

SPECTRUM PHARMACEUTICALS INC
Form 10-K
March 14, 2007
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

þ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2006

Or

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 000-28782

Spectrum Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction

of incorporation or organization)

93-0979187
(I.R.S. Employer

Identification No.)

157 Technology Drive

92618

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Irvine, California
(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code:

(949) 788-6700

Securities registered pursuant to Section 12(b) of the Act:

None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, \$.001 par value

Common Stock Purchase Warrants

Rights to Purchase Series B Junior Participating Preferred Stock

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K

Indicate by check mark whether the registrant is a large accelerated filer, accelerated filer, or a non-accelerated filer (as defined in Rule 12b-2 of the Act).

Large accelerated filer Accelerated filer Non-accelerated filer

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12B-2 of the Exchange Act). Yes No

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2006 was \$94,476,000 based on the closing sale price of such common equity on such date.

As of March 9, 2007 there were 25,325,683 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the Registrant's 2007 Annual Meeting of Stockholders, to be filed on or before April 30, 2007, are incorporated by reference into Part III of this Form 10-K.

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FORWARD-LOOKING STATEMENTS

Spectrum Pharmaceuticals, Inc.'s Annual Report on Form 10-K contains certain words, not limited to, believes, may, will, expects, intends, estimates, anticipates, plans, seeks, or continues, and also contains predictions, estimates and other 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, and in reliance upon the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are based on the current beliefs of the Company's management as well as assumptions made by and information currently available to the Company's management. Readers should not put undue reliance on these forward-looking statements. Reference is made in particular to forward looking statements regarding the success of our drug candidates, product approvals, product sales, revenue, development timelines, product acquisitions, liquidity and capital resources and trends. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. Spectrum Pharmaceuticals, Inc.'s actual results may differ materially from the results projected in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this Report, including the Risk Factors in Item 1A Risk Factors, and in Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations included in Part II. We do not undertake to update any such forward-looking statements and expressly disclaim any duty to update the information contained in this filing except as required by law.

Unless the context otherwise requires, all references to the Company, we, us, our, Spectrum and Spectrum Pharmaceuticals refer to Spectrum Pharmaceuticals, Inc. and its subsidiaries, as a consolidated entity. We primarily conduct all our activities as Spectrum Pharmaceuticals.

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PART I

Item 1. Business

Overview

We are a biopharmaceutical company that acquires and advances a diversified portfolio of drug candidates, with a focus on oncology, urology and other critical health challenges for which there are few other treatment options. Our expertise lies in identifying undervalued drugs with demonstrated safety and efficacy, and adding value through further clinical development and selection of the most viable and low-risk methods of commercialization. We currently have ten drugs in development, including five in late stage clinical development. We expect to have two drugs approved by the United States Food and Drug Administration, or FDA, and to begin two registrational Phase 3 clinical trials in 2007, or soon thereafter. Additionally, we expect to launch another drug in 2008.

The pillars of our risk-reduced business model are: 1) reduce scientific and clinical risk as much as is commercially viable by developing a broad and diverse pipeline with a late-stage focus with emphasis on known mechanisms of action; 2) utilize organizational, collaborative, scientific and commercial efficiencies from a therapeutic focus on oncology and urology; 3) finance the development of our proprietary pipeline with multiple sources of financing, not just equity; and 4) build and maintain a team with significant drug development experience, in other words, a team that has done it before. Our strategy allows us the opportunity to build a diversified portfolio of drugs, strengthen our development and commercialization capabilities, while sharing risk through business alliances and leveraging near-term revenue opportunities. Our commitment is to build a successful commercial biopharmaceutical company with sustainable future growth from revenue-generating prescription drugs in oncology and urology.

Since August 2002, we have accomplished a successful turnaround by shifting our strategic focus from drug discovery, neurology drugs and genomics research, to development of a diversified drug portfolio containing primarily clinical stage oncology, or anti-cancer, drugs. During this period, we have enhanced our financial strength and capabilities by securing over \$100 million in equity financing and upfront license fees, and entering into several strategic business alliances. These actions enabled us to acquire development rights to several new proprietary drug product candidates, strengthen our management team, enhance our developmental and regulatory capabilities, and accelerate the development timelines of our key drug product candidates.

Business Strategy

Our mission at Spectrum Pharmaceuticals is to bring our expertise and passion for excellence to acquire, develop and commercialize pharmaceuticals for unmet medical needs while building value for our shareholders. Our business model is unique in that it is tightly focused to reduce risk and improve our odds of success. The tenets of our business strategy to fulfill this mission are:

Reduce scientific and clinical risk: We take a portfolio approach to managing our pipeline that balances the size of the market opportunities with clear and defined clinical and regulatory paths to approval. We acquire and develop multiple novel, late-stage oncology product candidates that address niche markets. Each of these work differently and are based on diverse technologies. Just like the physicians and patients that we serve, we are not constrained by any one technology. A late stage focus helps us effectively manage the high cost of drug development by focusing on compounds that have already passed the many costly hurdles in the pre-clinical and clinical process.

