SPECTRUM PHARMACEUTICALS INC
Form S-3/A
June 22, 2005

Table of Contents

As filed with the Securities and Exchange Commission on June 22, 2005

Registration No. 333-125208

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 1
TO

FORM S-3

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

SPECTRUM PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**93-079187**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

157 Technology Drive
Irvine, California 92618
(949) 788-6700

(Address, Including Zip Code and Telephone Number, Including Area Code, of Registrant s Principal Executive Offices)

Rajesh C. Shrotriya, M.D.
Chief Executive Officer
157 Technology Drive
Irvine, California 92618
(949) 788-6700

(Name, Address, Including Zip Code and Telephone Number, Including Area Code, of Agent for Service)

Copies to:

Cary K. Hyden, Esq.
Gavin Stuttard, Esq.
Latham & Watkins LLP
650 Town Center Drive, Twentieth Floor
Costa Mesa, California 92626
(714) 540-1235

Approximate date of commencement of proposed sale to the public: As soon as practical after this Registration Statement becomes effective.

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

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, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. þ

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 of the same offering. o

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. o

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

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 the 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

Subject to Completion, dated June 22, 2005

INFORMATION CONTAINED IN THIS PROSPECTUS IS SUBJECT TO COMPLETION OR AMENDMENT. A REGISTRATION STATEMENT RELATING TO THESE SECURITIES HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION. THESE SECURITIES MAY NOT BE SOLD NOR MAY OFFERS TO BUY BE ACCEPTED PRIOR TO THE TIME THE REGISTRATION STATEMENT BECOMES EFFECTIVE. THIS PROSPECTUS SHALL NOT CONSTITUTE AN OFFER TO SELL OR THE SOLICITATION OF AN OFFER TO BUY NOR SHALL THERE BE ANY SALE OF THESE SECURITIES IN ANY STATE IN WHICH SUCH OFFER, SOLICITATION OR SALE WOULD BE UNLAWFUL PRIOR TO REGISTRATION OR QUALIFICATION UNDER THE SECURITIES LAWS OF ANY SUCH STATE.

PROSPECTUS

SPECTRUM PHARMACEUTICALS, INC.

1,454,751 SHARES OF COMMON STOCK OFFERED BY SELLING STOCKHOLDERS

Our common stock is traded on the NASDAQ National Market under the symbol SPPI. On June 20, 2005, the closing price of our common stock was $4.95.

This prospectus relates to the sale of 1,454,751 shares of our common stock by the selling stockholders named in this prospectus. The shares of our common stock and the securities which are convertible into or exercisable for the shares of our common stock which are being offered by this prospectus were issued to the selling stockholder pursuant to financing transactions. See Issuance of Common Stock to Selling Stockholders on page 16. We will not receive any of the proceeds from the sale of these shares.

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 1.

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 _____ ____, 2005

TABLE OF CONTENTS

Table of Contents

ABOUT SPECTRUM PHARMACEUTICALS, INC.

Spectrum Pharmaceuticals, Inc. is a Delaware corporation that 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. Prior to August 2002, when we announced a shift in our strategic focus, we were engaged in the discovery and development of neurology drugs as well as functional genomics research.

We are a specialty pharmaceutical company engaged in the business of acquiring, developing and commercializing prescription drug products for various indications. Our business model is to acquire and develop a diversified portfolio of proprietary and generic drug products, with a mix of near-term and long-term revenue potential. While our primary strategic focus is on proprietary drug products addressing cancer and other unmet medical needs, we are also leveraging our developmental and regulatory capabilities, and those of our strategic alliance partners, to enhance the potential for realizing near-term revenues by taking advantage of opportunities for developing and commercializing select generic drug products with a focus on specific niche categories. We plan to execute our business strategy by attracting and retaining talented people, entering into strategic business alliances, and maintaining a strong cash position.

