SPECTRUM PHARMACEUTICALS INC
Form 424B3
January 25, 2005

Table of Contents

Filed pursuant to Rule 424(b)(3)
Registration Statement No. 333-121612

PROSPECTUS

$100,000,000

SPECTRUM PHARMACEUTICALS, INC.

DEBT SECURITIES, PREFERRED STOCK, COMMON STOCK,
PREFERRED STOCK WARRANTS, AND COMMON STOCK WARRANTS

100,000 SHARES OF COMMON STOCK OFFERED BY
SELLING STOCKHOLDERS

Spectrum Pharmaceuticals, Inc. may from time to time offer in one or more series:

our debt securities, which may either be senior or subordinated;

shares of our preferred stock, $0.001 par value per share;

shares of our common stock, $0.001 par value per share;

warrants to purchase shares of our preferred stock; and

warrants to purchase shares of our common stock.

The offering may be at an aggregate public offering price of up to $100,000,000 on terms to be determined at the time of the offering. In addition, up to 100,000 shares of our common stock may be sold from time to time in one or more offerings pursuant to the registration statement of which this prospectus forms a part by the stockholders named in the Selling Stockholders section of this Prospectus. We will not receive any proceeds from sales of shares of common stock by the selling stockholders. Our debt securities, our preferred stock, our common stock (sold either by us or by the selling stockholders), our warrants to purchase shares of our preferred stock and our warrants to purchase shares of our common stock (collectively referred to as our securities), may be offered, separately or together, in separate series, in amounts, at prices and on terms that will be set forth in one or more supplements to this prospectus.

The specific terms of the securities with respect to which this prospectus is being delivered will be set forth in the applicable prospectus supplement and will include, where applicable:

in the case of our debt securities, the specific title, aggregate principal amount, currency, form (which may be registered, bearer, certificated or global), authorized denominations, maturity, rate (or manner of calculating the rate) and time of payment of interest, terms for redemption at out option or repayment at the holder s option, terms for sinking fund payments, terms for conversion into shares of our preferred stock or common stock, covenants and any initial public offering price;

in the case of our preferred stock, the specific designation, preferences, conversion and other rights, voting powers, restrictions, limitations as to transferability, dividends and other distributions and terms and conditions of redemption and any initial public offering price;

in the case of our common stock, any initial public offering price;

in the case of the warrants to purchase shares of our preferred stock, the class or series of preferred stock, duration, offering price, exercise price and detachability; and

in the case of the warrants to purchase shares of our common stock, the duration, offering price, exercise price and detachability.

Our common stock is traded on the NASDAQ National Market under the symbol SPPI. On January 19, 2005, the closing price of our common stock was $6.39.

Table of Contents

Our securities may be offered directly, through agents designated from time to time by us, or to or through underwriters or dealers. If any agents or underwriters are involved in the sale of any of our securities, their names, and any applicable purchase price, fee, commission or discount arrangement between or among them and us, will be set forth in the applicable prospectus supplement. None of our securities may be sold without delivery of the applicable prospectus supplement describing the method and terms of the offering of those securities.

Investing in our common stock involves a high degree of risk. See risk factors beginning on page 2.

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 the prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is January 24, 2005

You should rely only on the information contained in this prospectus. We have not, and the selling stockholders have not, authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the selling stockholders are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

TABLE OF CONTENTS

Table of Contents

ABOUT SPECTRUM PHARMACEUTICALS, INC.

We are a specialty pharmaceutical company engaged in the business of acquiring, developing and commercializing proprietary and generic drug products for various indications. Our current proprietary drug products, those with respect to which we have patent rights, either directly or through licenses, are primarily focused on the treatment of cancer and related disorders. Our generic drug products are versions of marketed drugs for which patent protection has expired. Spectrum Pharmaceuticals, Inc. is a Delaware corporation which was originally incorporated in Colorado as Americus Funding Corporation in December 1987, became NeoTherapeutics, Inc. in August 1996, was reincorporated in Delaware in June 1997, and was renamed Spectrum Pharmaceuticals, Inc. in December 2002.

Our business strategy, which has a primary focus on developing clinical stage proprietary products, is designed to address certain risks of new drug development by shortening the timeline to marketability, and reducing the risk of failure, which is higher with pre-clinical stage products. Currently, we have four oncology product candidates under development: satraplatin, EOquin , elsamitrucin, and SPI-153, which we are evaluating or developing for the treatment of hormone refractory prostate cancer, superficial bladder cancer, radiation sensitization as it relates to radiation treatment for cancer, refractory non-Hodgkin s lymphoma, and for hormone-dependent cancers as well as benign, proliferative disorders (such as benign prostatic hypertrophy and endometriosis). Each of these drug candidates relates to life threatening diseases and we believe each is novel in its treatment or indication, therefore, we hope expedited regulatory approval will be appropriate. Of these product candidates, satraplatin is being co-developed by a third-party pharmaceutical company under an exclusive license, and the others are being developed by us. We also plan to continue to pursue acquisitions, or in-licensing, of additional clinical-stage proprietary drugs from other companies and institutions. In addition to the above oncology product candidates, we have available for out-license for development certain of our neurology drug compounds that include: SPI-034 for dementia, SPI-339 for attention deficit disorders, SPI-356 for psychosis, schizophrenia and other mood disorders. We also have Neotrofin (SPI-082) that may be reviewed for neurodegenerative diseases.

Because new drug development is an inherently uncertain, lengthy and expensive process, we view the marketing and sales of generic drugs as a potential near-term revenue opportunity that could help defray our operating expenses and potentially some of the costs of our proprietary drug development. In this regard, we identify selected generic drugs and apply our expertise and experience to further develop and pursue regulatory approval for marketing those drugs in the United States. Our strategy is to enter into alliances with companies with cost-effective manufacturing capacity and then either directly or through third party alliances, market and distribute those generic drugs into retail and institutional channels. Currently, we have six generic drug product candidates for which we have filed abbreviated new drug applications, or ANDAs, with the FDA: ciprofloxacin and fluconazole in tablet form; injectable carboplatin and one additional injectable product; and two ophthalmic products. Our goal is to continue to pursue additional ANDA filings, including several injectable products, and to have 15-20 generic drugs FDA approved and marketed in the U.S. before 2009. In this regard we are evaluating several drug candidates for feasibility. The evaluation of feasibility includes many factors, including, but not limited to, evaluation of market potential, competition, potential patent extensions, and availability of active pharmaceutical ingredients and manufacturing capacity.

We have incurred losses in every year of our existence and expect to continue to incur significant operating losses for the next several years. We may never generate significant revenue or become profitable because all of our drug candidates are currently either in clinical trials or under review by the FDA and our clinical trials may fail, or we may not receive approval of the FDA, or even if approved, they may not become commercially viable or achieve market acceptance. Our ciprofloxacin ANDA was approved by the FDA on September 10, 2004. Lannett Company, Inc., our marketing partner, began marketing ciprofloxacin, our first generic drug, in the fourth quarter of 2004.

The pharmaceutical marketplace in which we operate is highly competitive, and includes many large, well-established companies pursuing treatments for the applications we are pursuing. See Risk Factors below.

This prospectus is part of a registration statement that we filed with the SEC utilizing a shelf registration process. Under this shelf registration process, we may sell any combination of the securities described in this prospectus in one or more offerings up to a total dollar amount of $100,000,000. In addition, up to 100,000 shares of our common stock may be sold from time to time in one or more offerings by the selling stockholders. See

Table of Contents

Selling Stockholders. We will not receive any proceeds from sales of shares of common stock by the selling stockholders. This prospectus provides you with a general description of the securities we may offer. Each time we and/or any selling stockholder sell securities, we and/or any selling stockholder will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add, update or change information contained in this prospectus. You should read both this prospectus and any prospectus supplement together with additional information described under the heading Where You Can Find More Information.