Executing on our portfolio strategy, we currently have ten drugs in development, including five in late stage clinical development. We expect to have two drugs approved by the FDA and to begin two registrational Phase 3 clinical trials in 2007. Additionally, we expect to launch an additional drug in 2008. Finally, while we continue to advance our existing product portfolio, we are evaluating additional promising proprietary drugs for acquisition or in-licensing from third parties.

Realize efficiencies from therapeutic focus: Our model allows us to leverage organizational, collaborative, commercial and scientific efficiencies from a therapeutic focus on oncology, and a near-term commercialization

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focus on urology. Our model lets us pursue promising technologies without tying-up our resources on unpromising candidates.

If we participate in the U.S. co-promotion of satraplatin, our lead drug, in prostate cancer, it will serve as a platform to introduce EOquin® for non-invasive bladder cancer and ozarelix for benign prostate hypertrophy, or BPH, because all of these diseases are treated by urologists.

Finally, our therapeutic concentration allows us to focus our business development efforts to better cover the depth and breadth of the scientific and commercial communities in our relevant areas of focus to find appropriate drug candidates for acquisition or in-license.

Non-dilutive funding: We plan to continue financing a portion of the development of our proprietary pipeline with multiple sources of financing, such as various collaborations, partnering and co-development arrangements, and near-term revenue opportunities (like with our generics collaboration with Par Pharmaceutical Companies, Inc., or Par) in order to reduce the need for dilution to our shareholders from equity offerings.

Strategic Alliances: To mitigate risks inherent in the drug development process, to accelerate drug development timelines, and to opportunistically generate cash, we will seek to out-license rights to certain of our intellectual property and proprietary products for the development and commercialization of those products, particularly outside the United States, in exchange for upfront fees, milestones, royalties and other commercialization privileges.

Near-term Revenues: Recognizing that new drug development is a lengthy process, we focus primarily on late stage proprietary compounds with the potential for generating revenues in the near-term. Our current near-term revenue drivers are satraplatin, expected to be launched in 2007, or soon thereafter, if approved by the FDA; and Levofolinic Acid, or LFA, and sumatriptan injection, the generic form of Imitrex® injection. In addition, as EOquin and ozarelix are poised to commence Phase 3 trials in 2007, we may, at the appropriate time, seek partners to provide us with upfront licensing fees, milestone payments and royalties on sales for ex-North American rights to the development and commercialization of these drugs.

Product Commercialization: As our drugs progress through development, to the point of potential FDA approval for marketing in the United States, we plan to expand our sales and marketing capability. However, the costs of establishing and maintaining a sales force to effectively market proprietary drug products in the United States are significant. Accordingly, to accelerate the market penetration of our proprietary products, when approved by the FDA, we may seek collaborations with entities with proven sales, marketing and distribution capabilities in the United States.

Experienced Team: We have built the foundation of a team with significant experience in oncology drug development. We endeavor to leverage the talents of our team and add people who have relevant experience. Members of our team have been responsible for the development of drugs such as adriamycin, cisplatin, carboplatin, paclitaxel, doxorubicin, Etoposide, Buspar, Nefazodone and Stadol, among others. We also plan to bring commercialization experience to the Company as our products obtain FDA approval.

Recent Developments

In December 2006, we announced that the patent litigation relating to sumatriptan injection, the generic version of GlaxoSmithKline's, or GSK, Imitrex® injection, had been dismissed by the United States District Court for the District of Delaware pursuant to a settlement agreement between us and GSK. The terms of the confidential agreement 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 that begins on August 6, 2008, but with the launch occurring not later than November 6, 2008. We will launch sumatriptan injection products through our partner for the sale and distribution of the drug, Par, with whom we entered into a strategic alliance with in February 2006. This will enable Par to continue with the launch of sumatriptan injection products ahead of GSK's patent expiration and allow us to begin receiving profits upon sales as early as 2008. Pursuant to the agreement with Par, as amended, we received a \$5 million payment from Par related to sumatriptan injection for, which our Abbreviated New Drug Application, or ANDA, was granted tentative approval by the FDA in October 2006.

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In January 2007, the FDA accepted our Investigational New Drug, or IND, application for ozarelix in BPH and also approved the protocol for a Phase 2b study of ozarelix for the treatment of BPH. The Phase 2b study is a randomized, placebo-controlled trial of ozarelix involving approximately 75 men suffering from BPH. In this trial, the men will be dosed with 15 mg of ozarelix or placebo on day 1 and day 15 and will be followed for at least twelve weeks for assessing efficacy. The study will evaluate safety and assess the clinical efficacy of ozarelix as a treatment for BPH. The primary endpoint of the study will be the improvement of BPH symptoms as measured by the International Prostate Symptom Score, or IPSS, the standard method of assessing BPH symptoms. The study will also measure urine flow, residual urine volume and quality of life. This study is currently underway with nearly half of the targeted patients enrolled. Data from this trial is expected to be available in the second half of 2007. We anticipate commencing a Phase 3 clinical trial in BPH before the end of 2007, or soon thereafter. Safety and efficacy data from this trial will be used to support a NDA for ozarelix.

