturers in a timely manner and would be unable to manufacture Natrecor to meet market needs.

Table of Contents

From time to time changes will be made in the process used by BioChemie to manufacture the bulk active pharmaceutical ingredient used in Natrecor or in the process used by Abbott to blend, fill and package the final drug product. Depending on the extent of these changes, we may need to obtain prior approval from the FDA to sell Natrecor that was manufactured or blended using the changed processes, and if such approval is denied or delayed, our ability to deliver Natrecor could be impaired. We believe that changes made by BioChemie in 2002 to the process for manufacturing the bulk active pharmaceutical ingredient may require us to obtain prior approval from the FDA to sell Natrecor incorporating the bulk active pharmaceutical ingredient manufactured after those changes were made.

In the area of acute congestive heart failure, we face competition from companies with substantial financial, technical and marketing resources, which could limit our future revenues from Natrecor.

Many therapeutic options are available for patients with acute congestive heart failure. Competing drugs fall into three main categories: vasodilators, inotropes and diuretics. Natrecor competes against both vasodilators and inotropes in the acute congestive heart failure market. Many of these drugs are available in generic formulation with an associated low cost. We may not be able to compete effectively with these long-standing current forms of therapy. In addition, Natrecor costs more than many of these existing drugs, which may harm our competitive position relative to these drugs.

New drugs in development for the treatment of acute congestive heart failure would also compete with Natrecor if approved by the FDA or other regulatory agencies. Veletri, a drug which targets both receptors of endothelin, a naturally occurring hormone thought to be damaging to the heart during congestive heart failure, is being developed by Actelion Ltd. Actelion recently completed Phase II clinical trials with Veletri for the treatment of acute congestive heart failure. Based on the results of the Phase II clinical trials, Actelion announced in September 2002 that it intends to proceed with a Phase III trial with Veletri to evaluate mortality and morbidity benefits.

In addition, we understand that Abbott is in Phase III development of Simdax, which is thought to work by increasing the sensitivity of the heart to calcium and thereby stimulate its ability to contract during congestive heart failure. If any such new drug in development is approved by the FDA or other regulatory agencies, we may not be able to compete effectively with these new forms of therapy.

Many other companies are targeting the same diseases and conditions as we are. Competitive products from other companies could significantly reduce the market acceptance of our products.

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

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

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

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

devote greater resources to market or sell their products;

adapt more quickly to new technologies and scientific advances;

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

Table of Contents

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

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

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

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

We are aware of several pharmaceutical and biotechnology companies that are actively developing or have commercialized products addressing the same disease indication as our p38 kinase inhibitor. Current commercial competition for rheumatoid arthritis treatments include generic methotrexate, the injectible TNF inhibitors such as Centocor's Remicade (Centocor is a subsidiary of Johnson & Johnson) and Amgen's Enbrel and their recent launch of an injectible interleukin-1 inhibitor, Kineret. In addition, competition will result from the most often prescribed drugs to treat rheumatoid arthritis, including the non-steroidal antiinflammatory drugs such as ibuprofen and the COX-2 inhibitors such as Pharmacia's Celebrex and Merck's Vioxx.

In addition, we are aware of pharmaceutical and biotechnology companies that are specifically developing p38 kinase inhibitors for treating rheumatoid arthritis, including Boehringer Ingelheim and Vertex Pharmaceuticals. In 2001, Vertex Pharmaceuticals suspended the development of its lead oral p38 kinase inhibitor compound indicated for rheumatoid arthritis, but initiated clinical trials with two back-up compounds during 2002. Phase I trials for their lead back-up p38 kinase inhibitor are expected to be completed in 2003. Boehringer Ingelheim is currently in Phase II trials with their lead p38 kinase inhibitor in Europe for the treatment of rheumatoid arthritis.

If we fail to gain approval for Natrecor and our other product candidates in international markets, our market opportunities will be limited.

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

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

In March 2002, we entered into an agreement with Glaxo Group Ltd., an affiliate of GlaxoSmithKline, in all European markets. Under the terms of the agreement, Glaxo Group Ltd. has the rights to sell and distribute Natrecor for which we have received an up-front fee and may receive milestone payments, in addition to future royalties on net sales of Natrecor in the identified European markets. Accordingly, our revenue from sales of Natrecor in Europe will be highly dependent on Glaxo Group Ltd.'s ability to effectively market and sell Natrecor. We will be responsible for the manufacture and supply of bulk active pharmaceutical ingredient to Glaxo Group Ltd.