As allowed by SEC rules, this prospectus does not contain all the information you can find in the registration statement or the exhibits to the registration statement. For further information, we refer you to the registration statement, including its exhibits and schedules. Statements contained in this prospectus about the provisions or contents of any contract, agreement or any other document to are not necessarily complete. For each of these contracts, agreements or documents filed as an exhibit to the registration statement, we refer you to the actual exhibit for a more complete description of the matters involved. You should not assume that the information in this prospectus or any applicable prospectus supplement is accurate as of any date other than the date on the front of those documents. For further information about us or the securities offered under this prospectus, you should refer to the registration statement, which you can obtain from the SEC as described below under the heading Where You Can Find More Information.

Our executive offices are located at 157 Technology Drive, Irvine, California 92618. Our telephone number is (949) 788-6700. Our web site address is www.spectrumpharm.com. Information contained in our web site does not constitute part of this prospectus.

RISK FACTORS

An investment in our securities involves a high degree of risk. You should consider the risks described below and the other information contained in this prospectus carefully before deciding to invest in our securities. If any of the following risks actually occur, our business, financial condition and operating results would be harmed. As a result, the trading price of our common stock could decline, and you could lose a part or all of your investment.

Risks Related to Our Business

Our losses will continue to increase as we expand our development efforts, and our efforts may never result in profitability.

Our cumulative losses since our inception in 1987 through September 30, 2004 were in excess of $160 million, almost all of which consisted of research and development and general and administrative expenses. We lost approximately $10 million in 2003, $18 million in 2002 and $28 million in 2001, and approximately $9 million in the first nine months of 2004. We expect to continue to incur losses in the future, particularly as we continue to invest in the development of our oncology drug candidates, and expand the scope of our generics operations. We recently received approval to market our first generic drug product, ciprofloxacin, in the United States, however, we currently do not sell any other products or services and we may never achieve significant revenues from sales of products or become profitable. Even if we eventually generate significant revenues from sales, we may continue to incur operating losses over the next several years.

Our business does not generate the cash needed to finance our ongoing operations and therefore, we will need to raise additional capital.

Our business does not generate cash from operations needed to finance our ongoing operations. We have relied primarily on raising capital through the sale of our securities, and/or out-licensing our drug candidates and technology, to meet our financial needs. We believe our existing cash and investment securities will allow us to fund our current planned operations for at least the next twelve months. While anticipated profits from the sale of generic drugs, if we are successful in generating significant revenues from generics, may help defray some of the expenses of operating our business, we believe that in order to prepare the company for future drug product acquisition and development, and to capitalize on growth opportunities, we will, for the foreseeable future, need to continue to raise funds through public or private financings.

Table of Contents

We may not be able to raise additional capital on favorable terms, if at all. Accordingly, we may be forced to significantly change our business plans and restructure our operations to conserve cash, which would likely involve out-licensing or selling some or all of our intellectual, technological and/or tangible property not presently contemplated and at terms that we believe would not be favorable to us and/or reducing the scope and nature of our currently planned research and drug development activities. An inability to raise additional capital would also impact our ability to expand operations.

Clinical trials may fail to demonstrate the safety and efficacy of our oncology drug candidates, which could prevent or significantly delay obtaining regulatory approval.

Prior to receiving approval to commercialize each of our existing four oncology drug candidates, satraplatin, EOquin, elsamitrucin and SPI-153 and any drug candidates we acquire in the future, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA, and other regulatory authorities in the United States and other countries that each of the products is both safe and effective. For each current and future product candidate, we will need to demonstrate the efficacy and monitor its safety throughout the process. All of our drug candidates are in various stages of clinical trials. If these trials are unsuccessful, our business and reputation would be harmed and our stock price would be adversely affected.

All of our product candidates are prone to the risks of failure inherent in drug development. The results of pre-clinical studies and early-stage clinical trials of our product candidates do not necessarily predict the results of later-stage clinical trials. Later-stage clinical trials may fail to demonstrate that a product candidate is safe and effective despite having progressed through initial clinical testing. Even if we believe the data collected from clinical trials of our drug candidates are promising, such data may not be sufficient to support approval by the FDA or any other United States or foreign regulatory approval. Pre-clinical and clinical data can be interpreted in different ways. Accordingly, FDA officials could interpret such data in different ways than we or our partners do, which could delay, limit or prevent regulatory approval. The FDA, other regulatory authorities, our institutional review boards, our contract research organization, or we may suspend or terminate our clinical trials for our drug candidates. Any failure or significant delay in completing clinical trials for our product candidates, or in receiving regulatory approval for the sale of any drugs resulting from our drug candidates, may severely harm our business and reputation. Even if we receive FDA and other regulatory approvals, our product candidates may later exhibit adverse effects that may limit or prevent their widespread use, may cause FDA to revoke, suspend or limit their approval, or may force us to withdraw products derived from those candidates from the market.

Our oncology drug candidates, their target indications, and status of development are summarized in the following table:

Drug Candidate	Target Indication	Development Status
Satraplatin	Hormone Refractory Prostate Cancer	Phase 3 clinical trial
EOquin	Superficial Bladder Cancer Radiation Sensitization	Phase 2 clinical trial Pre-clinical
Elsamitrucin	Refractory non-Hodgkin s Lymphoma	Phase 2 clinical trial
SPI-153	Hormone Dependent Cancers and Benign Proliferative Disorders	Phase 2 clinical trial

Our oncology drug candidates may not be more effective, safer or more cost efficient than competing drugs and otherwise may not have any competitive advantage, which could hinder our ability to successfully commercialize our drug candidates.

Oncology drugs produced by other companies are currently on the market for each cancer type we are pursuing. Even if one or more of our oncology drug candidates ultimately received FDA approval, our drug

Table of Contents

candidates may not have better efficacy in treating the target indication than a competing drug, may not have a more favorable side-effect profile than a competing drug, may not be more cost efficient to manufacture or apply, or otherwise may not demonstrate a competitive advantage over competing therapies. Accordingly, even if FDA approval is obtained for one or more of our drug candidates, they may not gain acceptance by the medical field or become commercially successful.

The development of our lead drug candidate, satraplatin, depends on the efforts of a third party and, therefore, its eventual success or commercial viability is largely beyond our control.

In September 2002, we entered into a co-development and license agreement with GPC Biotech AG for the development and commercialization of our lead drug candidate, satraplatin. GPC Biotech has agreed to fully fund development and commercialization expenses for satraplatin. We will not have control over the drug development process and therefore, the success of our lead drug candidate will depend upon the efforts of GPC Biotech. GPC Biotech may not be successful in the clinical development of the drug, the achievement of any milestones such as the acceptance of a New Drug Application, or an NDA, filing by the FDA or the eventual commercialization of satraplatin.

Our efforts to acquire or in-license and develop additional proprietary drug candidates may fail, which would limit our ability to grow our proprietary business.

The long-term success of our strategy depends in part on obtaining clinical stage drug candidates in addition to our existing portfolio of satraplatin, EOquin, elsamitrucin and SPI-153. We are actively seeking to acquire, or in-license, additional clinical stage proprietary drug candidates that demonstrate the potential to be both medically and commercially viable. We have certain criteria that we are looking for in any drug candidate acquisition and therefore, we may not be successful in locating and acquiring, or in-licensing, additional desirable drug candidates on acceptable terms.

Price and other competitive pressures may make the marketing and sale of our generic drugs not commercially feasible and not profitable.