In February 2007, we announced the completion of the New Drug Application, or NDA, submission, with the FDA for satraplatin, an orally bioavailable platinum compound, for use in combination with prednisone as a second-line chemotherapy treatment for patients with hormone-refractory prostate cancer, or HRPC. If the FDA approves the NDA, sales of satraplatin could commence in the United States as early as late 2007, or early 2008. In 2001, we in-licensed worldwide rights to satraplatin from Johnson Matthey, PLC, or Johnson Matthey. In 2002, in exchange for an upfront license fee and future milestones and royalties, we entered into a Co-Development and License Agreement with GPC Biotech AG, or GPC Biotech, for worldwide rights for further development and commercialization of satraplatin. Under the terms of this agreement, GPC Biotech agreed to fully fund the development expenses for satraplatin. In December 2005, GPC Biotech licensed commercialization rights for Europe, Turkey, the Middle East, Australia and New Zealand to Pharmion Corporation, who expects to submit for European marketing authorization in the first half of 2007, pending concurrence with the European Agency for the Evaluation of Medicinal Products, or EMEA, the FDA's European counterpart. A successful worldwide launch of satraplatin and achievement of all regulatory and sales milestone revenues could generate revenues in excess of \$50 million for us, net of our milestone payment obligations to Johnson Matthey. In addition, we will receive a royalty on worldwide sales of satraplatin, reduced by royalties payable by us to Johnson Matthey. Also, under certain conditions, we may have co-promotion rights for satraplatin in the U.S. As of the date of this report, we are in arbitration with GPC Biotech over a contractual dispute, which arbitration is described in further detail at Item 3 Legal Proceedings of this report.

We recently reached an agreement with the FDA for a Special Protocol Assessment, or SPA, procedure for a Phase 3 study for treatment of non-invasive bladder with EOquin. The SPA process allows for a written agreement between us and the FDA on the design of a study, including clinical drug supply, pivotal trial design, clinical endpoints, conduct, data analysis, and other clinical trial issues, and is intended to provide assurance that if pre-specified trial results are achieved, they may serve as the primary basis for an efficacy claim in support of a NDA. The SPA calls for randomized, double-blind, placebo-controlled Phase 3 clinical trials, each with 562 patients with T_AG1G2 non-invasive bladder cancer. Patients will be randomized in a one-to-one ratio to EOquin or placebo. The primary endpoint will be a statistically significant difference ($p < 0.05$) in the rate of tumor recurrence at year two between the EOquin patient group and the placebo group. We currently anticipate enrollment of the first patients in the United States trial in the second quarter of 2007.

Drug Product Candidates

New drug development, which is the process whereby drug product candidates are tested for the purpose of filing a NDA (or similar filing in other countries) and eventually obtaining marketing approval from the FDA or a marketing authorization from other regulatory authorities outside of the United States, is an inherently uncertain, lengthy and expensive process which requires several phases of clinical trials to demonstrate to the satisfaction of the FDA in the United States, and regulatory authorities in other countries, that the products are both safe and effective for their respective indications. Our strategy is designed to address the significant risks of drug development by focusing our acquisition and development efforts on clinical stage drug candidates (those in human trials). We do, however, also undertake the acquisition and development of promising pre-clinical drug candidates when we believe that the therapy is novel and/or when we believe the drug candidates have a higher probability of regulatory approval than that of a typical compound at a similar stage of development.

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Our drug candidates, their target indications, and status of development are summarized in the following table, and discussed below in further detail:

Drug Candidate	Target Indication	Development Status
Satraplatin	Hormone Refractory Prostate Cancer In multiple trials in other cancer types; in combination with radiation therapy; and in combination with other chemotherapies	NDA submitted February 2007 Phase(s) 1-2
Levofolinic acid, or LFA	High dose methotrexate rescue in Osteogenic Sarcoma Colorectal Cancer	NDA on file with FDA; Chemistry, Manufacturing and Controls, or CMC, responses pending Planned regulatory filing
Sumatriptan injection	Migraines (generic form of GSK's Imitrex® injection)	ANDA with Paragraph IV filed, litigation settled, launch expected in the second half of 2008
EOquin	Non-invasive Bladder Cancer	Phase 2 completed; SPA negotiated with FDA; Phase 3 to start in the first half of 2007
Ozarelix	Benign Prostatic Hypertrophy Hormone dependent prostate cancer	Phase 2b initiated first quarter of 2007; Phase 3/Safety Study to initiate by late 2007 Phase 2 study completed in 2006; Phase 2b study in progress in Europe
Elsamitrucin	Endometriosis Various potential cancers	Phase 1 study in second half of 2007 Phase 1/2
Lucanthone	Radiation Sensitizer for Glioblastoma Multiforme and other Brain Tumors and Brain Metastases	Phase 1 expected to initiate in second half of 2007
SPI-1620	Adjunct to Chemotherapy	Pre-clinical
RenaZorb	Hyperphosphatemia in End-stage Renal Disease	Pre-clinical
SPI-205	Chemotherapy Induced Neuropathy	Pre-clinical

While other indications have not yet been identified, some of our drug candidates may prove to be beneficial in additional disease indications as we continue to study and develop these drug candidates. In addition, we have intellectual property rights to neurology compounds that we may out-license to third parties for further development.

We believe our drug candidates have the potential to be effective therapeutic agents with some advantages over existing therapies. Our goal is to develop and commercialize many of these drugs in the United States and license the rights for Japan and Europe to local companies in those countries (to the extent that we have rights in those territories).