As of the date of filing this report, we have seven proprietary drug product candidates under development: satraplatin, EOquin , elsamitrucin, SPI-153; RenaZorb ; SPI-1620 and lucanthone, two Abbreviated New Drug Applications, or ANDAs, for ciprofloxacin tablets and carboplatin injection, approved by the United States Food and Drug Administration (FDA) and eight ANDAs pending at the FDA. We plan to continue to evaluate acquisitions, or in-licensing, of additional promising clinical-stage as well as near-clinical-stage drugs from other companies and institutions; and expect to file additional ANDAs in 2005 and beyond and to have several generic drugs FDA approved and marketed in the U.S. over the next 5 years. In addition, we plan to seek additional strategic alliances to manufacture, develop and market our current and future drug products.

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 relates to the sale of up to 1,454,751 shares of our common stock which may be sold from time to time in one or more offerings by the selling stockholders. See Selling Stockholders. The securities were issued and sold to the selling stockholders in private placement transactions. We will not receive any proceeds from sales of shares of common stock by the selling stockholders.

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 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 common stock involves a high degree of risk. Our business, financial condition, operating results and prospects can be impacted by a number of factors, any one of which could cause our actual results to differ materially from recent results or from our anticipated future results. As a result, the trading price of our

Table of Contents

common stock could decline, and you could lose a part or all of your investment. You should carefully consider the risks described below with all of the other information included in this Prospectus and the Registration Statement.

Failure to satisfactorily achieve any of our objectives or avoid any of the risks described below or other risks listed in our Annual Report on Form 10-K would likely have a material adverse effect on our business and results of operations.

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 March 31, 2005 were in excess of $170 million. We lost approximately $12 million in 2004, $10 million in 2003, $18 million in 2002 and approximately $5 million in the three-month period ended March 31, 2005. We expect to continue to incur losses in the future, particularly as we continue to invest in the development of our drug product candidates, acquire additional drug candidates and expand the scope of our operations. We recently received approval to market our first generic drug product, ciprofloxacin, in the United States and recorded modest revenue in 2004 and no revenue in the first quarter of 2005. 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 will likely continue to incur 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 current business operations do not generate sufficient operating cash to finance the clinical development of our drug product candidates. We have historically relied primarily on raising capital through the sale of our securities and out-licensing our drug candidates and technology to meet our financial needs. 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 continued future drug product development and acquisition, and to capitalize on growth opportunities, we will, for the foreseeable future, need to continue to raise funds through public or private financings.

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 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 proprietary drug candidates, which could prevent or significantly delay obtaining regulatory approval.

Prior to receiving approval to commercialize any of our proprietary drug candidates, 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 product candidate, we will need to demonstrate its efficacy and monitor its safety throughout the process. If such development is 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.

Table of Contents

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 the FDA to revoke, suspend or limit their approval, or may force us to withdraw products derived from those candidates from the market.

Our proprietary 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	Late Phase 3 clinical trial
EOquin (EO9)	Refractory Superficial Bladder Cancer	Late Phase 2 clinical trial
Elsamitrucin	Refractory non-Hodgkin s Lymphoma	Phase 2 clinical trial
SPI-153	Hormone Dependent Prostate Cancer	Phase 2 clinical trial
SPI-153	Benign Prostatic Hypertrophy	Phase 2 clinical trial
Lucanthone	Brain tumors and metastasis to the CNS	Phase 2 clinical trial
Satraplatin	Non-small cell lung cancer	Phase 1/2 clinical trial
EO9	Radiation Sensitizer	Pre-clinical
RenaZorb	End-stage Renal Disease, Chronic Kidney Disease	Pre-clinical
SPI-1620	Adjunct to Chemotherapy	Pre-clinical

The development of our 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 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 do not have control over the drug development process and therefore the success of our lead drug candidate depends upon the efforts of GPC Biotech. GPC Biotech may not be successful in the clinical development of the drug, the achievement of any additional milestones such as the acceptance of a New Drug Application, or NDA, filing by the FDA, or the eventual commercialization of satraplatin.