The generic drug market in the United States is extremely competitive, characterized by many participants and constant downward price pressure on generic drug products. Consequently, margins are continually reduced and it is necessary to continually introduce new products to achieve and maintain profitability. We have only obtained regulatory approval for one of our generic drug candidates. While we have entered into agreements with third parties to manufacture the drug products for us, given the price volatility of the generic market, we believe it is imprudent to enter into definitive agreements on transfer prices with the manufacturers of our generic drug product candidates prior to FDA approval, and we do not expect to do so until we receive FDA approval and are ready to begin selling the generic drug products. Our ability to compete effectively in the generic drug market depends largely on our ability to obtain transfer price agreements that ensure a supply of our generic drug products at favorable prices. Even if we obtain regulatory approval to market one or more generic drug candidates in the United States, we may not be able to complete a transfer price arrangement with the manufacturers of the drug candidates that will allow us to market any generic drug products in the United States on terms favorable to us, or at all.

Also, if we fail to obtain approval of our ANDAs from the FDA in a timely manner, preferably before the patent and any additional exclusivity granted by the FDA to the branded drug product expire, our profitability will be significantly affected due to the significant price erosion caused by the typically large number of the generic companies entering the market. The U.S. patent for Cipro®, the branded form of our generic drug product ciprofloxacin, expired in December 2003. The FDA granted pediatric exclusivity to Cipro which expired in June 2004. We received approval from the FDA of our ANDA for ciprofloxacin in September 2004, however, twelve other

companies have previously received FDA approval to market generic versions of ciprofloxacin, and we have observed a significant reduction in the market price for ciprofloxacin since June 2004. The patents and all exclusivities for our two ophthalmic products have previously expired, and a number of other companies are currently selling their own generic versions of the products. In addition, we did not obtain approval of our ANDAs for fluconazole and carboplatin prior to the expirations in July and October 2004, respectively, of the patents and exclusivities granted by the FDA to the corresponding branded products. Consequently, our ability to achieve a profit may be significantly harmed as we have reductions in the market prices for these products as well. The patents for our one injectible ANDA, filed in October 2004, has not yet expired.

Table of Contents

We may face opposition from the producers of the branded versions of the generic drugs for which we obtain approval. Branded pharmaceutical companies have aggressively sought to prevent generic competition, including the extensive use of litigation.

In addition, many branded pharmaceutical companies increasingly have used state and federal legislative and regulatory means to delay generic competition. These efforts have included:

- pursuing new patents for existing products which may be granted just before the expiration of one patent, which could extend patent protection for a number of years or otherwise delay the launch of generics;
- using the citizen petition process, a process by which any person can submit a petition to the Commissioner of the FDA to issue, amend or revoke a regulation or order or take or refrain from taking any other administrative action, to request amendments to FDA standards;
- seeking changes to the United States Pharmacopoeia, an organization which publishes industry recognized compendia of drug standards; and
- attaching patent extension amendments to non-related federal legislation.

We are a small company relative to our principal competitors and our limited financial resources may limit our ability to develop and market our oncology drug candidates and our generic drug candidates.

Many companies, both public and private, including well-known pharmaceutical companies and smaller niche-focused companies, are developing products to treat all of the diseases we are pursuing, or distributing generic drug products directly competitive to the generic drugs we intend to market and distribute. Many of these companies have substantially greater financial, research and development, manufacturing, marketing and sales experience and resources than us. As a result, our competitors may be more successful than us in developing their products, obtaining regulatory approvals and marketing their products to consumers.

Our success in the marketing of generics depends significantly upon our ability to identify generic drugs that we believe represent desirable market opportunities and that our products suppliers based in India and other countries can produce for us cost-effectively. In addition, we must be able to expand our distribution channel relationships in the United States because we currently have no internal manufacturing and an alliance with only one distributor. However, since we are new generic competitor and the marketplace is made up of many well-established companies, we may not be able to successfully compete.

As a new generic competitor, we will be competing against established generic companies such as Teva Pharmaceuticals, Sandoz, Barr Laboratories, Mylan, Watson Pharmaceuticals, Inc., Genpharm, Dr. Reddy s, American Pharmaceutical Partners, Bedford Laboratories and others. These companies may have greater economies of scale in the production of their products and in certain cases may produce their own product supplies, or can procure product supplies on more favorable terms which may provide significant cost and supply advantages to customers in the retail prescription market. Since price is the primary basis for competition among generic versions of a given drug, any ability by our competitors to reduce production costs can provide them with a significant competitive advantage, and our ability to compete will be largely dependent on our ability to obtain supplies of our generic drug product manufacturers at favorable prices. For those products which we intend to develop as generic equivalents to certain branded products, we expect that the market will be competitive and will be largely dominated by the competitors listed above who will target many if not all of the same products for development as Spectrum.

Spectrum currently has five generic drug candidates approved or under review at the FDA and one for which an ANDA has been filed with the FDA but not yet accepted for review. For ciprofloxacin, our first generic product

candidate filed with FDA, and for which we obtained approval in September 2004, there are currently fifteen generic manufacturers approved to sell versions of ciprofloxacin, which include Apotex, Barr, Cobalt, Taro, Teva, West Ward, Eon Labs, Carlsbad Technology, IVAX, Sandoz, Genpharm, Ranbaxy, Dr. Reddy s, Martec and Mylan. The pediatric exclusivity for Diflucan, the branded form of fluconazole, our second generic product filed with the FDA, expired on July 29, 2004. The market is very competitive with versions from generic drug manufacturers such as Taro Pharmaceutical Industries, Mylan, Sandoz, Ranbaxy, IVAX, Genpharm, Gedeon

Table of Contents

Richter, TEVA, Torpharm, Roxane and Pliva approved by the FDA for sale in the U.S. We have not yet obtained approval from the FDA for fluconazole and can give no assurance for when approval is likely to come, if at all. Carboplatin, our third generic drug ANDA filed with FDA, is the generic equivalent of Bristol Meyers Squibb s brand Paraplatin, for which the patent expired in April 2004. The FDA granted approval, following the expiration of pediatric exclusivity in October 2004, for carboplatin to five generic companies, including Pharmachemie, APP, Bedford, Mayne and Pliva. TEVA Pharmaceuticals, through an agreement with Bristol Meyers Squibb, is currently selling carboplatin produced by Bristol Meyers Squibb as a generic drug. We have not yet obtained approval from the FDA for carboplatin and can give no assurance for when approval is likely to come, if at all. Based on the guidelines available to us, and our experience with the FDA approval process, we do not anticipate receiving approval for our other ANDAs, filed in 2004, before the first quarter of 2006, if at all, and some or all approvals will come after patents and/or exclusivities expire and after some of our competitors have already obtained approval.

We have four oncology drug candidates currently in clinical trials. Our lead compound satraplatin, being developed by our co-development partner, GPC Biotech, is in a Phase 3 clinical trial for hormone-refractory prostate cancer and our second and third compounds, EOquin and elsamitrucin are in Phase 2 clinical studies for superficial bladder cancer and Non-Hodgkin s lymphoma, respectively. In August 2004 we acquired rights to SPI-153, which has previously been in Phase 2 clinical trials for hormone-dependent cancers and benign, proliferative disorders. We plan to expand the development of SPI-153 by initiating additional trials in one or more indications as soon as feasible. We may not be successful in any or all of these studies; or if successful, and if approved by FDA, we may encounter direct competition from other companies who may be developing products for similar or the same indications as our oncology drug candidates. Companies active in the areas of oncology include Bristol Meyers Squibb, Pfizer, Novartis, Genentech, Roche and others who are more established and are currently marketing products for the treatment of various forms of cancer including the forms our oncology drug candidates target.