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Overview of Major Indications We Are Targeting

Cancer

Cancer is the second leading cause of death in the United States, accounting for approximately 25% of all deaths. In its most recent annual report, the American Cancer Society reported that in the under-85 age group, cancer is the leading cause of death. In the United States, approximately 1.4 million new cancer cases are expected to be diagnosed in 2007 and over 560,000 persons are expected to die from the disease in 2007. Accordingly, there is significant demand for improved and novel cancer treatments.

Cancer occurs when abnormal cells divide without control. These cells can invade nearby tissues or spread through the bloodstream and lymphatic system to other parts of the body. Five to ten percent of all cancers are believed to be due to inheriting a faulty gene. The remaining 90 to 95 percent are believed to be caused by damage to the genes during a person's lifetime. This damage can be caused by internal agents, such as hormones or an altered immune system, or external agents, such as viruses, exposure to chemicals or harmful ultraviolet sunrays. Sometimes ten or more years may pass between exposure and cancer detection. Cancer is currently treated by surgery, chemotherapy, radiation therapy, hormonal therapy and immunotherapy. Cancer is referred to as refractory when it has not responded or is no longer responding to a treatment.

We believe that traditional chemotherapeutic agents are likely to remain the mainstay therapy for cancer for the foreseeable future. However, we continue to seek additional novel drugs, drug delivery methods and combination therapies that address cancer or cancer related indications with significant unmet medical need. Accordingly, we are actively seeking novel and proprietary oncology drug candidates that:

have demonstrated initial safety and efficacy in clinical trials and/or we believe have a higher probability of regulatory approval than that of a typical compound at a similar stage of development;

target cancer indications with significant unmet medical need, where current treatments either do not exist or are not effective; and

we believe we can acquire at a fair value based on our judgment of clinical and commercial potential.

Benign Prostatic Hypertrophy

BPH is a non-cancerous enlargement of the prostate leading to difficulty in passing urine, reduced flow of urine, discomfort or pain while passing urine and increased frequency of urination. Enlargement of the prostate is caused by testosterone. According to Urology Today, benign prostatic hypertrophy affects more than 50% of men over age 50 and as many as 80% of men over the age of 70. Treatment options for benign prostatic hypertrophy include surgery and medications to reduce the amount of tissue and increase the flow of urine.

Our drug candidates

Satraplatin: Satraplatin, an orally administered platinum-derived chemotherapy agent, is being developed by our co-development partner, GPC Biotech AG, as a second-line chemotherapy treatment for its intended initial indication, hormone-refractory prostate cancer, or HRPC. In addition to hormone-refractory prostate cancer, satraplatin has shown indication of anti-tumor activity in clinical studies in solid tumors such as ovarian and lung cancer.

Prostate cancer is the most common cancer among men in the U.S. and Europe. According to the American Cancer Society, approximately 219,000 men in the U.S. are expected to be diagnosed with the disease in 2007 and over 27,000 men are expected to die from the disease. In the European Union, over 200,000 new cases are expected to be diagnosed, and over 60,000 patients are expected to die each year. Since the incidence of prostate cancer

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increases with age, the aging of the overall population is expected to further increase the number of prostate cancer patients. Most patients diagnosed with prostate cancer initially receive surgery or radiation therapy, and some of these patients are cured. For many others, however, the disease recurs. At this point, the recurrent disease is treated with hormone therapy, and most patients initially respond well to this treatment. Eventually, however, the tumor cells become resistant to the hormones or hormone-refractory and the tumor again progresses. Increasingly, chemotherapy is being used as an effective first-line treatment for hormone-refractory prostate cancer. However, it is not a cure, and so this is creating a need for effective therapeutic options for these patients once they have progressed.

Platinum compounds continue to represent one of the most widely used classes of chemotherapeutic agents in modern cancer therapy and are typically used in combination with other chemotherapeutic agents for the treatment of various types of cancer. While the platinum compounds currently on the market are intravenously administered, satraplatin is an orally administered compound. We believe an orally administered platinum-derived chemotherapeutic agent may offer important clinical and commercial advantages over platinum compounds that need to be intravenously administered in a hospital setting, including ease of administration and patient convenience.

A pivotal phase 3 trial, the Satraplatin and Prednisone Against Refractory Cancer, or SPARC, trial for satraplatin in HRPC, was initiated by our partner, GPC Biotech, in September 2003, following completion of a SPA. In September 2006, the independent data monitoring board for the trial announced positive results from the SPARC trial. In February 2007, an NDA was submitted to the FDA.

In February 2004, the EMEA, the FDA's European counterpart, issued a Scientific Advice Letter enabling the pivotal Phase 3 trial on satraplatin to proceed in Europe using the SPARC protocol. In December 2005, GPC Biotech licensed commercialization rights for Europe, Turkey, the Middle East, Australia and New Zealand to Pharmion Corporation, who expects to submit for European marketing authorization in the first half of 2007, pending concurrence with the EMEA.

Satraplatin has demonstrated anti-tumor activity in several cancers in clinical studies; accordingly, in order to maximize its potential, in addition to the SPARC trial in HRPC, satraplatin is being studied in multiple trials in other cancer types, in combination with radiation therapy and in combination with other chemotherapies.