The development of our drug candidate, SPI-153, may be adversely affected by the development efforts of Zentaris GmbH who retained certain rights to the product.

Zentaris GmbH licensed the rights to us to develop and market SPI-153 in the United States, Canada, Mexico and India. Zentaris may conduct their own clinical trials on SPI-153 for regulatory approval in other parts of the world. We will not have control over Zentaris efforts in this area and our own development efforts for SPI-153 may be adversely impacted if their efforts are not successful.

From time to time we may need to license proprietary technologies from third parties, which may be difficult or expensive to obtain.

We may need to obtain licenses to patents and other proprietary rights held by third parties to successfully develop, manufacture and market our drug products. As an example, it may be necessary to use a third party s proprietary technology to reformulate one of our drug products in order to improve upon the capabilities of the drug product. If we are unable to timely obtain these licenses on reasonable terms, our ability to commercially exploit our drug products may be inhibited or prevented.

Table of Contents

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 inability to retain and attract 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, our Chief Scientific Officer. 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 our structural reorganization. Dr. Lenaz has been President of our Oncology Division from November 2000 to February 2005 and Chief Scientific Officer since 2005, and has played a key role in the identification and development of our proprietary 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, 2006, with automatic one year renewals thereafter unless we, or Dr. Lenaz, 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.

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

We may not conduct clinical trials ourselves, and we will not manufacture any of our proposed proprietary products for commercial sale nor do we have the resources necessary to do so. In addition, we currently 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 or co-marketing rights to certain of our proprietary 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 proprietary products or our proposed proprietary 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 proprietary 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.

Table of Contents

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 drug candidates in addition to our existing portfolio. We are actively seeking to acquire, or in-license, additional 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 we may not be successful in locating and acquiring, or in-licensing, additional desirable drug candidates on acceptable terms.

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

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.

Competition for branded proprietary 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. We have seven proprietary drug candidates currently under development. We may not be successful in any or all of these studies; or if successful, and if one or more of our proprietary drug candidates is approved by the FDA, we may encounter direct competition from other companies who may be developing products for similar or the same indications as our drug candidates. Companies active in the areas of oncology which is our focus include Astra Zeneca, Amgen, Inc., Bayer AG, Eli Lilly and Co., Genentech, Inc., Novartis Pharmaceuticals Corporation, Bristol-Myers Squibb Company, GlaxoSmithKline, Biogen-IDEC Pharmaceuticals, Inc., Guilford Pharmaceuticals, Inc., Cephalon, Inc., Sanofi-Aventis Inc., Pfizer, Inc., Chiron Corp., Genta Inc., Imclone Systems Incorporated, MGI Pharma, Inc., SuperGen, Inc., Roche Pharmaceuticals 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. Many of our competitors are large and well capitalized companies 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.

Any proprietary product for which we obtain FDA approval must compete for market acceptance and market share. For example, cisplatin injection and carboplatin injection 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.

With regard to our drug product candidate, RenaZorb , under the new National Kidney Foundation K/DOQI guidelines for treating hyperphosphatemia, non-calcium, non-aluminum binders are the recommended first-line long-term therapy for managing high phosphate levels. Genzyme corporations s Renagel ® and Shire Pharmaceutical s Fosrenol ® are the only two FDA approved non-calcium, non-aluminum, branded pharmaceuticals specifically for the treatment of hyperphosphatemia in end stage renal disease. We expect to compete with these products and potentially others based upon phosphate binding capacity, patient compliance, side effects and cost. While we believe RenaZorb has the potential to perform better than these competitors, if RenaZorb is successfully developed and receives FDA

approval, it will be a number of years after Renagel ® and Fosrenol ® have been FDA approved and marketed. In addition, Genzyme and Shire may seek to modify their products or create new therapies that could reduce or eliminate any perceived benefit we believe RenaZorb may have over these products.