Any oncology product for which we obtain FDA approval must compete for market acceptance and market share. For example, cisplatin and carboplatin are the most prevalent platinum-based derivatives used in chemotherapy and are the primary treatment for many of the cancer types we are pursuing. Our drug candidate, satraplatin, if the FDA approves it for sale, would likely compete against these drugs directly. Unless satraplatin is shown to have better efficacy and is as cost effective, if not more cost effective, than cisplatin and carboplatin, it may not gain acceptance by the medical field and therefore may never be successful commercially. Competition for branded drugs is less driven by price and is more focused on innovation in treatment of disease, advanced drug delivery and specific clinical benefits over competitive drug therapies.

Our oncology competitors that have products on the market or in research and development that are in the same clinical focus as us include Astra Zeneca, Amgen, Inc., Bayer AG, Eli Lilly and Co., Novartis Pharmaceuticals Corporation, Bristol-Myers Squibb Company, Glaxo SmithKline, Biogen-IDEC Pharmaceuticals, Inc., Guilford Pharmaceuticals, Inc., Cephalon, Inc., Aventis Pharmaceuticals Inc., Pfizer, Inc., Chiron Corp., Genta Inc., Imclone Systems Incorporated, MGI Pharma, Inc., and SuperGen, Inc., among others. Many of our competitors are large and well capitalized companies such as Eli Lilly and Co. and Bristol-Myers Squibb focusing on a wide range of diseases and drug indications, and have substantially greater financial, research and development, human and other resources than we do. Furthermore, large pharmaceutical companies have significantly more experience than we do in pre-clinical testing, human clinical trials and regulatory approval procedures, among other things.

Technologies under development by these and other pharmaceutical companies could result in treatments for diseases and disorders for which we are developing our own treatments. Several other companies are engaged in research and development of compounds that are similar to our research. In the event that one or more of these programs is successful, the market for some of our drug candidates could be reduced or eliminated.

We may not be successful in establishing additional generic drug supply relationships, which would limit our ability to grow our generic drug business.

Long-term success in the marketing of generic drugs depends in part on our ability to expand and enhance our existing relationships and establish new relationships for supplying generic drug products. We do not presently intend to focus our research and development efforts on developing active pharmaceutical ingredients or the dosage form for generic drugs. In addition, we currently have no capacity to manufacture generic drug products and do not

Table of Contents

intend to spend our capital resources to develop the capacity to do so. Therefore, we must rely on relationships with other companies to supply our generic drug products. We may not be successful in expanding or enhancing our existing relationships or in securing new relationships. If we fail to expand our existing relationships or secure new relationships, our ability to expand our generic drug business will be harmed.

We may not be successful in expanding our generic drug distribution capabilities in the United States, our only target market for generic drugs, which would limit our ability to grow our generic drug business.

Many of our competitors have substantial, established direct and indirect distribution channels. We have not yet undertaken the marketing and distribution of a generic drug product and we currently have no direct sales and marketing organization and our limited sales and marketing resources are devoted to establishing and enhancing our third party distribution relationships. We have established a relationship with a distributor for the distribution of ciprofloxacin; and commenced distribution of ciprofloxacin during the fourth quarter of 2004. The long-term success in the marketing of our generic drugs will depend in part on our drug distribution capabilities in the U.S., our only target market for generic drugs. We may not be successful in expanding our existing distribution channel, establishing new, additional distribution channels or establishing a direct generic drug marketing capability sufficient to effectively and successfully compete in the generic drug market.

Our supply of generic drug products will be dependent upon the production capabilities of our supply sources, which may limit our ability to meet demand for our products and ensure regulatory compliance.

We have no internal manufacturing capacity for our generic drug product candidates, and therefore, we have entered into agreements with third-party manufacturers to supply us with our generic drug products, subject to further agreement on pricing for particular drug products. Consequently, we will be dependent on our manufacturing partners for our supply of generic drug products. Most of these manufacturing facilities are located outside the United States. The manufacture of generic drug products, including the acquisition of compounds used in the manufacture of the finished generic drug product, may require considerable lead times. Further, sales of a new generic drug product may be difficult to forecast. Also, we will have little or no control over the production process. Accordingly, while we do not currently anticipate shortages of supply, there could arise circumstances in which market demand for a particular generic product could outstrip the ability of our supply source to timely manufacture and deliver the product, thereby causing us to lose sales.

Reliance on a third-party manufacturers entails risks to which we would not be subject if we manufactured products ourselves, including reliance on the third party for regulatory compliance and adhering to FDA s current Good Manufacturing Practices or cGMP requirements, the possible breach of the manufacturing agreement by the third party because of factors beyond our control and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us. Before we can obtain marketing approval for our product candidates, our supplier s manufacturing facilities must pass an FDA pre-approval inspection. In order to obtain approval, all of the facility s manufacturing methods, equipment and processes must comply with cGMP requirements. The cGMP requirements govern all areas of record keeping, production processes and controls, personnel and quality control. One of our generic drug manufacturing partners in India, J.B. Chemicals & Pharmaceuticals, Limited, has received FDA approval to manufacture tablet dosage forms of drug products, including ciprofloxacin and fluconazole, our first two generic drug product candidates, at its pharmaceutical manufacturing facility in India for marketing in the United States. However, additional inspections and review of these facilities may be required in the future. Any failure of our third party manufacturers or us to comply with applicable regulations, including an FDA pre-approval inspection and cGMP requirements, could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delay, suspension or withdrawal of approvals, license revocation, seizures or recalls of product, operation restrictions and criminal prosecutions, any of which could significantly and adversely

affect our business.

We are dependent on third parties for clinical testing, manufacturing and marketing our proposed products. If we are not able to secure favorable arrangements with such third parties, our business and financial condition could be harmed.

Table of Contents

We may not conduct clinical trials ourselves, and we will not manufacture any of our proposed products for commercial sale nor do we have the resources necessary to do so. In addition, we do not have the capability to market our drug products ourselves. We intend to contract with larger pharmaceutical companies or contract research organizations to conduct such activities. In connection with our efforts to secure corporate partners, we may seek to retain certain co-promotional and/or co-marketing rights to certain of our drug candidates, so that we may promote our products to selected medical specialists while our corporate partner promotes these products to the medical market generally. We may not be able to enter into any partnering arrangements on this or any other basis. If we are not able to secure adequate partnering arrangements, our business and financial condition could be harmed. In addition, we will have to hire additional employees or consultants, since our current employees have limited experience in these areas. Sufficient employees with relevant skills may not be available to us. Any increase in the number of our employees would increase our expense level, and could have an adverse effect on our financial position.

In addition, we, or our potential corporate partners, may not successfully introduce our proposed products or our proposed products may not achieve acceptance by patients, health care providers and insurance companies. Further, it is possible that we may not be able to secure arrangements to manufacture and market our proposed products at prices that would permit us to make a profit. To the extent that clinical trials are conducted by corporate partners, we may not be able to control the design and conduct of these clinical trials.

Our limited experience at managing and conducting clinical trials ourselves may delay the trials and increase our costs.

We may manage and conduct some future clinical trials ourselves rather than hiring outside clinical trial contractors. While some of our management has had experience at conducting clinical trials, we have limited experience in doing so as a company. If we move forward with self-conducted clinical trials, our limited experience may delay the completion of our clinical trials and increase our costs.

The loss of key personnel could significantly hinder our growth strategy and might cause our business to fail.