The following describes the commercial terms relating to satraplatin licensing and development.

In 2001, we in-licensed exclusive worldwide rights to satraplatin from its developer, Johnson Matthey, PLC, or Johnson Matthey, in exchange for an upfront fee, additional payments to be made based upon achievement of certain milestones and royalties based on any net sales, if any, if and when a commercial drug is approved and sales are initiated. The term of the agreement expires on a country-by-country basis upon the expiration of the last to expire patents granted in each country, although some obligations, such as provisions relating to confidentiality, survive termination. In addition, the agreement may be terminated earlier by Johnson Matthey if we fail to make any milestone or royalty payments on the date due, by us at any time upon sixty days' notice, or by either party upon breach of the agreement or commencement of bankruptcy or insolvency proceedings involving the other. We paid to Johnson Matthey \$500,000 upon submission of the complete NDA filing in February 2007 and are required to pay \$500,000 upon acceptance of the NDA by the FDA. Each of our contingent future cash payment milestone obligations to Johnson Matthey is generally matched by a corresponding, greater milestone receivable from GPC Biotech (see below).

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In 2002, in exchange for an upfront license fee and future milestones and royalties, we entered into a Co-Development and License Agreement with GPC Biotech for worldwide rights for further development and commercialization of satraplatin. Under the terms of this agreement, GPC Biotech agreed to fully fund the development expenses for satraplatin. In December 2005, GPC Biotech licensed commercialization rights for Europe, Turkey, the Middle East, Australia and New Zealand to Pharmion Corporation. To date, we have received \$3,000,000 in milestone payments and \$129,000 in commissions on the sale of satraplatin product to GPC Biotech. In addition, during 2003, pursuant to the license agreement, GPC Biotech made an equity investment of \$1,000,000 to purchase 128,370 shares of our common stock at \$7.79 per share. On February 16, 2007, we announced that the rolling submission of the NDA for satraplatin was submitted to the FDA was completed. The FDA's acceptance of the NDA will trigger a \$4 million milestone payment to us. We are entitled to additional revenues upon: achievement of specified milestones by GPC Biotech and Pharmion, which are generally based on developmental, regulatory events and sales and milestones; and royalties on worldwide sales, if any, of the product. The term of the agreement expires on a product-by-product and country-by-country basis upon the expiration of the last to expire patents granted in each country covering such product, although some obligations, such as provisions relating to confidentiality and indemnification, survive termination. In addition, the license agreement may be terminated earlier by either party (in some cases either in whole or on a product-by-product and/or country-by-country basis), based upon material breach or the commencement of bankruptcy or insolvency proceedings involving the other, or by GPC Biotech upon six months' notice to us. We are in arbitration with GPC Biotech over a contractual dispute, which arbitration is described in further detail at Item 3 Legal Proceedings of this report.

Levofolinic acid, or 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, also known as levoleucovorin, in the field of oncology in North America. LFA is the pure active isomer of leucovorin calcium, a component of standard of care 5-fluorouracil, or 5-FU, containing regimens for the treatment of colorectal cancer and other malignancies. Leucovorin calcium is also used after the administration of high-dose methotrexate in treating osteogenic sarcoma. An NDA for LFA has been filed with the FDA for the osteosarcoma indication. We expect to respond in the first half of this year to chemistry and manufacturing questions raised by the FDA during the review of the application and hope to have the NDA approved before the end of the year. After receiving approval of the NDA, we plan to file a supplemental NDA for the colorectal cancer indication. We are also contemplating a combination study with capecitabine this year. LFA is currently marketed and sold by Wyeth, Sanofi-Aventis Inc. and others in certain parts of the world, including Europe and Japan.

In April 2006, we completed the acquisition of all of the oncology drug product assets of Targent, and agreed to issue to Targent, or its stockholders, an aggregate amount of 600,000 shares of our common stock at closing. Only one-third (200,000) of these shares will be registered for resale. The remaining two-thirds (400,000) shares will not be registered and therefore will be subject to restrictions on resale under Rule 144 under the Securities Act of 1933, or the Securities Act. In addition, Targent is eligible to receive payments, in the form of our common stock and/or cash, upon achievement of certain regulatory and sales milestones, if any. At our option, any amounts due in cash under the purchase agreement may be paid by issuing shares of our common stock having a value, determined as provided in the purchase agreement, equal to the cash payment amount.

In May 2006, we amended and restated a license agreement with Merck Eprova AG, a Swiss corporation, or Eprova, that we assumed in connection with the acquisition of the assets of Targent, Inc. Pursuant to the license agreement, we obtained the exclusive license to use regulatory filings related to LFA and a non-exclusive license under certain patents and know-how related to LFA to develop, make, have made, use, sell and have sold LFA in the field of oncology in North America. Also, we have the right of first opportunity to negotiate an exclusive license to manufacture, have manufactured, use and sell LFA products outside the field of oncology in North America. Under the terms of the license agreement, Eprova is eligible to receive payments upon achievement of certain regulatory milestones, in addition to royalties on potential net sales, if any. The term of the license agreement is determined on a product-by-product and country-by-country basis until royalties are no longer owed under the license agreement.

