SPECTRUM PHARMACEUTICALS INC
Form 424B5
December 06, 2006
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Registration Statement No. 333-121612

PROSPECTUS SUPPLEMENT

(to prospectus dated January 24, 2005)

UP TO 120,000 SHARES OF COMMON STOCK

OF

SPECTRUM PHARMACEUTICALS, INC.

This prospectus supplement relates to an offering by us of up to 120,000 shares of our common stock to one investor for aggregate proceeds of approximately $1,000,000, or $8.33 per share. In connection with this offering, we will not pay any fees or commissions to a placement agent, finder or any other person.

You should read this prospectus supplement, the accompanying prospectus, and the documents incorporated by reference herein and therein, carefully before you invest. Such documents contain information you should consider when making your investment decision. The information included in the registration statement on Form S-3 (No. 333-121612) filed with the Securities and Exchange Commission on December 23, 2004, as amended, is hereby incorporated by reference into this prospectus supplement.

Our common stock is traded on the Nasdaq Market under the symbol SPPI. On December 5, 2006, the last sale price of our common stock on the Nasdaq Market was $5.56 per share. As of December 4, 2006, we had 25,093,477 shares of our common stock outstanding.

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page S-3.

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

The date of this prospectus is December 6, 2006.

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You should rely only on the information contained or incorporated by reference in this prospectus supplement and the accompanying prospectus that is also part of this document. We have not authorized anyone to provide information different from that contained or incorporated in this prospectus supplement and the accompanying prospectus. We are offering to sell shares of common stock only in jurisdictions where offers and sales are permitted. The information contained or incorporated in this prospectus supplement and the accompanying prospectus is accurate only as of the date of such information, regardless of the time of delivery of this prospectus supplement and the accompanying prospectus or of any sale of share of our common stock.

ABOUT SPECTRUM PHARMACEUTICALS, INC.

Spectrum Pharmaceuticals, Inc. is a pharmaceutical company engaged in the business of acquiring, developing and commercializing prescription drugs for various indications. While we directly own certain patent rights, the drugs we are currently developing, which are focused on the treatment of cancer and other unmet medical needs, are in-licensed from third parties whereby we acquired rights to develop and commercialize those compounds in territories specified in the agreements.

We are developing our proprietary drugs for the treatment of a variety of cancers and other unmet medical needs. As of September 30, 2006, we had several proprietary drugs under development, and through the date of this report we have filed multiple, and received approval for some, Abbreviated New Drug Applications, or ANDAs, with the U.S. Food and Drug Administration, or FDA.

In general, we direct and pay for all aspects of the drug development process, and consequently incur the risks and rewards of drug development, which is an inherently uncertain process. To mitigate such risks we enter into alliances where we believe that our partners can provide strategic advantage in the development, manufacturing or distribution of our drugs. In such situations, the alliance partners may share in the risks and rewards of the drug development and commercialization.

Our primary business focus for 2006, and beyond, will be to continue to acquire, develop and commercialize a portfolio of marketable prescription drug products with a mix of near-term and long-term revenue potential. The following is a brief description of the most advanced products under development, and the key developments anticipated in the next 12 to 18 months are:

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Satraplatin: Satraplatin is an orally administered chemotherapeutic agent that is being studied for the treatment of hormone refractory prostate cancer in a phase 3 clinical trial. In September 2006, we announced positive results from the trial, which is being conducted by our development partner, GPC Biotech AG, or GPC Biotech. A rolling submission of a New Drug Application, or NDA, with the FDA had commenced in December 2005, and is expected to complete in the fourth quarter of 2006 or shortly thereafter. Acceptance of the NDA by the FDA will trigger a milestone payment from GPC Biotech to us.

Levofolinic acid (LFA): In April 2006, we completed the acquisition of all of the oncology drug assets of Targent, Inc. The principal asset in the transaction was a license agreement to market levofolinic acid, or LFA, in the field of oncology in North America. LFA is the pure active isomer of calcium leucovorin, a component of standard of care 5-fluorouracil, or 5-FU, containing regimens for the treatment of colorectal cancer and other malignancies. Calcium leucovorin is also used after the administration of high-dose methotrexate in treating certain malignancies. A NDA for LFA has been filed with the FDA for the osteosarcoma indication. We expect to respond in early 2007 to certain chemistry and manufacturing questions raised by the FDA during the review of the application.

EOquin: EOquin, a synthetic drug which is activated by certain enzymes present in higher amounts in cancer cells than in normal tissues, is currently being developed for superficial (non-invasive) bladder cancer. Earlier in 2006, we held a pre-IND and end of phase 2 meeting with the FDA and have filed an IND with the FDA, with the view to initiating phase 3 trials in the United States in the next few months to evaluate EOquin in superficial (non-invasive) bladder cancer after completion of a 20-patient pilot study which has recently begun and approval of a special protocol assessment by the FDA.