Table of Contents

Our success in the marketing of our generic drug products will depend significantly upon our ability to forecast market conditions that may prevail after we obtain ANDA approval and identify generic drugs that our strategic partners and associated suppliers can produce for us cost-effectively. In addition, we must be able to expand our marketing, selling and distribution relationships in the United States since we currently do not have any internal distribution capabilities and alliance(s) with two product distributor(s). Furthermore, as a new generic competitor entering the marketplace, which is made up of many well-established companies, with established customers as well as established sales, marketing and distribution organizations, we may not be able to successfully compete.

Because 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 from manufacturers at favorable prices. As a new generic competitor, we will be competing against established generic companies such as Teva Pharmaceuticals, Sandoz, Barr Laboratories, Mylan Laboratories Inc., Watson Pharmaceuticals, Inc., Genpharm, Dr. Reddy s, Ranbaxy, 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, such as active pharmaceutical ingredients, or can procure product supplies on more favorable terms which may provide significant cost and supply advantages to customers in the retail prescription market. We expect that the generic 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 us.

We currently have eight generic drug candidates under review at the FDA. For ciprofloxacin tablets, 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 tablets, which include Apotex, Barr, Cobalt, Taro, Teva, West Ward, Eon Labs, Carlsbad Technology, IVAX, Sandoz, Genpharm, Ranbaxy, Dr. Reddy s, Martec and Mylan Laboratories, Inc. 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 Laboratories, Inc, Sandoz, Ranbaxy, IVAX, Genpharm, Gedeon 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 tablets and can give no assurance for when approval is likely to come, if at all. Carboplatin injection, our third generic drug ANDA filed with FDA, and for which we obtained approval in June 2005, 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 injection to five generic companies, including Pharmachemie, APP, Bedford, Mayne and Pliva. TEVA Pharmaceuticals, through an agreement with Bristol Myers Squibb, is currently selling carboplatin injection produced by Bristol Myers Squibb as a generic drug. The patent for Imitrex ® injection, the brand name for sumatriptan succinate injection, for which we filed an ANDA with paragraph IV certification, has not yet expired. However, we have initiated a challenge of the patent and are currently in litigation with GlaxoSmithKline, the patent holder for Imitrex ® injection. Based on the guidelines available to us, and our experience with the FDA approval process, we do not anticipate receiving approval for our six other ANDAs, filed in 2004 and in 2005, before the first quarter of 2006, if at all, and all approvals will come after patents and/or exclusivities expire and after some of our competitors have already obtained approval and begun marketing.

Our proprietary 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.

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

Table of Contents

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 and pediatric exclusivity for Cipro ®, the branded form of our generic drug product ciprofloxacin, had both expired by June 2004. We received approval from the FDA of our ANDA for ciprofloxacin tablets in September 2004, however, fifteen other companies have received FDA approval to market generic versions of ciprofloxacin tablets, and we have observed a significant reduction in the market price for ciprofloxacin since June 2004. The patents and all exclusivities for our four ophthalmic products and our two undisclosed 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 tablets and carboplatin injection 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 observed significant reductions in the market prices for these products as well. The patents for sumatriptan succinate injection, the generic version of Imitrex ®, marketed by GlaxoSmithKline, for which we filed an ANDA with paragraph IV certification in October 2004, have not yet expired.

In addition to competitive pressures related to price, 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. On February 18, 2005, GlaxoSmithKline filed suit in U.S. federal court to prevent us from proceeding with the commercialization of our generic version of Imitrex ® which action formally initiates our challenge of the patent listed by GlaxoSmithKline in connection with Imitrex ® injection. For information regarding the risks of this litigation, please see the risk factor below.

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.

Table of Contents

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 ourselves 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 relationships with distributors for the distribution of ciprofloxacin tablets and carboplatin injection; we commenced distribution of ciprofloxacin tablets during the fourth quarter of 2004 and expect to launch the distribution of carboplatin injection shortly. 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.

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 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.