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

Table of Contents

approvals, Glaxo Group Ltd. expects to launch Natrecor in Europe in 2004. However, while the clinical data used to support the FDA submission are expected to be adequate for European approval, further clinical trials may be necessary and adverse results from such additional trials could result in a failure to receive European approval. Even if additional trials are successful, a requirement to conduct further clinical trials would delay the launch of Natrecor in Europe, which may result in lower than anticipated revenues.

The companies intend to conduct a health outcomes trial, commencing in 2003, which the companies hope to use to enhance market acceptance of Natrecor in major European countries. The health outcomes trial could affect the price at which Natrecor will be sold. We cannot assure you that a preferred price for Natrecor will be obtained and that market acceptance of Natrecor will be achieved.

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

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

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

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

Our operating results are subject to fluctuations that may cause our stock price to decline.

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

- our success in selling Natrecor;
- the timing and realization of milestone and other payments from our corporate partners;
- the timing and amount of expenses relating to our research and development, product development and manufacturing activities; and
- the extent and timing of costs related to our activities to obtain patents on our inventions and to extend, enforce and/or defend our patents and other rights to our intellectual property.

Because of these fluctuations, it is possible that our operating results for a particular quarter or quarters will not meet the expectations of public market analysts and investors, causing the market price of our common stock

Table of Contents

to decline. We believe that period-to-period comparisons of our operating results are not a good indication of our future performance, and you should not rely on those comparisons to predict our future operating or share price performance.

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

While we are not dependent upon any one key employee, the loss of a significant number of scientific, clinical research or management personnel could harm our business. Our ability to pursue the development of our current and future product candidates depends largely on retaining the services of our existing personnel and hiring additional qualified scientific personnel to perform research and development. We also rely on personnel with expertise in clinical testing, government regulation, manufacturing, sales and marketing. Attracting and retaining qualified personnel will be critical to our success. We may not be able to attract and retain personnel on acceptable terms given the competition for such personnel among biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions. Failure to retain our key scientific personnel or to attract additional highly qualified personnel could delay the development of our product candidates and harm our business. In addition, other than with Richard Brewer, our President and Chief Executive Officer, we do not have employment agreements with any of our key employees, and we do not have key person insurance policies with any of our key employees.

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

We face the risk of failure normally found in developing biotechnology products based on new technologies. Successfully developing, manufacturing, introducing and marketing our early-stage product candidates, including SCIO-469 and our inhibitors of TGF-beta, will require at least several years and substantial additional capital.

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

We cannot assure you that we will receive the regulatory approvals necessary to commercialize our product candidates, which could cause our business to fail. Our product candidates are subject to extensive and rigorous government regulation by the FDA and comparable agencies in other countries. The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertising, promotion, sale and distribution of biopharmaceutical products. If our potential products are marketed abroad, they will also be subject to extensive regulation by foreign governments. In addition, we have only limited experience in filing and pursuing applications necessary to gain regulatory approvals, which may impede our ability to obtain such approvals.

The results of preclinical studies and clinical trials of our products may not be favorable.

In order to obtain regulatory approval for the commercial sale of any of our product candidates, we must conduct both preclinical studies and human clinical trials. These studies and trials must demonstrate that the product is safe and effective for the clinical use for which we are seeking approval. In the first quarter of 2002, we began Phase IIa clinical trials of our lead p38 kinase inhibitor small molecule compound. The results of these or other clinical trials that we may conduct in the future may not be successful. Adverse results from our current or any future trials would harm our business. We also face the risk that we will not be permitted to undertake or continue clinical trials for any of our product candidates in the future. Even if we are able to conduct such trials, we may not be able to satisfactorily demonstrate that the products are safe and effective and thus qualify for the regulatory approvals needed to market and sell them. Results from preclinical studies and early clinical trials are often not accurate indicators of results of later-stage clinical trials that involve larger human populations.