Ozarelix: Ozarelix, a fourth generation LHRH (Luteinizing Hormone Releasing Hormone, also known as GnRH or Gonadotropin Releasing Hormone) antagonist is under evaluation for its intended initial indications, hormone-dependent prostate cancer and benign prostatic hypertrophy (BPH). Evaluation of the data from the Phase 2 clinical trials in each of those indications is proceeding. We recently announced preliminary data from these trials, and anticipate commencing a phase 3 clinical trial in BPH in 2007.

Sumatriptan succinate injection: On November 10, 2006, we settled our patent litigation with GlaxoSmithKline, or GSK, relating to sumatriptan injection, the generic version of GSK s Imitrex® injection. The confidential terms of the settlement, which remain subject to government review, provide that we may exclusively distribute authorized generic versions of certain sumatriptan injection products in the United States with an expected launch during GSK s sumatriptan pediatric exclusivity period which begins on August 6, 2008, but with the launch occurring not later than November 6, 2008. We will launch sumatriptan injection through Par Pharmaceuticals Companies, Inc. our partner for the sale and distribution of the drug.

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 have never generated significant revenues from product sales and we may never generate significant revenue sales of products or become profitable. In addition, even if we eventually generate significant revenues from sales, we will likely continue to incur losses over the next several years.

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.

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.

FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein contain certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, in reliance upon the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding our future product development activities and costs, the revenue potential (licensing, royalty and sales) of our product candidates, the safety and efficacy of our drug products, the timing and likelihood of achieving development milestones and product revenues, the sufficiency of our capital resources, and other statements containing forward-looking words, such as, believes, may, could, will, expects, intends, estimates, anticipates, plans, seeks, or continues. Such forward-looking statements are based on the beliefs of management as well as assumptions made by and information currently available to our management. You should not put undue reliance on these forward-looking statements. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified; therefore, our actual results may differ materially from those described in any forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed below, including under Risk Factors, as well as those discussed in our periodic reports filed with the Securities and Exchange Commission including our Annual Report on Form 10-K. These factors include, but

are not limited to:

our ability to successfully develop, obtain regulatory approvals for and market our products;

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our ability to generate and maintain sufficient cash resources to fund our business;

our ability to enter into and maintain strategic alliances with partners for manufacturing, development and commercialization;

our ability to identify new product candidates;

the timing or results of pending or future clinical trials;

competition in the marketplace for our generic drugs;

actions by the FDA and other regulatory agencies;

demand and market acceptance for our approved products; and

the effect of changing economic conditions.

We do not plan to update any such forward-looking statements and expressly disclaim any duty to update the information contained in this report except as required by law.

R ISK 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 supplement and the accompanying 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.

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, 2006 were in excess of $200 million. We lost approximately $19 million in 2005, $12 million in 2004, and $10 million in 2003, and approximately $22 million in the nine-month period ended September 30, 2006. 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 have received FDA approval to market certain generic drug products in the United States and recorded modest revenue to date. However, 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 may need to continue 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 or milestone payments from our partners 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 may 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 drug development activities. An inability to raise additional capital would also impact our ability to expand operations.

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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.

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 organizations, 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; rolling NDA submission has begun
	Metastatic breast cancer	Phase 2
	With Taxol® in Non-small Cell Lung Cancer	Phase 2
	With Tarceva® in inoperable advanced Non-small Cell Lung Cancer	Phase 2
	With radiation therapy in Non-small Cell Lung Cancer	Phase 1 / 2
	With radiation therapy and Xeloda® in rectal cancer	Phase 1 / 2
	With Taxotere® in advanced solid tumors	Phase 1
	With Xeloda® in advanced solid tumors	Phase 1
	With Gemzar® in advanced solid tumors	Phase 1
Levofolinic acid (LFA),	Osteogenic Sarcoma	NDA on file with FDA; CMC responses pending
	Colorectal Cancer	
EOquin	Superficial (non-invasive) Bladder Cancer	Phase 2 completed; end of phase 2 meeting held with the FDA; IND filed; Pilot Safety Study initiated

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Drug Candidate	Target Indication	Development Status
Elsamitrucin	Refractory non-Hodgkin s Lymphoma	Phase 2
Ozarelix (formerly SPI-153)	Hormone Dependent Prostate Cancer	Phase 2
		Phase 2
	Benign Prostatic Hypertrophy	
Lucanthone	Radiation Sensitizer for Brain Tumors and Brain Metastases	Phase 2
RenaZorb	Hyperphosphatemia in End-stage Renal Disease	Pre-clinical
SPI-1620	Adjunct to Chemotherapy	Pre-clinical
SPI-205	Chemotherapy Induced Neuropathy	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 worldwide 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 and its new sublicensee. GPC Biotech and its sublicensee 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.