Our success depends upon the contributions of our key management and scientific personnel, especially Dr. Rajesh C. Shrotriya, our Chairman, President and Chief Executive Officer and Dr. Luigi Lenaz, the President of our Oncology division. Dr. Shrotriya has been President since 2000 and Chief Executive Officer since 2002, and has spearheaded the major changes in our business strategy and coordinated structural reorganization. Dr. Lenaz has been President of our Oncology Division since 2000 and has played a key role in the identification and development of our oncology drug candidates. The loss of the services of Dr. Shrotriya, Dr. Lenaz or any other key personnel could delay or preclude us from achieving our business objectives. Dr. Shrotriya has an employment agreement with us that will expire on December 31, 2005, with automatic one-year renewals thereafter unless we, or Dr. Shrotriya, give notice of intent not to renew at least 90 days in advance of the renewal date. Dr. Lenaz has an employment agreement with us that will expire on July 1, 2005, with automatic one year renewals thereafter unless Dr. Lenaz or we give notice of intent not to renew at least 90 days in advance of the renewal date.

We also may need substantial additional expertise in marketing and other areas in order to achieve our business objectives. Competition for qualified personnel among pharmaceutical companies is intense, and the loss of key personnel, or the delay or inability to attract and retain the additional skilled personnel required for the expansion of our business, could significantly damage our business.

Risks Related to Our Industry

Rapid technological advancement may render our oncology drug candidates or generic product candidates obsolete before we recover expenses incurred in connection with their development. As a result, certain drug candidates and generic products may never become profitable.

The pharmaceutical industry is characterized by rapidly evolving technology. Technologies under development by other pharmaceutical companies could result in treatments for diseases and disorders for which we are developing our own treatments. Several other companies are engaged in research and development of compounds that are similar to our research. A competitor could develop a new technology, product or therapy that

Table of Contents

has better efficacy, a more favorable side-effect profile or is more cost effective than one or more of our drug candidates or generic products and thereby cause our drug candidate or generic product to become commercially obsolete. Some drug candidates and generic products may become obsolete before we recover the expenses incurred in their development. As a result, such products may never become profitable.

Competition for patients in conducting clinical trials may prevent or delay product development and strain our limited financial resources.

Many pharmaceutical companies are conducting clinical trials in patients with the cancer types that our drug candidates target. As a result, we must compete with them for clinical sites, physicians and the limited number of patients who fulfill the stringent requirements for participation in clinical trials. Also, due to the confidential nature of clinical trials, we do not know how many of the eligible cancer patients may be enrolled in competing studies and consequently not available to us. Our clinical trials may be delayed or terminated due to the inability to enroll enough patients to complete our clinical trials. Patient enrollment depends on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites and the eligibility criteria for the study. The delay or inability to meet planned patient enrollment may result in increased costs and delays or termination of the trial, which could have a harmful effect on our ability to develop products.

We may not be successful in obtaining regulatory approval to market and sell our oncology or generic drug candidates.

Before our drug candidates can be marketed and sold, regulatory approval must be obtained from the FDA and comparable foreign regulatory agencies. We must demonstrate to the FDA and other regulatory authorities in the United States and abroad that our product candidates satisfy rigorous standards of safety and efficacy. We will need to conduct significant additional research, pre-clinical testing and clinical testing, before we can file applications with the FDA for approval of our product candidates. The process of obtaining FDA and other regulatory approvals is time consuming, expensive, and difficult to design and implement. The review and approval, or denial, process for an application can take years. The FDA, or comparable foreign regulatory agencies, may not timely, or ever, approve an application. Among the many possibilities, the FDA may require substantial additional testing or clinical trials or find our drug candidate is not sufficiently safe or effective in treating the targeted disease. This could result in the denial or delay of product approval. Our product development costs will increase if we experience delays in testing or approvals. Further, a competitor may develop a competing drug or therapy that impairs or eliminates the commercial feasibility of our drug candidates.

In order to obtain approval for our generic drug candidates, we will need to scientifically demonstrate that our drug product is safe and bioequivalent to the innovator drug. Bioequivalency may be demonstrated by comparing the generic drug candidate to the innovator drug product in dosage form, strength, route of administration, quality, performance characteristics and intended use. We plan to use our management s experience with the regulatory approval process in the United States to prepare, file and prosecute appropriate Abbreviated New Drug Applications, or ANDAs, for our current and future generic drug candidates. During 2003 we filed three ANDAs for ciprofloxacin, carboplatin and fluconazole, and in 2004 we filed three additional ANDAs. In September 2004, we received approval from the FDA to market ciprofloxacin in the United States. We intend to file additional ANDAs in the foreseeable future. The FDA may not agree that our safety and bioequivalency studies provide sufficient support for approval. This could result in denial or delay of FDA approval of our generic products. Generic drugs generally have a relatively short window in which they can be profitable before other manufacturers introduce competing products that impose downward pressure on prices and reduce market share for other versions of the generic drug. Consequently, delays in obtaining FDA approval may also significantly impair our ability to compete.

Our failure to comply with extensive governmental regulation to which we are subject may delay or prevent approval of our product candidates and may subject us to penalties.

The FDA and comparable agencies in foreign countries impose many requirements on the introduction of new drugs through lengthy and detailed clinical testing and data collection procedures, and other costly and time consuming compliance procedures. These requirements apply to every stage of the clinical trial process and make it difficult to estimate when any of our drug candidates will be available commercially, if at all. While we believe that we are currently in compliance with applicable FDA regulations, if we, our partners, or contract research

Table of Contents

organizations fail to comply with the regulations applicable to our clinical testing, the FDA may delay, suspend or cancel our clinical trials, or the FDA might not accept the test results. The FDA, an institutional review board at our clinical trial sites, our third-party investigators, any comparable regulatory agency in another country, or we, may suspend clinical trials at any time if the trials expose subjects participating in such trials to unacceptable health risks. Further, human clinical testing may not show any current or future product candidate to be safe and effective to the satisfaction of the FDA or comparable regulatory agencies or the data derived from the clinical tests may be unsuitable for submission to the FDA or other regulatory agencies.

Once we submit a drug candidate for commercial sale approval, the FDA or other regulatory agencies may not issue their approvals on a timely basis, if at all. If we are delayed or fail to obtain these approvals, our business and prospects may be significantly damaged. Even if we obtain regulatory approval for our product candidates, we, our partners, our manufacturers, and other contract entities will continue to be subject to extensive requirements by a number of national, foreign, state and local agencies. These regulations will impact many aspects of our operations, including testing, research and development, manufacturing, safety, effectiveness, labeling, storage, quality control, adverse event reporting, record keeping, approval, advertising and promotion of our future products. Failure to comply with applicable regulatory requirements could, among other things, result in:

- fines;
- changes in advertising;
- revocation or suspension of regulatory approvals of products;
- product recalls or seizures;
- delays, interruption, or suspension of product distribution, marketing and sale;
- civil or criminal sanctions; and
- refusals to approve new products.

The later discovery of previously unknown problems with our products may result in restrictions of the product candidate, including withdrawal from manufacture. In addition, the FDA may revisit and change its prior determinations with regard to the safety and efficacy of our future products. If the FDA s position changes, we may be required to change our labeling or to cease manufacture and marketing of the challenged products. Even prior to any formal regulatory action, we could voluntarily decide to cease the distribution and sale or recall any of our future products if concerns about their safety or effectiveness develop.

In their regulation of advertising, the FDA and the Federal Trade Commission from time to time issue correspondence alleging that some advertising or promotional practices are false, misleading or deceptive. The FDA has the power to impose a wide array of sanctions on companies for such advertising practices, and the receipt of correspondence from the FDA alleging these practices could result in any of the following:

- incurring substantial expenses, including fines, penalties, legal fees and costs to comply with the FDA s requirements;
- changes in the methods of marketing and selling products;
- taking FDA-mandated corrective action, which may include placing advertisements or sending letters to physicians, rescinding previous advertisements or promotions; and

disruption in the distribution of products and loss of sales until compliance with the FDA s position is obtained.