Table of Contents

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

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

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

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

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

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

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

In addition, although we own a number of patents, including issued patents and patent applications relating to Natrecor and certain of our p38 kinase and TGF-beta inhibitors, the issuance of a patent is not conclusive as to its validity or enforceability, and third parties may challenge the validity or enforceability of our patents. We cannot assure you how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court or in other proceedings. It is possible that a competitor may successfully challenge our patents or that challenges will result in limitations of their coverage. In addition, the cost of litigation to uphold the validity of patents can be substantial. If we are unsuccessful in such litigation, third parties may be able to use our patented technologies without paying licensing fees or royalties to us.

Moreover, competitors may infringe our patents or successfully avoid them through design innovation. To prevent infringement or unauthorized use, we may need to file infringement claims, which are expensive and time consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or may refuse to stop the other party from using the technology at issue on the grounds that its technology is not covered by our patents. Policing unauthorized use of our intellectual property is difficult, and we cannot assure you that we will be able to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Table of Contents

In addition to our patented technology, we also rely on unpatented technology, trade secrets and confidential information. We may not be able to effectively protect our rights to this technology or information. Other parties may independently develop substantially equivalent information and techniques or otherwise gain access to or disclose our technology. We require each of our employees, consultants and corporate partners to execute a confidentiality agreement at the commencement of an employment, consulting or collaborative relationship with us. However, these agreements may not provide effective protection of our technology or information or, in the event of unauthorized use or disclosure, they may not provide adequate remedies.

If we fail to negotiate or maintain successful arrangements with third parties, our development and marketing activities may be delayed or reduced.

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

We face uncertainties over reimbursement and healthcare reform.

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

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

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

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

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

Table of Contents

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

We are at risk of securities class action litigation.

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

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

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

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

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

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

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

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

Some of the above provisions may also have possible anti-takeover effects, which may make an acquisition of us by a third party more difficult, even if such an acquisition could be beneficial to our stockholders. In addition, our certificate of incorporation also authorizes us to issue up to 20,000,000 shares of preferred stock in one or more different series with terms to be determined by our board of directors at time of issuance. As of September 30, 2002, an aggregate of 71,053 shares of preferred stock had been designated for issuance as Series A or Series B preferred stock by the board of directors and 4,991 shares of Series B preferred stock were issued and outstanding. Issuance of other shares of preferred stock could also be used as an anti-takeover device.

Risks related to this offering

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

At September 30, 2002, we had total indebtedness of \$179.5 million, including \$150.0 million of indebtedness under the notes. This significant indebtedness could have important consequences to you. For example, it could:

increase our vulnerability to general adverse economic and industry conditions;

Table of Contents

require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, thereby reducing the availability of our cash flow to fund working capital, capital expenditures and other general corporate purposes;

limit our flexibility in reacting to changes in our business and the industry in which we operate;

place us at a competitive disadvantage compared with our competitors that have less debt; and

limit, among other things, our ability to raise or borrow additional funds.

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

Our stock price continues to experience large fluctuations, which may adversely impact your investment in the notes or our common stock.

The market price of our common stock has been and is likely to continue to be highly volatile. From October 1, 2000 through November 13, 2002, the reported sales price of our common stock has fluctuated between \$8.75 per share and \$32.98 per share, closing at \$29.88 per share on November 13, 2002. Fluctuations in the trading price of our common stock will affect the trading price of the notes. 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 or debt securities;

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.

These and other conditions and factors that generally affect the market for shares of similar companies could cause the price of our common stock, and therefore the price of the notes, to fluctuate substantially over short periods.

The notes are subordinated, and holders of any senior indebtedness will be paid before holders of the notes are paid.

Except as described below in the section entitled "Description of notes - Security," the notes are unsecured and subordinated in right of payment to any existing and future senior indebtedness. As of September 30, 2002, we had approximately \$28.3 million of indebtedness that constituted senior indebtedness. In addition, we may incur new indebtedness, which may be senior to the indebtedness represented by the notes. We are not prohibited

Table of Contents

from incurring debt, including indebtedness secured by our assets, under the indenture governing the notes. In the event of our bankruptcy, liquidation or reorganization or upon acceleration of the notes due to an event of default under the indenture and in certain other events, our assets, other than the U.S. government securities pledged to secure the first six interest payments on the notes, will be available to pay obligations on the notes only after all of our secured indebtedness and other senior indebtedness has been paid. As a result, there may not be sufficient assets remaining to pay amounts due on any or all of the outstanding notes. For a description of the subordination provisions of the notes, see the [Description of notes Subordination of the notes](#) section of this prospectus.