Our supply of 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 drug product candidates, and therefore, we have entered into agreements with third-party manufacturers to supply us with our 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 drug products. Some of these manufacturing facilities are located outside the United States. The manufacture of drug products, including the acquisition of compounds used in the manufacture of the finished drug product, may require considerable lead times. Further, with regard to our generic drug products, sales of a new generic drug product may be difficult to forecast. 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 non-renewal 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. 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.

Table of Contents

GlaxoSmithKline filed suit in U.S. federal court asserting that Spectrum has infringed their patent for Imitrex ® injection by filing our ANDA for sumatriptan injection, the generic form of Imitrex ® injection. This challenge may prevent us from commercializing sumatriptan until after the patent has expired and may require us to incur substantial expense and the significant effort of technical and management personnel.

On February 18, 2005, GlaxoSmithKline filed suit in U.S. federal court to prevent us from proceeding with the commercialization of our generic form of sumatriptan injection. Since patent litigation has been initiated, the FDA will not approve our ANDA until the earlier of 30 months from the GlaxoSmithKline s receipt of our notice of ANDA acceptance (the 30-month stay) or the issuance of a final non-appealed, or non-appealable court decision finding the Imitrex ® patent invalid, unenforceable or not infringed. If the patent is found to be infringed by the filing of our ANDA, GlaxoSmithKline could seek an injunction to block the launch of our generic product until the patent expires. This would prohibit us from obtaining the 180-day marketing exclusivity afforded by the FDA to companies who are the first to file an ANDA with a paragraph IV certification for a generic equivalent to a brand name product. We believe we are the first to file an ANDA with a paragraph IV certification for sumatriptan injection.

Our defense against the charge of infringement by GlaxoSmithKline could require us to incur substantial legal expense and to divert significant effort of our technical and management personnel away from their regular activities in our business, which could substantially hinder our ability to conduct, advance and grow our business.

Risks Related to Our Industry

Rapid technological advancement may render our drug candidates obsolete before we recover expenses incurred in connection with their development. As a result, our drug 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 has better efficacy, a more favorable side-effect profile or is more cost effective than one or more of our drug candidates and thereby cause our drug candidate to become commercially obsolete. Some drug candidates 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 disease indications 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 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 proprietary or generic drug candidates.

Before our proprietary 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

Table of Contents

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. Since 2003 we have filed ten ANDAs with the FDA. In September 2004, we received approval from the FDA to market ciprofloxacin tablets in the United States and in June 2005 we received approval from the FDA to market carboplatin injection 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 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;

Table of Contents

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.

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, Improvement and Modernization Act of 2003, or the Medicare

Modernization 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 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.

Table of Contents

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 an ANDA applicant who is the first to file a legal challenge to patents of branded drugs. We believe we were the first to file an ANDA for sumatriptan succinate injection, the generic form of GlaxoSmithKline s Imitrex ® injection, and are currently in litigation with GlaxoSmithKline regarding the patent that covers this product. However, it is difficult to predict the effects such changes may have on our business or our current case. 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 our sumatriptan succinate injection ANDA or 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.

As part of the Medicare Modernization Act, companies are now required to file with the Federal Trade Commission and the Department of Justice certain types of agreements entered into between branded and generic pharmaceutical companies related to the manufacture, marketing and sale of generic versions of branded drugs. This new requirement could affect the manner in which generic drug manufacturers resolve intellectual property litigation and other disputes with branded pharmaceutical companies, and could result generally in an increase in private-party litigation against pharmaceutical companies. The impact of this new requirement, and the potential private-party lawsuits associated with arrangements between brand name and generic drug manufacturers, is uncertain and could adversely affect our business.

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.

If we are unable to adequately protect our technology or enforce our patent rights, our business could suffer.