If we were to become subject to any of the above requirements, it could be damaging to our reputation, and our business condition could be adversely affected.

Table of Contents

Physicians may prescribe pharmaceutical products for uses that are not described in a product s labeling or differ from those tested by us and approved by the FDA. While such off-label uses are common and the FDA does not regulate physicians choice of treatments, the FDA does restrict a manufacturer s communications on the subject of off-label use. Companies cannot actively promote FDA-approved pharmaceutical products for off-label uses, but they may disseminate to physicians articles published in peer-reviewed journals. If our promotional activities fail to comply with the FDA s regulations or guidelines, we may be subject to warnings from, or enforcement action by, the FDA.

Legislative or regulatory reform of the healthcare system and pharmaceutical industry may hurt our ability to sell our products profitably or at all.

In both the United States and certain foreign jurisdictions, there have been and may continue to be a number of legislative and regulatory proposals to change the healthcare system and pharmaceutical industry in ways that could impact upon our ability to sell our products profitably. For example, sales of our products will depend in part on the availability of reimbursement from third-party payers such as government health administration authorities, private health insurers, health maintenance organizations including pharmacy benefit managers and other health care-related organizations. Both the federal and state governments in the United States and foreign governments continue to propose and pass new legislation, rules and regulations designed to contain or reduce the cost of health care. As an example, the Medicare Prescription Drug and Improvement Act of 2003, the Medicare Act, was recently enacted. This legislation provides a new Medicare prescription drug benefit beginning in 2006 and mandates other reforms. Also, the passage of the Medicare Modernization Act in 2003 reduces reimbursement for certain drugs used in the treatment of cancer. Although we cannot predict the full effects on our business of the implementation of this new legislation, it is possible that the new benefit, which will be managed by private health insurers, pharmacy benefit managers and other managed care organizations, will result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce the prices charged for prescription drugs. This could harm our ability to market our products and generate revenues.

It is also possible that other proposals will be adopted. As a result of the new Medicare prescription drug benefit, or any other proposals, we may determine to change our current manner of operation which could harm our ability to operate our business efficiently. Existing regulations that affect the price of pharmaceutical and other medical products may also change before any of our products are approved for marketing. Cost control initiatives could decrease the price that we receive for any of our products we are developing. In addition, 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 pharmaceutical products. Our products may not be considered cost effective, or adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize a return on our investments.

In addition, new court decisions, FDA interpretations, and legislative changes have modified the rules governing eligibility for and the timing of 180-day market exclusivity periods, a period of marketing exclusivity that the FDA may grant to a abbreviated new drug application (ANDA) applicant who is the first to file a legal challenge to patents of branded drugs. It is difficult to predict the effects such changes may have on our business. Any changes in FDA regulations, procedures, or interpretations may make ANDA approvals of generic drugs more difficult or otherwise limit the benefits available to us through the granting of 180-day marketing exclusivity. If we are not able to exploit the 180-day exclusivity period for one of our generic product candidates that we were first to file, for any reason, our product may not gain market share, which could materially adversely affect our results of operations.

Additional government regulations, legislation, or policies may be enacted which could prevent or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of adverse government action that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able

to maintain regulatory compliance, we might not be permitted to market our products and our business could suffer.

Intellectual property rights are complex and uncertain and therefore may subject us to infringement claims.

The patent positions related to our proprietary drug candidates that we have in-licensed from third parties and those related to our generic drug candidate portfolio are inherently uncertain and involve complex legal and

Table of Contents

factual issues. Although we are not aware of any infringement by any of our drug candidates on the rights of any third party, there may be third party patents or other intellectual property rights relevant to our drug candidates of which we are not aware. Third parties may assert patent or other intellectual property infringement claims against us with respect to our drug candidates or our generic drug products. This could draw us into costly litigation as well as result in the loss of our use of the intellectual property that is critical to our business strategy.

Intellectual property litigation is increasingly common and increasingly expensive and may result in restrictions on our business and substantial costs, even if we prevail.

Patent and other intellectual property litigation is becoming more common in the pharmaceutical industry. Litigation is sometimes necessary to defend against or assert claims of infringement, to enforce our patent rights, to protect trade secrets or to determine the scope and validity of proprietary rights of third parties. No third party has asserted that we are infringing upon their patent rights or other intellectual property, nor are we aware or believe that we are infringing upon any third party s patent rights or other intellectual property. We may, however, be infringing upon a third party s patent rights or other intellectual property, and litigation asserting such claims might be initiated in which we would not prevail or we would not be able to obtain the necessary licenses on reasonable terms, if at all. All such litigation, whether meritorious or not, as well as litigation initiated by us against third parties, is time consuming and very expensive to defend or prosecute and to resolve.

If our competitors prepare and file patent applications in the United States that claim technology we also claim, we may have to participate in interference proceedings required by the Patent and Trademark Office to determine priority of invention, which could result in substantial costs, even if we ultimately prevail. Results of interference proceedings are highly unpredictable and may result in us having to try to obtain licenses in order to continue to develop or market certain of our drug candidates.

We also rely on trade secret protection and contractual protections for our unpatented, confidential and proprietary technology. Trade secrets are difficult to protect. While we enter into proprietary information agreements with our employees, consultants and others, these agreements may not successfully protect our trade secrets or other confidential and proprietary information.

We may be subject to product liability claims, and may not have sufficient product liability insurance to cover any such claims, which may expose us to substantial liabilities.

We may be exposed to product liability claims from patients who participate in our clinical trials or from consumers of our products. Although we currently carry product liability insurance in the amount of at least $3 million in the aggregate, it is possible that this coverage will be insufficient to protect us from future claims.

Further, we may not be able to maintain our existing insurance or obtain or maintain additional insurance on acceptable terms for our clinical and commercial activities or that such additional insurance would be sufficient to cover any potential product liability claim or recall. Failure to maintain sufficient insurance coverage could have a material adverse effect on our business, prospects and results of operations if claims are made that exceed our coverage.

The use of hazardous materials in our research and development efforts imposes certain compliance costs on us and may subject us to liability for claims arising from the use or misuse of these materials.

Our research and development efforts involved and may involve the use of hazardous materials, including biological materials, chemicals and radioactive materials. We are subject to federal, state and local laws and regulations governing the storage, use and disposal of these materials and some waste products. We believe that our

safety procedures for the storage, use and disposal of these materials comply with the standards prescribed by federal, state and local regulations. However, we cannot completely eliminate the risk of accidental contamination or injury from these materials. If there were to be an accident, we could be held liable for any damages that result, which could exceed our financial resources. We currently maintain insurance coverage for injuries resulting from the hazardous materials we use, and for pollution clean up and removal; however, future claims may exceed the amount of our coverage. Currently the costs of complying with federal, state and local regulations are not significant, and consist primarily of waste disposal expenses.

Table of Contents

Risks Related to Our Stock

There are a substantial number of shares of our common stock eligible for future sale in the public market. The sale of these shares could cause the market price of our common stock to fall. Any future equity issuances by us may have dilutive and other effects on our existing stockholders.

As of January 19, 2005, there were approximately 14.8 million shares of our common stock outstanding, and in addition, security holders held options, warrants and preferred stock which, if exercised or converted, would obligate us to issue up to approximately 10 million additional shares of common stock. A substantial number of those shares, when we issue them upon conversion or exercise, will be available for immediate resale in the public market. In addition, this prospectus relates to the sale of up to $100 million of our securities, some or all of which may be shares of our common stock or securities convertible into or exercisable for shares of our common stock, and all of which would be available for immediate resale in the market. In accordance with the rules applicable to shelf registrations of this type, we may issue and sell all of these securities within two years after the date of this prospectus. If we were to sell the full $100 million available under this prospectus as common stock at a price equal to the current market price of our common stock as of the date of this prospectus, we would issue approximately 16.0 million new shares of our common stock. The market price of our common stock could fall as a result of resales of any of these shares of common stock due to the increased number of shares available for sale in the market.