We may not be able to obtain co-promotion rights in the United States with regard to our drug candidate, satraplatin, under our co-development and license agreement with GPC Biotech AG which may adversely affect our ability to timely establish our own sales force in the United States, if and when we choose to do so.

Pursuant to the terms of our co-development and license agreement with GPC Biotech, in the event GPC Biotech determines to market satraplatin itself within the United States, we will have the right to co-promote satraplatin in the United States with GPC Biotech pursuant to terms to be negotiated by both parties. If GPC Biotech grants rights to a third party to market satraplatin in the United States, then GPC Biotech is only obligated to use commercially reasonable efforts to obtain co-promotion rights for us with such third party. Therefore, we may not be able to obtain co-promotion rights for satraplatin in the United States, which may adversely affect our ability to timely establish our own sales force in the United States, if and when we choose to do so.

The development of our drug candidate, ozarelix, may be adversely affected if the development efforts of Zentaris GmbH who retained certain rights to the product, are not successful.

Zentaris GmbH licensed the rights to us to develop and market ozarelix in the United States, Canada, Mexico and India. Zentaris may conduct their own clinical trials on ozarelix 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 ozarelix may be adversely impacted if their efforts are not successful.

The eventual FDA approval and subsequent marketing and sale of our drug candidate LFA, may be adversely affected by the marketing and sale efforts of third parties who sell LFA outside North America.

We have only licensed the rights to develop, market and sell LFA in North America. Other companies, such as Wyeth and Sanofi-Aventis Inc., market and sell LFA in other parts of the world. If, as a result of their actions, negative publicity is associated with LFA, our own efforts to successfully receive FDA approval for, and subsequently, market and sell LFA, may be adversely impacted.

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Our proprietary drug candidate LFA 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 it.

LFA is the pure active isomer of calcium leucovorin, a component of standard of care 5-FU containing regimens for the treatment of colorectal cancer and other malignancies. Leucovorin has been sold as a generic product on the market for a number of years. There are a number of generic companies currently selling the product. Even if LFA ultimately receives FDA approval, it may not have better efficacy in treating the target indication or a more favorable side-effect profile than generic leucovorin. If we are not able to demonstrate a competitive advantage over generic leucovorin, we may not be able to obtain a price premium over generic leucovorin. If we are not able to obtain a price premium, we may not be able to manufacture LFA in a cost efficient manner or at a cost below the generic leucovorin cost price. Also, LFA will be offered as part of a treatment regimen, and that regimen may change to exclude LFA. Accordingly, even if FDA approval is obtained for LFA, it may not gain acceptance by the medical field or become commercially successful.

From time to time we may need to license patents, intellectual property and 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.

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 direction of in our business strategy. Dr. Lenaz has been President of our Oncology Division from November 2000 to February 2005 and Chief Scientific Officer since February 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, 2007, 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, 2007, 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, pharmaceutical drug development 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.

Our collaborations with outside scientists may be subject to change, which could limit our access to their expertise.

We work with scientific advisors and collaborators at academic research institutions. These scientists are not our employees and may have other commitments that would limit their availability to us. If a conflict of interest between their work for us and their work for another entity arises, we may lose their services. Although our scientific advisors and academic collaborators sign agreements not to disclose our confidential information, it is possible that some of our valuable proprietary knowledge may become publicly known through them.

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We are dependent on third parties for manufacturing and may be for the marketing of 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 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 to manufacture our proposed proprietary products. In connection with our efforts to commercialize our proposed proprietary products, we may seek to secure favorable arrangements with third parties to promote and market our proposed proprietary products. If we are not able to secure favorable commercial terms or arrangements with third parties for marketing and promotion of our proposed proprietary products, we may choose to retain promotional and marketing rights and seek to develop the commercial resources necessary to promote or co-promote or co-market certain or all of our proprietary drug candidates to the appropriate channels of distribution in order to reach the specific medical market that we are targeting. We may not be able to enter into any partnering arrangements on this or any other basis. If we are not able to secure favorable partnering arrangements, or are unable to develop the appropriate resources necessary for the commercialization of our proposed proprietary products, 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 commercial 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 favorable commercial terms that would permit us to make a profit. To the extent that corporate partners conduct clinical trials, we may not be able to control the design and conduct of these clinical trials.

We may rely on contract research organizations and other third parties to conduct clinical trials and, in such cases, we are unable to directly control the timing, conduct and expense of our clinical trials.

We may rely, in full or in part, on third parties to conduct our clinical trials. In such situations, we have less control over the conduct of our clinical trials, the timing and completion of the trials, the required reporting of adverse events and the management of data developed through the trial than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may have staffing difficulties, may undergo changes in priorities or may become financially distressed, adversely affecting their willingness or ability to conduct our trials. We may experience unexpected cost increases that are beyond our control. Problems with the timeliness or quality of the work of a contract research organization may lead us to seek to terminate the relationship and use an alternative service provider. However, making this change may be costly and may delay our trials, and contractual restrictions may make such a change difficult or impossible. Additionally, it may be impossible to find a replacement organization that can conduct our trials in an acceptable manner and at an acceptable cost.