In May 2006, we also entered into a manufacturing and supply with Eprova, whereby Eprova shall manufacture calcium levofolate (the active pharmaceutical ingredient of LFA) for us. The manufacturing and supply agreement shall remain in force as long as we are obligated to pay royalty payments to Eprova under certain sections of the license agreement. After a certain period of time, we have the ability to use a third party to manufacture the product at a lower price, provided Eprova has the opportunity to meet the competitive offer price.

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Sumatriptan injection: In October 2004, we filed an ANDA, with paragraph IV certification, with the FDA, for GSK's sumatriptan injection, the generic form of GSK's Imitrex® injection. In February 2005, GSK commenced suit against us, alleging that the filing of our ANDA infringes their patent covering Imitrex. In December 2006, we announced that the litigation had been dismissed by the United States District Court for the District of Delaware pursuant to a settlement agreement between GSK and us. The terms of the confidential agreement 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 that begins on August 6, 2008, but with the launch occurring not later than November 6, 2008. We will launch sumatriptan injection through our partner, Par, for the sale and distribution of the drug. This will enable Par to continue with the launch of sumatriptan injection ahead of GSK's patent expiration and allow us to begin receiving profits upon sales as early as 2008. Pursuant to the terms of our agreement with Par, we will receive a majority of the profits from the sale of sumatriptan injection.

EOquin: EOquin is an anti-cancer agent that becomes activated by certain enzymes present in higher amounts in cancer cells than in normal cells. It is currently being developed for the treatment of non-invasive bladder cancer, which is cancer that has not invaded the muscle of the bladder wall. EOquin is the trademarked name for the drug substance apaziquone formulated for administration directly into the urinary bladder (intravesical instillation).

The American Cancer Society estimates that there will be more than 67,160 new cases of and 13,750 deaths from bladder cancer in 2007 in the United States. The estimated patient population with bladder cancer is over 400,000 in the United States and even greater in Europe. Non-invasive bladder cancer accounts for 75 to 80 percent of all cases of bladder cancer at first diagnosis. The initial treatment of this cancer is surgical removal of the tumor. Because of the high frequency of early recurrences of the tumor, patients are usually prescribed additional therapy to prevent or delay such recurrences. This additional therapy generally consists of immunotherapy or chemotherapy drugs instilled directly into the bladder. During the past 20 years no new drugs have been introduced in the market for treatment of non-invasive bladder cancer.

EOquin is activated to a greater degree within tumor cells than in the normal bladder lining. Also, it is not absorbed in any detectable significant amount from the bladder wall into the bloodstream and thus carries a lesser risk of systemic side effects. During 2005, we completed a multi-center phase 2 clinical trial to evaluate the level of anti-tumor activity of EOquin as well as the safety of treatment.

Phase 2 data has confirmed anti-tumor activity against recurrent multiple non-invasive bladder cancer, as evidenced by thirty-one of forty-six patients (67%) showing a complete response after receiving six weekly treatments with EOquin instilled into the urinary bladder. In clinical trials performed to date, EOquin has shown to be well-tolerated, with no significant systemic toxicity, and local toxicity limited to temporary chemical cystitis (inflammation of the urinary bladder) resulting in increased urinary frequency, dysuria (painful urination) and hematuria (blood in the urine) in a few patients. In addition, there was no adverse effect on wound healing when administered immediately after surgery.

In September 2005, we initiated a multicenter clinical study in Europe, of EOquin in high-risk non-invasive bladder cancer patients who risk early relapse, sometimes in the form of invasive, life-threatening stages of bladder cancer. Enrollment is over half complete.

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In March 2006, we filed an IND for EOquin with the FDA to begin a Phase 3 registration study for the treatment of non-invasive bladder cancer. Subsequent to the filing and a meeting with the FDA, we began a 20 patient pilot safety study, for which patient accrual was recently completed. In this study, EOquin was found to be well tolerated when administered to patients immediately following surgery for non-invasive bladder cancer in clinical results to date. In addition, there was no adverse effect on wound healing and was not absorbed into the bloodstream. We recently reached an agreement with the FDA for a SPA procedure for a Phase 3 study for treatment non-invasive bladder. The SPA calls for randomized, double-blind, placebo-controlled Phase 3 clinical trials, each with 562 patients with T_AG1G2 non-invasive bladder cancer. Patients will be randomized in a one-to-one ratio to EOquin or placebo. The primary endpoint will be a statistically significant difference ($p < 0.05$) in the rate of tumor recurrence at year two between the EOquin patient group and the placebo group. We currently anticipate enrollment of the first patients in the United States trial in the second quarter of 2007.

The following describes the commercial terms relating to Eoquin licensing and development.

In 2001, we in-licensed exclusive worldwide rights to EOquin and numerous related derivatives from the INC Research[®], formerly NDDO Research Foundation, in the Netherlands, in exchange for an up front fee, additional payments based upon achievement of certain milestones and a royalty based on net sales, if any, if and when a commercial drug is approved and sales are initiated. The term of the agreement expires when all patents that are the subject of the license in the agreement expire, although some obligations survive termination. In addition, the agreement may be terminated earlier by us upon three months notice to INC Research[®]. The specific consequences of termination under each scenario are provided in the agreement that has been filed with the SEC.