Our success with proprietary products that we develop will depend, in part, on our ability to obtain and maintain patent protection for these products. We currently have a number of U.S. and foreign patents issued and pending, however, we primarily rely on patent rights licensed from others. These patents generally give us the right and/or obligation to maintain and enforce the subject patents. We cannot be sure that we will receive patents for any of our pending patent applications or any patent applications we may file in the future. If our pending and future patent applications are not approved or, if approved, if such patents and the patents we have licensed are not upheld in a court of law, it may reduce our ability to competitively exploit our proprietary products would be substantially harmed. Also, such patents may or may not provide competitive advantages for their respective products or they may be challenged or circumvented by our competitors, in which case our ability to commercially exploit these products may be diminished.

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

Table of Contents

secrets or other confidential and proprietary information. It is possible that these agreements will be breached, or that they will not be enforceable in every instance, and that we will not have adequate remedies for any such breach. It is also possible that our trade secrets will become known or independently developed by our competitors.

If we are unable to adequately protect our technology, trade secrets or proprietary know-how, or enforce our patents, our business, financial condition and prospects could suffer.

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

The patent positions related to our proprietary and generic drug candidates are inherently uncertain and involve complex legal and 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 proprietary 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 including those we have licensed from others, including those we have licensed from others, to protect trade secrets or to determine the scope and validity of proprietary rights of third parties. Other than the lawsuit filed against us by GlaxoSmithKline related to our ANDA for sumatriptan injection, currently 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. In addition, if we infringe the intellectual property rights of others, we could lose our right to develop, manufacture or sell our products or could be required to pay monetary damages or royalties to license proprietary rights from third parties. An adverse determination in a judicial or administrative proceeding or a failure to obtain necessary licenses could prevent us from manufacturing or selling our products, which could harm our business, financial condition and prospects.

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 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.

Table of Contents

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 currently involve the use of hazardous 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.

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 March 31, 2005, there were approximately 15.3 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 11 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, we have filed a shelf registration statement that allows us to sell 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. We may issue and sell all of these securities within two years after January 24, 2005, the date of the effectiveness of the registration statement. If we were to sell the full $100 million available under the registration statement as common stock at a price approximately equal to the current market price of our common stock, we would issue approximately 20.0 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, per share 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 2004, the price of our common stock ranged between $3.92 and $10.13, and the daily trading volume was as high as 1,391,800 shares and as low as 9,900 shares. During 2005 through June

Table of Contents

20, 2005, the price of our common stock has ranged between $4.52 and $7.50, and the daily trading volume has been as high as 360,200 shares and as low as 18,400 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;
- 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.

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

Table of Contents

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.

ISSUANCE OF COMMON STOCK TO THE SELLING STOCKHOLDERS

Pursuant to an agreement with Lekar Pharma Limited dated March 26, 2003, we issued to Lekar Pharma Limited 119,617 shares of Spectrum s common stock, at a purchase price of $6.27 per share for an aggregate purchase price of $750,000, which we received on February 18, 2005. This investment was contractually triggered by the FDA approval of an Abbreviated New Drug Application for ciprofloxacin in September 2004. The per share price was equal to the closing price of our common stock on the date immediately prior to the date of FDA approval.

We are also registering for resale up to 348,628 shares of our common stock issuable to SDS Capital Group SPC Ltd. upon conversion of shares of our Series D 8% Cumulative Convertible Voting Preferred Stock and up to 936,506 shares of our common stock issuable to SDS Capital Group SPC Ltd. upon exercise of Series D and Series E warrants. SDS Capital Group SPC Ltd. acquired the preferred stock and warrants from SDS Merchant Fund, LP, who acquired the shares of preferred stock and warrants from us in private placement transactions completed on May 7, 2003 and September 26, 2003. The shares of common stock underlying these shares of preferred stock and warrants now being registered for resale by SDS Capital Group SPC Ltd. were previously registered for resale by SDS Merchant Fund, LP on registration statements, 333-105814 and 333-110103.

USE OF PROCEEDS

We will not receive any of the proceeds from sales of our common stock by the selling stockholders. However, if the warrants held by SDS Capital Group SPC Ltd. are exercised, we will receive cash proceeds of approximately $4.5 million, which we expect to use for general corporate purposes.