We may have conflicts with our partners that could delay or prevent the development or commercialization of our product candidates.

We may have conflicts with our partners, such as conflicts concerning the interpretation of preclinical or clinical data, the achievement of milestones, royalty and milestone payments, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. If any conflicts arise with any of our partners, such partner may act in a manner that is adverse to our best interests. Any such disagreement could have an adverse effect on the Company, including resulting in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating revenues:

unwillingness on the part of a partner to pay us milestone payments or royalties we believe are due to us under a collaboration;

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uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations;

unwillingness by the partner to cooperate in the development or manufacture of the product, including providing us with product data or materials;

unwillingness on the part of a partner to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities;

initiating of litigation or alternative dispute resolution options by either party to resolve the dispute; or

attempts by either party to terminate the agreement.

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 our ability to acquire or in-license drug candidates in addition to those drug candidates currently in 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. In addition, many other large and small companies within the pharmaceutical and biotechnology industry seek to establish collaborative arrangements for product research and development, or otherwise acquire products in late-stage clinical development, in competition with us. We face additional competition from public and private research organizations, academic institutions and governmental agencies in establishing collaborative arrangements for product candidates in late-stage clinical development. Many of the companies and institutions that compete against us have substantially greater capital resources, research and development staffs and facilities than we have, and greater experience in conducting business development activities. These entities represent significant competition to us as we seek to expand our pipeline through the in-license or acquisition of compounds. Moreover, while it is not feasible to predict the actual cost of acquiring additional product candidates, that cost could be substantial and we may need to raise additional financing or issue additional equity securities, either of which may further dilute existing stockholders, in order to acquire new product candidates.

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 many if not all of the diseases we are pursuing; or are currently distributing or may be developing generic drug products directly competitive to the generic drugs we intend to develop, 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 or 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 nine 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 that have products on the market or in research and development that target the same indications as our products target include Ardana Bioscience, Astra Zeneca LP, Amgen, Inc., Bayer AG, Bioniche Life Sciences Inc., Eli Lilly and Co., Ferring Pharmaceuticals, NeoRx Corporation, Genentech, Inc., Novartis Pharmaceuticals Corporation, Bristol-Myers Squibb Company, GlaxoSmithKline, Biogen-IDEC Pharmaceuticals, Inc., OSI Pharmaceuticals, Inc., Cephalon, Inc., Sanofi-Aventis Inc., Pfizer, Inc., AVI Biopharma, Inc., Chiron Corp., Genta Inc., Genzyme Corporation, Imclone Systems Incorporated, Millennium Pharmaceuticals, MGI Pharma, Inc., SuperGen, Inc., Shire Pharmaceuticals, TAP Pharmaceuticals, Inc., QLT Inc., Threshold

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Pharmaceuticals, Inc., Roche Pharmaceuticals, Schering-Plough, Johnson & Johnson and others who may be more advanced in development of competing drug candidates or are more established and are currently marketing products for the treatment of various indications that our 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, marketing, 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.

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.

Any proprietary product for which we obtain FDA approval must compete for market acceptance and market share. 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.

We are dependent on a third party to market, sell and distribute our lead generic product sumatriptan injection.

We entered into a development and marketing agreement with Par Pharmaceutical Companies, Inc., whereby Par has agreed to market, sell and distribute our lead generic product sumatriptan injection. While we have responsibility for all development activities associated with sumatriptan injection, Par has the ultimate responsibility for the selling and marketing of the drug product and therefore the success of sumatriptan injection depends upon the specific selling and marketing efforts undertaken by Par. Par may not be successful in the marketing of sumatriptan injection, which may adversely affect our ability to commercially exploit this product.

Intense competition from a large number of generic companies may make the marketing and sale of our generic drugs not commercially feasible and not profitable.

We will be competing against 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, Mayne Pharmaceuticals and others. In addition, we anticipate that many foreign manufacturers will continue to enter the generic market due to low barriers to entry. 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. In addition, we must expand our marketing, selling and distribution relationships in the U.S. since we currently do not have any internal distribution capabilities and allliances for just two products.

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 domestic and foreign participants and constant downward price pressure on generic drug prices. 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 several generic drugs. 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 until we are prepared to take order for a shipment. Our ability to compete effectively in the generic drug

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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 our 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 the generic drug products in the United States on terms favorable to us, or at all.

Failure to obtain timely approval of our generic product candidates by regulatory agencies, including the Food and Drug Administration, may make it difficult to capture enough market share to make a profit.