We have financed our operations, and for the foreseeable future we expect to continue to finance a substantial portion of our operating cash requirements, primarily by issuing and selling our common stock or securities convertible into or exercisable for shares of our common stock. Any issuances by us of equity securities may be at or below the prevailing market price of our common stock and may have a dilutive impact on our other stockholders. These issuances would also cause our net income, if any, to decrease or our loss per share to decrease in future periods. As a result, the market price of our common stock could drop.

The market price and volume of our common stock fluctuate significantly and could result in substantial losses for individual investors.

The stock market from time to time experiences significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These broad market fluctuations may cause the market price and volume of our common stock to decrease. In addition, the market price and volume of our common stock is highly volatile. Factors that may cause the market price and volume of our common stock to decrease include fluctuations in our results of operations, timing and announcements of our technological innovations or new products or those of our competitors, FDA and foreign regulatory actions, developments with respect to patents and proprietary rights, public concern as to the safety of products developed by us or others, changes in health care policy in the United States and in foreign countries, changes in stock market analyst recommendations regarding our common stock, the pharmaceutical industry generally and general market conditions. In addition, the market price and volume of our common stock may decrease if our results of operations fail to meet the expectations of stock market analysts and investors. While a decrease in market price could result in direct economic loss for an individual investor, low trading volume could limit an individual investor s ability to sell our common stock, which could result in substantial economic loss as well. During 2003, the price of our common stock ranged between $1.66 and $10.37, and the daily trading volume was as high as 3,338,000 shares and as low as 1,300 shares. During 2004, the price of our common stock ranged between $4.41 and $10.13, and the daily trading volume has been as high as 1,391,800 shares and as low as 9,900 shares.

Provisions of our charter, bylaws and stockholder rights plan may make it more difficult for someone to acquire control of us or replace current management even if doing so would benefit our stockholders, which may lower the price an acquirer or investor would pay for our stock.

Provisions of our certificate of incorporation, as amended, and bylaws may make it more difficult for someone to acquire control of us or replace our current management. These provisions include:

the ability of our board of directors to amend our bylaws without stockholder approval;

Table of Contents

the inability of stockholders to call special meetings;

the ability of members of the board of directors to fill vacancies on the board of directors;

the inability of stockholders to act by written consent, unless such consent is unanimous;

the establishment of advance notice requirements for nomination for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

These provisions may make it more difficult for stockholders to take certain corporate actions and could delay, discourage or prevent someone from acquiring our business or replacing our current management, even if doing so would benefit our stockholders. These provisions could limit the price that certain investors might be willing to pay for shares of our common stock.

In December 2000, we adopted a stockholder rights plan pursuant to which we distributed rights to purchase units of our Series B junior participating preferred stock. The rights become exercisable upon the earlier of ten days after a person or group of affiliated or associated persons has acquired 20% or more of the outstanding shares of our common stock or ten business days after a tender offer has commenced that would result in a person or group beneficially owning 20% or more of our outstanding common stock. These rights could delay or discourage someone from acquiring our business, even if doing so would benefit our stockholders. We currently have no stockholders who own 20% or more of the outstanding shares of our common stock.

We do not anticipate declaring any cash dividends on our common stock.

We have never declared or paid cash dividends on our common stock and do not plan to pay any cash dividends in the near future. Our current policy is to retain all funds and any earnings for use in the operation and expansion of our business.

RATIO OF EARNINGS TO FIXED CHARGES

Our ratio of earnings to fixed charges are as follows for the periods indicated:

	Year Ended December 31,					Nine Months Ended September 30,
	1999	2000	2001	2002	2003	2004
Ratio of earnings to fixed charges(1)	N/A	N/A	N/A	N/A	N/A	N/A

(1) Earnings have been inadequate to cover fixed charges. The dollar amount of the coverage deficiency was approximately $25,990,000, $46,548,000, $27,787,000, $17,634,000, $10,390,000 for each of the years in the five year period ended December 31, 2003, and $8,809,000 for the nine-month period ended September 30, 2004.

The ratios of earnings to fixed charges were computed by dividing earnings by fixed charges. For this purpose, earnings consist of pre-tax loss before minority interest in loss of consolidated subsidiary and fixed charges included in the determination of pre-tax loss. Fixed charges consist of interest costs, whether expensed or capitalized, the amortization of debt discount and issuance costs, the interest factor of rental expense and preference security dividends of consolidated subsidiary. Preference security dividends of consolidated subsidiary are presented on a

pre-tax basis, assuming a 40% tax rate.

Table of Contents

RATIO OF EARNINGS TO COMBINED FIXED CHARGES AND PREFERRED SHARE DIVIDENDS

Our ratio of earnings to combined fixed charges and preferred share dividends are as follows for the periods indicated:

	Year Ended December 31,					Nine Months Ended September 30,
	1999	2000	2001	2002	2003	2004
Ratio of earnings to combined fixed charges and preferred share dividends (1)	N/A	N/A	N/A	N/A	N/A	N/A

(1) Earnings have been inadequate to cover fixed charges and preferred dividends. The dollar amount of the coverage deficiency was approximately $26,217,000, $46,548,000, $29,147,000, $17,634,000, $10,792,000 for each of the years in the five year period ended December 31, 2003, and $9,026,000 for the nine-month period ended September 30, 2004.

The ratio of earnings to fixed charges and preferred dividends is calculated in a similar manner to the ratio of earnings to fixed charges, except that preference dividends of Spectrum Pharmaceuticals are included in fixed charges on a pre-tax basis, assuming a 40% tax rate. The deficiency amount is the amount of earnings required for a ratio of 1.0x.

FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference into this prospectus contain forward-looking statements that are based on current expectations, estimates and projections about our industry, management s beliefs, and assumptions made by management. Words such as anticipates, expects, intends, plans, believes, seeks, and variations of such words and similar expressions are intended to identify such forward-looking statements. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and assumptions that are difficult to predict; therefore, actual results may differ materially from those expressed or forecasted in any forward-looking statements. The risks and uncertainties include those noted in Risk Factors above and in the documents incorporated by reference.

We undertake no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except to the extent that we are required to do so by law. We also may make additional disclosures in our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K that we may file from time to time with the Securities and Exchange Commission, or SEC. Please also note that we provide a cautionary discussion of risks and uncertainties under the section entitled Risk Factors in our Annual Report on Form 10-K. These are factors that we think could cause our actual results to differ materially from expected results. Other factors besides those listed here could also adversely affect us. This discussion is provided as permitted by the Private Securities Litigation Reform Act of 1995.

USE OF PROCEEDS

Unless we indicate otherwise in the applicable prospectus supplement, the net proceeds from the sale of the securities offered from time to time hereby will be used for general corporate purposes, including, without limitation, making acquisitions of assets, businesses or securities, share repurchases and capital expenditures and for working capital. When a particular series of securities is offered, the prospectus supplement relation thereto will set forth our intended use of the net proceeds we receive from the sale of the securities. Pending the application of the net proceeds, we may invest the proceeds in short-term, interest-bearing instruments or other securities.

We will not receive any of the proceeds from sales of our common stock by selling stockholders.