You cannot be sure that a public market will develop for the notes.

On August 5, 2002, we issued the notes to the initial purchasers in a private placement. The notes are eligible to trade in PORTAL, the Private Offering, Resale and Trading through Automated Linkages Market of the National Association of Securities Dealers, Inc., a screen-based automated market for trading securities for qualified institutional buyers. However, the notes resold pursuant to this prospectus will no longer trade on the PORTAL market. As a result, there may be a limited market for the notes. We do not intend to list the notes on any national securities exchange or on the Nasdaq National Market.

A public market may not develop for the notes. Although the initial purchasers have advised us that they intend to make a market in the notes, they are not obligated to do so and may discontinue such market making at any time without notice. In addition, such market making activity will be subject to the limits imposed by the Securities Act and the Exchange Act. Accordingly, we cannot assure you that any market for the notes will develop or, if one does develop, that it will be maintained. If a public market for the notes fails to develop or be sustained, the trading price of the notes could be materially adversely affected.

The notes are not protected by restrictive covenants.

The indenture governing the notes does not contain any financial or operating covenants or restrictions on the payment of dividends, the incurrence of indebtedness or the issuance or repurchase of securities by us or any of our subsidiaries. The indenture contains no covenants or other provisions to afford protection to holders of notes in the event of a change in control involving us, except to the extent described under [Description of notes Repurchase at option of holders](#).

Our ability to repurchase the notes for cash upon a change in control is limited and the failure to do so would cause an event of default under the indenture governing the notes.

Upon the occurrence of a change in control, we will be required to offer to repurchase the notes for cash or common stock, or a combination thereof. If a change in control occurs, we may not have sufficient funds to repurchase all notes tendered by the holders of the notes in cash. The terms of any future credit facilities or other agreements relating to indebtedness may prohibit such purchases. If a change in control occurs at a time when we are prohibited from purchasing notes with cash, we could (if permitted) purchase the notes with common stock as set forth below under [Description of notes Repurchase at option of holders](#), seek the consent of our lenders to purchase the notes with cash, or attempt to refinance the borrowings that contain such prohibitions. If we do not obtain such a consent or repay such borrowings, we would remain prohibited from purchasing notes in cash, and if we cannot or do not repurchase the notes with shares of our common stock, an event of default would occur on the notes. The occurrence of an event of default under the notes could lead to the acceleration of all amounts outstanding under the notes, and may also trigger cross-default provisions resulting in the acceleration of our other indebtedness. These events in turn could harm our share price as well as our ability to continue our operations. Although we do not presently have any other indebtedness that has similar features, we are not prohibited from incurring such indebtedness in the future. Any such additional indebtedness would exacerbate the risks described above. For more details, see the [Description of notes Repurchase at option of holders](#) section of this prospectus.

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward looking statements. These statements related to future events or our future financial performance. We have attempted to identify these statements by terminology including anticipate, believe, can, continue, could, estimate, expect, intend, potential, predict, should, or will or the negative of these terms or other comparable terminology. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks and uncertainties outlined under Risk Factors, that may cause our or our industry s actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. We assume no obligation to update these forward-looking statements.

Although we believe that the expectations reflected in these statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

Table of Contents**USE OF PROCEEDS**

The selling securityholders will receive all of the proceeds from the sale under this prospectus of the notes and the common stock issuable upon conversion of the notes. We will not receive any proceeds from these sales.

PRICE RANGE OF COMMON STOCK AND DIVIDEND POLICY

Since 1983, our common stock has traded on the Nasdaq National Market. We currently trade under the symbol SCIO. The following table sets forth the high and low reported sale prices for our common stock for the periods indicated as reported on the Nasdaq National Market.

	High	Low
	<u> </u>	<u> </u>
2002		
First Quarter	\$ 31.80	\$ 19.18
Second Quarter	32.98	23.74
Third Quarter	32.75	21.91
Fourth Quarter (through November 13, 2002)	31.25	24.00
2001		
First Quarter	23.88	12.50
Second Quarter	30.50	