Ozarelix: Ozarelix, a LHRH (Luteinizing Hormone Releasing Hormone, also known as GnRH or Gonadotropin Releasing Hormone) antagonist (a substance that blocks the effects of a natural hormone found in the body) is currently being evaluated for its targeted indications in HDPC, BPH and endometriosis. Mechanistically, LHRH antagonists exert rapid inhibition of luteinizing hormone and follicle stimulating hormone with an accompanying rapid decrease in sex hormones and would therefore be expected to be effective in a variety of hormonally dependent disease states including ovarian cancer, prostate cancer, BPH, infertility, uterine myoma and endometriosis.

BPH is a non-cancerous enlargement of the prostate that is caused by testosterone. Unlike LHRH-like drugs (agonists), ozarelix, which is an antagonist of LHRH, has the potential to reduce testosterone just enough to reduce both prostate size and symptoms without the severe side effects associated with a reduction in testosterone.

Current therapies for BPH either address its symptoms but not the underlying condition, or block growth of new prostate cells and reduce prostate size with only moderate relief of symptoms. There are two classes of drugs to treat BPH. The first, alpha adrenergic receptor blockers, are believed to work by relaxing the smooth muscle in the urethra and bladder without addressing the underlying condition of the enlarged prostate. Drugs in the second category, 5-alpha reductase inhibitors, work by blocking production of the hormones that stimulate the growth of new prostate cells thereby stopping and eventually reversing enlargement of the prostate. This class of drugs has a slow onset of action, typically requiring daily treatment for many months before improving patient symptoms. Drugs in both classes can have significant side effects, including decreased libido, impotence, abnormal ejaculation, rhinitis and cardiovascular effects such as dizziness, fainting and lightheadedness. Many patients ultimately fail existing medical therapy, leading to over 350,000 surgical procedures annually in the United States, despite the risks of serious surgical complications including impotence and incontinence. We believe that ozarelix could provide rapid relief of the symptoms of BPH.

Phase 2 data with Ozarelix in patients with BPH had very positive results. Highly statistically significant ($p < 0.0001$) and clinically meaningful results were seen for the primary endpoint in favor of ozarelix. Clinical improvement was maintained for six months following initial dosing of ozarelix. Ozarelix was safe and well-tolerated.

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In January 2007, the FDA accepted our IND application for ozarelix in BPH; and also approved the protocol for a Phase 2b study of ozarelix for the treatment of BPH. The Phase 2b study is a randomized, placebo-controlled trial of ozarelix involving approximately 75 men suffering from BPH. In this trial, the men will be dosed with 15 mg of ozarelix or placebo on day 1 and day 15 and will be followed for efficacy for at least twelve weeks. The study will evaluate safety and assess the clinical efficacy of ozarelix as a treatment for BPH. The primary endpoint of the study will be the improvement of BPH symptoms as measured by the IPSS. The study will also measure urine flow, residual urine volume and quality of life. This study is currently underway with nearly half of the targeted patients enrolled as of the date of this report. Data from this trial is expected to be available in the second half of 2007. Safety and efficacy data from this trial will be used to support an NDA for ozarelix. We anticipate commencing a Phase 3 clinical trial in BPH in 2007, or soon thereafter.

As described earlier, in connection with satraplatin, the initial treatment of prostate cancer includes surgery along with radiation therapy and hormonal therapy. We believe ozarelix may prove to be an important addition in treating hormone-dependent prostate cancer patients because of its ability to induce prolonged testosterone suppression in healthy volunteers as shown in early trials. There are other LHRH antagonist and agonists (a substance that mimics the effects of a natural hormone found in the body) that are currently marketed or are being tested for the treatment of the indications we are pursuing. However, we believe that ozarelix may have certain advantages over other LHRH antagonists which include improved solubility, less tendency for aggregation resulting in greater bioavailability (absorption by the body) and minimal histamine release tendency which should reduce allergic reactions. We also believe that ozarelix has advantages over LHRH agonists which include immediate and dose dependent suppression of sex hormones and no risk of testosterone surge or clinical flare up which are currently clinically important and may be more important in the future as intermittent dosing strategies are being studied.

Phase 2 data for ozarelix in hormone dependent prostate cancer appears to be positive. Patients receiving 130 mg per cycle of ozarelix showed the greatest continuous testosterone suppression, the primary endpoint. In patients with continuous testosterone suppression, tumor response, as measured by PSA levels, was 97%. Ozarelix was well-tolerated at all doses. A Phase 2 trial, conducted by our licensor of the drug, Zentaris GmbH, a subsidiary of Aeterna Zentaris, Inc. is ongoing in Europe. We believe that data from this trial will be available late 2007, or soon thereafter.

Endometriosis is a condition where tissue similar to the lining of the uterus is also found elsewhere in the body, but mainly in the abdominal cavity. This condition typically affects women during their menstruating years and is rarely found after menopause. Currently, there is no cure for endometriosis. However, symptoms associated with endometriosis can be managed through a combination of treatments. In endometriosis, we are completing the preclinical studies (reproductive toxicology studies) required before initiating studies in female subjects. The Phase 1 study is expected to initiate in the second half of 2007.