DILUTION

The net tangible book value of our common stock on March 31, 2005 was approximately $29.7 million, or approximately $1.94 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 the preferred stock, payment of dividends, or exercise of the warrants, and, to the extent the warrants 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 issuable upon exercise of the warrants are being offered pursuant to this prospectus were exercised for cash, the net tangible book value of our common stock would be $39.6 million, or approximately $2.43 per share, excluding the effect of any other transactions occurring after March 31, 2005. Since we will not receive any of the proceeds from the sale of common stock sold 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 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.

SELLING STOCKHOLDERS

The following table sets forth information relating to the selling stockholders beneficial ownership of our common stock. The information regarding shares beneficially owned after the offering assumes the sale of all shares offered by the selling stockholders. The percentage ownership data is based on 15,352,949 shares of our common stock issued and outstanding as of May 19, 2005.

The shares of common stock covered by this prospectus may be sold by the selling stockholders, by those persons or entities to whom they transfer, donate, devise, or pledge their shares or by other successors in interest. We are registering the shares of our common stock for resale by the selling stockholders defined below. The shares

Table of Contents

are being registered to permit public secondary trading of the shares, and the selling stockholders may offer the shares for resale from time to time.

Name	Shares of Common Stock Beneficially Owned Before Offering (2) Number	% of Class	Number of Shares of Common Stock Offered Hereby	Shares of Common Stock Beneficially Owned Following the Offering(1) Number	% of Class
Lekar Pharma Ltd.(3)	119,617	*	119,617	0	*
SDS Capital Group SPC Ltd.(4)	1,632,333	9.78%	1,285,134	347,199	2.08%

* less than 1%.
(1) Assumes the sale by the selling stockholders of all of the shares of common stock available for resale under this Prospectus.

(2) Does not include shares of our common stock issuable as payment of dividends on the preferred stock. The holders of our Series D preferred stock are entitled to cumulative dividends at an annual rate of 8% of the stated value of the preferred stock, currently $10,000 per share. The dividends are payable quarterly in cash or in stock, at our option. If we pay the dividends in stock, we will issue a number of shares equal to the amount of the dividend divided by the average of the closing prices of our common stock on the NASDAQ National Market for the 20 trading days immediately prior to the dividend payment date.

(3) A.P. Mehta, a director of Lekar Pharma Limited, has voting and investment power over the securities beneficially owned by Lekar Pharma Limited.

(4) SDS Management, LLC is the Investment Manager of SDS Capital Group SPC Ltd. Steve Derby is the sole Managing Member of SDS Management, LLC, and is the natural person who exercises voting and investment control over the securities beneficially owned by SDS Capital Group SPC Ltd.

All expenses incurred with the shares of common stock owned by the selling stockholders will be borne by us; provided that we will not be obligated to pay any underwriting fees, discounts or commissions in connection with such registration.

Relationship with Selling Stockholder

Lekar Pharma Limited is an affiliate of J.B. Chemicals and Pharmaceuticals Ltd. of Mumbai, India, the parent company of our joint venture partner J.B. Life Science Overseas Limited and manufacturer of our generic drug product ciprofloxacin tablets.

PLAN OF DISTRIBUTION

We are registering the shares of common stock on behalf of the selling stockholders. Sales of shares may be made by selling stockholders, including their respective donees, transferees, pledgees or other successors-in-interest directly

to purchasers or to or through underwriters, broker-dealers or through agents. Sales may be made from time to time on the NASDAQ National Market, any other exchange or market upon which our shares may trade in the future, in the over-the-counter market or otherwise, at market prices prevailing at the time of sale, at prices related to market prices, or at negotiated or fixed prices. The shares may be sold by one or more of, or a combination of, the following:

a block trade in which the broker-dealer so engaged will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction (including crosses in which the same broker acts as agent for both sides of the transaction);

purchases by a broker-dealer as principal and resale by such broker-dealer, including resales for its account, pursuant to this prospectus;