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. We did not obtain approval of our ANDAs for the generic products we have available for sale prior to the expirations of the patents and exclusivities granted by the FDA to the corresponding branded products. Many other companies had received timely approval from the FDA to market the products, and, therefore, there was a significant reduction in the market price for the products by the time we entered the market. In addition, the patents and exclusivities for some of our other generic products for which we have ANDAs pending have previously expired, and a number of other companies are currently selling their own generic versions of the products. 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.

We may not be successful in establishing additional active pharmaceutical ingredient or finished dose 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 upon our ability to maintain, expand and enhance our existing relationships and establish new sources of supply for active pharmaceutical ingredients (API) or for the manufacture of our finished dose generic drug products. We do not presently intend to focus our research and development efforts on developing active pharmaceutical ingredients or manufacturing of dosage form for generic drugs. In addition, we currently have no capacity to manufacture APIs or finished dose 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 API suppliers and other contract manufacturing organizations (CMOs) to supply our active pharmaceutical ingredients and finished dose generic drug products. We may not be successful in maintaining, expanding or enhancing our existing relationships or in securing new relationships with API suppliers or CMOs. If we fail to maintain or expand our existing relationships or secure new relationships, our ability to sustain and expand our generic drug business will be harmed.

Our supply of drug products will be dependent upon the production capabilities of CMOs and component and packaging 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 CMOs to supply us with active pharmaceutical ingredients and our finished dose drug products, subject to further agreement on pricing for particular drug products. Consequently, we will be dependent on our CMO partners for our supply of drug products. Some of these manufacturing facilities are located outside the United States. The manufacture of finished 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 CMOs 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 CMO because of factors beyond our control and the possibility of termination or non-renewal of the agreement by the CMO, 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 CMO facilities must pass an FDA pre-approval inspection. In order to obtain

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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.

If our recent settlement agreement with GlaxoSmithKline, or GSK, relating to our paragraph four patent litigation for sumatriptan injection, the generic form of GSK s Imitrex® injection, does not pass government review, the litigation will be reinstated and we may incur the significant effort of technical and management personnel. In addition, if we are found to have infringed GSK s patents, we may be prevented from commercializing sumatriptan injection until after the patent has expired.

We recently entered into a settlement agreement with GSK relating to our paragraph four patent litigation for sumatriptan injection. If the settlement agreement does not pass government review, the litigation will be reinstated. Our continued defense against the charge of infringement by GSK could require us to divert the 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. However, through our strategic alliance with Par, Par is providing us with financial and legal support and therefore, the success of our continued defense is dependent on their efforts as well. In addition, if we are found to have infringed GSK s patent, we may be prevented from commercializing sumatriptan injection until after the patent has expired. During 2006, we made additional regulatory filings with the FDA, related to sumatriptan injection, which may result in additional legal proceedings related to this litigation that may delay the litigation and/or delay our ability to launch our generic product.

Risks Related to Our Industry

Rapid bio-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 biotechnology. Biotechnologies 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 biotechnology, 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 of our 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.

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The ability of branded competitors to successfully limit or delay competition for certain generic products through legislative, regulatory and litigation efforts, may limit our ability to generate revenue from the sale of our generic products.

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. We are currently in patent litigation with GlaxoSmithKline relating to our generic version of Imitrex® injection . For information regarding the risks of this litigation, please see the risk factor above.

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;
- attaching patent extension amendments to non-related federal legislation; and
- obtaining regulatory approval of new dosage strengths, dosage forms and/or formulations to try and obtain regulatory exclusivities or move consumers away from the generic product.

Also, branded pharmaceutical companies are selling generic versions of their own branded drugs, or authorizing other companies to sell generic versions. This could hurt our ability to capture market share and generate profits, especially if we are granted 180 days marketing exclusivity for one of our generic drugs.

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 regulatory approvals is time consuming, expensive, and can be 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. The FDA may not agree that our safety and bioequivalence 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.

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Our failure to comply with governmental regulations may delay or prevent approval of our product candidates and/or 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. If partners, our contract research organizations, or we 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/or

refusals to approve new products.

The discovery of previously unknown problems with drug products approved to go to market may raise costs or prevent us from marketing such product.

The later discovery of previously unknown problems with our products may result in restrictions of the product, 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.

Our failure to comply with advertising regulations enforced by the FDA and the Federal Trade Commission may subject us to sanctions, damage our reputation and adversely affect our business condition.

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;

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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/or

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. Sales of our products 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, including, the Medicare Prescription Drug, Improvement and Modernization Act of 2003, or the Medicare Modernization Act, which 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. The new benefit, which will be managed by private health insurers, pharmacy benefit managers and other managed care organizations, may 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 possible that other proposals will be adopted or 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 injection, the generic form of GlaxoSmithKline s, or GSK, Imitrex® injection, and are currently in litigation with GSK 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

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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 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. We have filed our settlement agreement with GSK relating to our patent litigation for sumatriptan injection with the Federal Trade Commission and the Department of Justice.