DILUTION

The net tangible book value of our common stock on September 30, 2004 was approximately $33.9 million, or approximately $2.37 per share. Net tangible book value per share represents the amount of our total tangible assets, less our total liabilities and the aggregate liquidation preference of our preferred stock outstanding, divided by the total number of shares of our common stock outstanding. The number of shares of our common stock outstanding may be increased by shares issued upon conversion of preferred stock, payment of dividends, exercise of warrants or exercise of options, and, to the extent warrants and options are exercised for cash, the net tangible book value of our common stock may increase. If all the warrants for which the shares of our common stock that are

Table of Contents

issuable upon exercise of the warrants which are being offered pursuant to this prospectus were exercised for cash (less estimated costs associated with the financing and the warrants), the net tangible book value of our common stock would be approximately $34.9 million, or approximately $2.43 per share, excluding the effect of any other transactions occurring after September 30, 2004. Since we will not receive any of the proceeds from the sale of common stock sold by the selling stockholders under this prospectus, the net tangible book value of our common stock will not be increased as a result of such sales, nor will the number of shares outstanding be affected by such sales. Consequently, there will be no change in net tangible book value per share of our common stock as a result of any sales made by the selling stockholders under this prospectus. However, any dilution to new investors will represent the difference between the amount per share paid by purchasers of shares of our common stock from the selling stockholders in this offering and the net tangible book value per share of our common stock at the time of the purchase.

It is not possible to estimate the effects on our net tangible book value per share of our common stock of issuances by us of the securities included in this prospectus as primary offering securities until the type, terms and pricing of such primary offering securities have been determined. We will include additional disclosure regarding dilution in the applicable prospectus supplement relating to each issuance of primary offering securities under this prospectus.

PLAN OF DISTRIBUTION

We may sell the securities described in this prospectus and any accompanying prospectus supplement, and any of the selling stockholders may sell shares of our common stock described in this prospectus and any accompanying prospectus supplement, from time to time in one or more transactions

to purchasers directly;

to underwriters for public offering and sale by them;

through agents;

through dealers; or

through a combination of any of the foregoing methods of sale.

We or the selling stockholders may distribute the securities from time to time in one or more transactions at:

a fixed price or prices, which may be changed;

market prices prevailing at the time of sale;

prices related to such prevailing market prices; or

negotiated prices.

Direct Sales

We and/or any selling stockholder may sell the securities directly to institutional investors or others. A prospectus supplement will describe the terms of any sale of securities we are offering hereunder.

To Underwriters

The applicable prospectus supplement will name any underwriter involved in a sale of securities. Underwriters may offer and sell securities at a fixed price or prices, which may be changed, or from time to time at market prices or at negotiated prices. Underwriters may be deemed to have received compensation from us from sales of securities in the form of underwriting discounts or commissions and may also receive commissions from purchasers of securities for whom they may act as agent.

Table of Contents

Underwriters may sell securities to or through dealers, and such dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters and/or commissions (which may be changed from time to time) from the purchasers for whom they may act as agent.

Unless otherwise provided in a prospectus supplement, the obligations of any underwriters to purchase securities or any series of securities will be subject to certain conditions precedent, and the underwriters will be obligated to purchase all such securities if any are purchased.

Through Agents and Dealers

We and/or any selling stockholder will name any agent involved in a sale of securities, as well as any commissions payable by us to such agent, in a prospectus supplement. Unless we indicate differently in the prospectus supplement, any such agent will be acting on a reasonable efforts basis for the period of its appointment.

If we and/or any selling stockholder utilize a dealer in the sale of the securities being offered pursuant to this prospectus, the securities will be sold to the dealer, as principal. The dealer may then resell the securities to the public at varying prices to be determined by the dealer at the time of resale.

Delayed Delivery Contracts

If specified in the applicable prospectus supplement, we and/or any selling stockholder will authorize underwriters, dealers and agents to solicit offers by certain institutions to purchase securities pursuant to contracts providing for payment and delivery on future dates. Such contracts will be subject to only those conditions set forth in the applicable prospectus supplement.

The underwriters, dealers and agents will not be responsible for the validity or performance of the contracts. We and/or any selling stockholders will set forth in the prospectus supplement relating to the contracts the price to be paid for the securities, the commissions payable for solicitation of the contracts and the date in the future for delivery of the securities.

General Information

Underwriters, dealers and agents participating in a sale of the securities may be deemed to be underwriters as defined in the Securities Act, and any discounts and commissions received by them and any profit realized by them on resale of the securities may be deemed to be underwriting discounts and commissions, under the Securities Act. We and/or any selling stockholder may have agreements with underwriters, dealers and agents to indemnify them against certain civil liabilities, including liabilities under the Securities Act, and to reimburse them for certain expenses.

Underwriters or agents and their associates may be customers of, engage in transactions with or perform services for us or our affiliates in the ordinary course of business.

Unless we indicate differently in a prospectus supplement, we will not list the securities on any securities exchange, other than shares of our common stock. The securities, except for our currently issued class of common stock, will be a new issue of securities with no established trading market. Any underwriters that purchase securities for public offering and sale may make a market in such securities, but such underwriters will not be obligated to do so and may discontinue any market making at any time without notice. We make no assurance as to the liquidity of or the trading markets for any securities.

To facilitate our offering of securities, certain persons participating in our offering may engage in transactions that stabilize, maintain, or otherwise affect the price of the securities. This may include over-allotments or short sales of the securities, which involve the sale by persons participating in an offering of more securities than we sold to them. In these circumstances, these persons would cover the over-allotments or short positions by making purchases in the open market or by exercising their over-allotment option, if any. In addition, these persons may stabilize or maintain the price of the securities by bidding for or purchasing securities in the open market or by imposing penalty bids, whereby selling concessions allowed to dealers participating in the offering may be reclaimed if securities sold by them are repurchased in connection with stabilization transactions. The effect of these

Table of Contents

transactions may be to stabilize or maintain the market price of the securities at a level above that which might otherwise prevail in the open market. These transactions may be discontinued at any time.

DESCRIPTION OF SECURITIES

The following is a general description of the terms and provisions of the securities we may offer and sell by this prospectus. These summaries are not meant to be a complete description of each security. This prospectus and any accompanying prospectus supplement will contain the material terms and conditions for each security. The accompanying prospectus supplement may add, update or change the terms and conditions of the securities as described in this prospectus.

DESCRIPTION OF DEBT SECURITIES

This prospectus describes the general terms and provisions of the debt securities we may offer from time to time. When we offer to sell a particular series of debt securities, we will describe the specific terms of the series in a supplement to this prospectus. We will also indicate in the supplement whether the general terms and provisions described in this prospectus apply to a particular series of debt securities.

We may offer debt securities in the form of either senior debt securities or subordinated debt securities. Unless otherwise specified in a supplement to this prospectus, the debt securities will be our direct, unsecured obligations and will rank equally with all of our other unsecured and unsubordinated indebtedness.

The debt securities will be issued under an indenture between us and a trustee. We have summarized the select portions of the indenture below. The summary is not complete. The form of indenture has been incorporated by reference as an exhibit to the registration statement and you should read the indenture for provisions that may be important to you. Capitalized terms used in the summary have the meanings specified in the indenture.

General

The terms of each series of debt securities, will be established by or pursuant to a resolution of our Board of Directors and set forth or determined in the manner provided in an officers certificate or by a supplemental indenture. The particular terms of each series of debt securities will be described in a prospectus supplement relating to such series, including any pricing supplement.

We can issue an unlimited amount of debt securities under the indenture that may be in one or more series with the same or various maturities, at par, at a premium, or at a discount. We will set forth in a prospectus supplement, including any pricing supplement, relating to any series of debt securities being offered, the aggregate principal amount and the following terms of the debt securities:

the title of the debt securities;

the price or prices, expressed as a percentage of the principal amount, at which we will sell the debt securities;