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.

Our corporate compliance program may not ensure that we are in compliance with all applicable fraud and abuse laws and regulations, and a failure to comply with such regulations or prevail in litigation related to noncompliance could harm our business.

Pharmaceutical and biotechnology companies have faced lawsuits and investigations pertaining to violations of health care fraud and abuse laws, such as the federal false claims act, the federal anti-kickback statute, and other state and federal laws and regulations. While we have developed and implemented a corporate compliance program based upon what we believe are the relevant current best practices, we cannot guarantee that this program will protect us from future lawsuits or investigations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

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 United States 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, 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 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.

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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 do not believe that any of our drug candidates infringe on the rights of any third party, there may be third party patents or other intellectual property rights relevant to our drug candidates that may ultimately be determined to have been infringed by our drug candidates. 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, 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 do we 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 $10 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 currently involves 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

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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 September 30, 2006, there were approximately 25 million shares of our common stock outstanding, and in addition, security holders held restricted stock, options, warrants and preferred stock which, if vested, exercised or converted, would obligate us to issue up to approximately 15 million additional shares of common stock. However, we will receive over $80 million from the issuance of all the shares of common stock upon exercise of all of the option and warrants. A substantial number of those shares, when we issue them upon vesting, conversion or exercise, will be available for immediate resale in the public market. In addition, we have filed a shelf registration statement of which this prospectus supplement is a part that allows us to sell up to $100 million of our securities in which approximately $31 million remains available for issuance, 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 resale in the market. If we were to sell the remaining $31 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 6 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 we anticipate that we will have to finance a large 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 bio-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. Also, certain dilutive securities such as warrants can be used as hedging tools which may increase volatility in our stock and cause a price decline. 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 2005, the price of our common stock ranged between $3.51 and $7.50, and the daily trading volume was as high as 1,368,400 shares and as low as 16,700 shares. During 2006 through December 4, 2006, the price of our common stock has ranged between $3.36 and $6.20, and the daily trading volume has been as high as 6,624,100 shares and as low as 24,300 shares.

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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; and
- 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, which we have since amended from time to time, 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 15% 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 15% 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 15% 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.

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USE OF PROCEEDS

We expect to use the net proceeds from this offering for general corporate purposes. In connection with this offering, we will not pay any fees or commissions to a placement agent, finder or any other person.

DILUTION

The net tangible book value of our common stock on September 30, 2006 was approximately $40.3 million, or approximately $1.65 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. Dilution in net tangible book value per share to new investors represents the difference between the amount per share paid by purchasers of shares of our common stock in this offering and the net tangible book value per share of our common stock immediately afterwards. Without taking into account any other changes in net tangible book value after September 30, 2006, our net tangible book value would have been approximately $41.3 million, or approximately $1.68 per share. This represents an immediate accretion in net tangible book value of approximately $.03 per share to existing stockholders and an immediate dilution in net tangible book value of approximately $6.65 per share to new investors.

Offering price per share		$ 8.33
Net tangible book value per share as of September 30, 2006	$ 1.65	
Increase per share attributable to new investors	$ .03	
As adjusted net tangible book value per share after the offering		$ 1.68
Decrease in net tangible book value per share to new investors		$ 6.65

This table excludes shares of common stock issuable upon exercise of options, warrants and other rights and the effect of shares of common stock issued, except as indicated above, since September 30, 2006. 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.

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PLAN OF DISTRIBUTION

Our common stock is traded on the Nasdaq Market under the symbol SPPI.

On August 4, 2006, we agreed to terminate the supply agreement dated April 16, 2002, by and between J.B. Chemicals & Pharmaceuticals Ltd., or JBCPL, and NeoJB LLC, or NeoJB, an 80% owned subsidiary, whereby in addition to certain named products we also had the right of first refusal on products sold by JBCPL in the U.S. In place of the supply agreement, we entered into a new supply agreement between the Company and JBCPL for four specified products, including ciprofloxacin and fluconazole tablets, to be supplied by JBCPL. In addition, pursuant to a share subscription agreement, JBCPL agreed to purchase 120,000 shares of our common stock for $1 million which shares are being offered pursuant to this prospectus supplement.

In connection with this offering, we will not pay any fees or commissions to a placement agent, finder or any other person. We have incurred only nominal expenses in connection with this offering.

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DESCRIPTION OF COMMON STOCK

The following summary of term of our common stock does not purport to be complete and is subject to and qualified in its entirety by reference to our Charter and Bylaws, copies of which are on file with the SEC. See Where You Can Find More Information.

We have authority to issue 100,000,000 shares of common stock, $0.001 par value per share. As of December 4, 2006, we had 25,093,477 shares of common stock outstanding, held of record by approximately 359 stockholders.

Terms

Holders of our common stock are entitled to one vote per share on all matters to be voted upon by the stockholders. The holders of common stock are not entitled to cumulative voting rights with respect to election of directors, and as a consequence, minority stockholders will not be able to elect directors on the basis of their shares alone. Our Board of Directors is divided into three classes, with the term of each class expiring every third year at the annual meeting of stockholders. The number of directors is distributed equally between the three classes.

No dividend on our common stock may be paid unless, at the time of such payment, all accrued dividends on our Series D 8% Cumulative Convertible Voting Preferred Stock have been paid, and we have on hand cash and other liquid assets sufficient to pay in full, in cash, the liquidation preference that would be payable to the holders of the preferred stock, as if such liquidation preference were then payable. Subject to this preference and the preferences that may be applicable to the holders of any other class of our preferred stock, if any, the holders of our common stock are entitled to receive ratably such lawful dividends as may be declared by the Board of Directors.

In the event of liquidation, dissolution or winding up of Spectrum, before any distribution of our assets shall be made to or set apart for the holders of our common stock, the holders of our Series D 8% Cumulative Convertible Voting Preferred Stock and our Series E Convertible Voting Preferred Stock shall be entitled to receive payment out of our assets in an amount equal to the liquidation preference set forth in the Certificate of Designations for the preferred stock. If the assets available for distribution to stockholders exceed the aggregate amount of the liquidation preference with respect to all shares of the preferred stock then outstanding, then the holders of our common stock shall be entitled to receive, subject to the rights of the holders of any other class of our preferred stock, if any, pro rata all of our remaining assets available for distribution to our stockholders.

Our common stock has no preemptive or conversion rights, other subscription rights, or redemption or sinking fund provisions. All outstanding shares of our common stock are fully paid and nonassessable. The rights, powers, preferences and privileges of holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock.

Stockholder Rights Plan

On December 13, 2000, we adopted a Stockholder Rights Plan pursuant to which we have 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 15% 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 15% or more of our outstanding common stock, other than pursuant to a transaction approved in advance by our Board of Directors. The description and terms of the rights are set forth in a Rights Agreement between us and U.S. Stock Transfer Corporation, as rights agent, filed with the SEC on December 26, 2000, as Exhibit 4.1 to our Form 8-A, as amended by Amendment No. 1 dated July 23, 2003, filed with the SEC on August 14, 2003, as Exhibit 4.1 to our Form 10-Q for the period ended June 30, 2003, by Amendments No. 2 and No. 3 each dated May 10, 2004, filed with the SEC on May 17, 2004, as Exhibit 4.1 and Exhibit 4.2, respectively, to our Form 10-Q for the period ended March 31, 2004, Amendment No. 4 dated July 7, 2006, filed with the SEC on July 7, 2006 as Exhibit 4.1 to our Form 8-K, and by Amendment No. 5 dated September 26, 2006, filed with the SEC on November 3, 2006 as Exhibit 4.2 to our Form 10-Q for the period ended September 30, 2006.

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Certain Provisions of Delaware Law and of the Company s Charter and Bylaws

The following paragraphs summarize certain provisions of the Delaware General Corporation Law and the Company s Charter and Bylaws. The summary does not purport to be complete and is subject to and qualified in its entirety by reference to the DGCL and to the Company s Charter and Bylaws, copies of which are on file with the SEC. See Where You Can Find More Information.

Our Certificate of Incorporation and Bylaws contain provisions that, together with the ownership position of the officers, directors and their affiliates, could discourage potential takeover attempts and make it more difficult for stockholders to change management, which could adversely affect the market price of our common stock.

Our Certificate of Incorporation limits the extent to which our directors are personally liable to Spectrum and our stockholders, to the fullest extent permitted by the Delaware General Corporation Law, or DGCL. The inclusion of this provision in our Certificate of Incorporation may reduce the likelihood of derivative litigation against directors and may discourage or deter stockholders or management from bringing a lawsuit against directors for breach of their duty of care.

Our Bylaws provide that special meetings of stockholders can be called only by the Board of Directors, the Chairman of the Board of Directors or the Chief Executive Officer. Stockholders are not permitted to call a special meeting and cannot require the Board of Directors to call a special meeting. There is no right of stockholders to act by written consent without a meeting, unless the consent is unanimous. Any vacancy on the Board of Directors resulting from death, resignation, removal or otherwise or newly created directorships may be filled only by vote of the majority of directors then in office, or by a sole remaining director. Our Bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, except for nominations made by or at the direction of the board of directors or a committee of the board. See Terms above.

We are subject to the business combination statute of the DGCL, an anti-takeover law enacted in 1988. In general, Section 203 of the DGCL prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, for a period of three years after the date of the transaction in which a person became an interested stockholder, unless:

- prior to such date the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder,
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding those shares owned (1) by persons who are directors and also officers and (2) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer, or
- at or subsequent to such time the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of a least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

A business combination includes mergers, stock or asset sales and other transactions resulting in a financial benefit to the interested stockholders. An interested stockholder is a person who, together with affiliates and associates, owns (or within three years, did own) 15% or more of the corporation s voting stock. Although Section 203 permits us to elect not to be governed by its provisions, we have not made this election. As a result of the application of Section 203, potential acquirers of Spectrum may be discouraged from attempting to effect an acquisition transaction with us, thereby possibly depriving holders of our securities of certain opportunities to sell or otherwise dispose of such securities at above-market prices pursuant to such transactions.

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Transfer Agent and Registrar

The transfer agent and registrar for the common stock is U.S. Stock Transfer Corporation.

VALIDITY OF SECURITIES

Latham & Watkins LLP, Costa Mesa, California, will pass on the validity of the securities offered by this prospectus.

EXPERTS

The consolidated financial statements of the Company as of December 31, 2005, December 31, 2004 and December 31, 2003 and for each of the three years in the period ended December 31, 2005, incorporated by reference in this registration statement have been audited by Kelly & Company, independent certified public accountants, as indicated in their report with respect thereto, and are included herein in reliance upon the authority of said firm as experts in giving said report.

LIMITATION ON LIABILITY AND DISCLOSURE OF SEC POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Our bylaws provide for indemnification of our directors and officers to the fullest extent permitted by law. Insofar as indemnification for liabilities under the Securities Act of 1933 may be permitted to directors, officers or controlling persons of the Company pursuant to the Company s Certificate of Incorporation, as amended, bylaws and the Delaware General Corporation Law, the Company has been informed that in the opinion of the SEC such indemnification is against public policy as expressed in such Act and is therefore unenforceable.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the SEC. You may read and copy any document we file at the SEC s public reference room at 100 F Street, N.E., Washington, D.C., 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference rooms. Our SEC filings are also available to the public at the SEC s web site at http://www.sec.gov.

The SEC allows us to incorporate by reference the information we file with them, which means that we can disclose important information to you by referring you to those documents instead of having to repeat the information in this prospectus supplement. The information incorporated by reference is considered to be part of this prospectus supplement, and later information that we file with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings made with the SEC under Sections 13(a), 13(c), 14, or 15(d) of the Securities Exchange Act of 1934 until all the securities are sold:

- Our annual report on Form 10-K for the fiscal year ended December 31, 2005, filed on March 15, 2006;
- Our quarterly reports on Form 10-Q for the quarter ended March 31, 2005, filed on May 8, 2006, for the quarter ended June 30, 2005, filed on August 8, 2006 and for the quarter ended September 30, 2006 filed on November 3, 2006;
- Our current reports on Form 8-K filed on January 5, 2006, January 23, 2006, February 28, 2006, March 20, 2006, April 26, 2006, May 30, 2006, July 12, 2006, September 25, 2006, October 2, 2006, October 10, 2006 and two on November 16, 2006;
- The description of our common stock contained in the Registration of Securities of Certain Successor Issuers filed pursuant to Section 12(g) of the Exchange Act on Form 8-B on June 27, 1997, including any amendment or reports filed for the purpose of updating such description; and

The description of our Rights to Purchase Series B Junior Participating Preferred Stock contained in the Registration of Certain Classes of Securities filed pursuant to Section 12(g) of the Exchange Act on Form 8-A on December 26, 2000, including any amendment or reports filed for the purpose of updating such description.

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You can request a copy of these filings, at no cost, by writing or telephoning us at the following address:

Spectrum Pharmaceuticals, Inc.

Attn: Investor Relations

157 Technology Drive

Irvine, California 92618

(949) 788-6700

You should rely only on the information contained in this prospectus supplement, the accompanying prospectus and in the documents incorporated by reference herein and therein. We have not authorized anyone else to provide you with different information. We will not make an offer of these shares in any state where the offer is not permitted. You should not assume that the information in this prospectus supplement, the accompanying prospectus or in the documents incorporated by reference herein and therein is accurate on any date other than the date on the front of those documents.

This prospectus supplement, the accompanying prospectus and any documents incorporated by reference herein and therein, are part of a registration statement we filed with the SEC (Registration No. 333-121612). The registration statement and the documents incorporated by reference into it and this prospectus supplement and the accompanying prospectus contain more information about the shares sold by us pursuant to this prospectus supplement. Because information about contracts referred to in this prospectus supplement and the accompanying prospectus is not always complete, you should read the full contracts which are incorporated by reference in the registration statement, this prospectus supplement and the accompanying prospectus. You may read and copy the full registration statement and the documents incorporated by reference into it at the SEC s public reference rooms or their web site.

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SPECTRUM PHARMACEUTICALS, INC.

120,000 SHARES

OF COMMON STOCK

PROSPECTUS

DECEMBER 6, 2006