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The following describes the commercial terms relating to ozarelix licensing and development.

In 2004, we entered into a license agreement with a subsidiary of Aeterna Zentaris, Zentaris GmbH, or Aeterna Zentaris, whereby we acquired an exclusive license to develop and commercialize ozarelix in North America (including Canada and Mexico) and India. In addition, we have a financial interest in any income Aeterna Zentaris derives from ozarelix in Japan. With certain exceptions, we are required to purchase all finished drug product from Aeterna Zentaris for the clinical development of ozarelix at a set price. We paid an up-front fee, and are contingently obligated to pay additional amounts based upon achievement of milestones and a royalty based on any future net sales. During 2006, upon the successful conclusion of the Phase 2 trials in 2006, we paid to Aeterna Zentaris a milestone payment of one million Euros (approximately \$1.3 million). Also, during 2006, Aeterna Zentaris entered into a licensing and collaboration agreement with Nippon Kayaku Co. Ltd. of Japan for the development and marketing of ozarelix for all potential oncological indications in Japan, and received an upfront payment and is eligible to receive payments upon achievement of certain development and regulatory milestones, in addition to low double-digit royalties on potential net sales. Under the terms of our license agreement with Aeterna Zentaris, we are entitled to receive fifty percent of the upfront and milestone payments and royalties received from Nippon Kayaku Co. Ltd. by Aeterna Zentaris. As of December 31, 2006, our share of the upfront payments received by Aeterna Zentaris in 2006 was recorded as deferred income and will be recorded as revenue in accordance with our revenue recognition policy, namely when we have no significant future performance obligations and collectibility of the fees is reasonably assured. In this regard, the payment of our non-refundable fifty percent \$891,000 was received in January 2007. In the event Zentaris, or another licensee, independently develops ozarelix for territories not licensed to us, we are entitled to receive and utilize the results of those development efforts. With certain exceptions, we are required to purchase all finished drug product from Zentaris for the clinical development of ozarelix at a set price. The parties agreed to discuss entering into a joint supply agreement for commercial supplies of finished drug product. The term of the license agreement expires ten (10) years after the first commercial sale of a product in any country within the territory or as long as any product is covered by a patent in any country in the territory, whichever term is longer, although some obligations survive termination. In addition, the agreement may be terminated earlier by either party (in some cases either in whole or on a product-by-product and/or country-by-country and/or indication-by-indication basis), based upon material breach or the commencement of bankruptcy or insolvency proceedings involving the other, or by us upon sixty (60) days notice to Zentaris. The specific consequences of termination under each scenario are provided in the agreement that has been filed with the SEC.

Elsamitrucin: Elsamitrucin is an anti-tumor antibiotic that acts as a dual inhibitor of two key enzymes involved in DNA replication, topoisomerase I and II. By inhibiting the activity of these two key enzymes involved in DNA replication, elsamitrucin is thought to lead to DNA breaks that prevent the correct replication of DNA and ultimately result in cancer cell death.

In April 2004, we initiated a multi-center, Phase 2 trial in patients with refractory non-Hodgkin's lymphoma. This trial was completed in the fourth quarter of 2006 and final results are expected in the first half of 2007. Preliminary results suggest limited efficacy of elsamitrucin given as a single agent in patients with non-Hodgkin's lymphoma. In experimental models, elsamitrucin appeared to have synergy with paclitaxel and platinum derivatives. We plan to initiate soon a Phase 1/2 study of elsamitrucin in combination with paclitaxel and carboplatin in patients with recurrent or advanced non-small cell lung cancer. The rationale for this, in addition to the above mentioned synergism, is that elsamitrucin has been shown in clinical studies to result in minimal toxicity to bone marrow, the main toxicity target of most anticancer agents; therefore, it may allow combinations with other drugs without a need to significantly reduce doses, which may result in improved therapeutic effects.

We in-licensed exclusive worldwide rights to elsamitrucin from its developer, Bristol-Myers Squibb, in 2001, in exchange for an upfront fee, additional payments based upon achievement of milestones and a royalty based on net sales, if any, if and when a commercial drug is approved and sales are initiated.

Lucanthon: Lucanthon is an orally administered small-molecule which inhibits Topoisomerase II and interferes with the repair of DNA damage that is caused by radiation. Specificity of lucanthon in combination with radiation for the treatment of brain tumors arises from the fact that lucanthon acts preferentially on cycling cells (most of the normal brain cells are non-cycling) and the fact that lucanthon crosses the blood brain barrier efficiently.

Lucanthon was originally used as an antiparasitic agent for the treatment of schistosomiasis in the 1950s and 1960s, and has a demonstrated safety profile. It was later discontinued because better antiparasitic medications became available. A Phase 1 study is planned for the treatment of brain tumors and brain metastases in 2007.

We plan to initiate a Phase 1 study for the treatment of glioblastoma multiforme, a form of brain cancer.

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In May 2005, we entered into a license Agreement with Dr. Robert E. Bases, the inventor of a method of treating cancer of the central nervous system through the administration of lucanthone and radiation, whereby we acquired worldwide exclusive rights to develop and commercialize a product based upon his invention. Under the terms of the agreement, we made a small upfront payment to Dr. Bases and we are obligated to make additional periodic payments, a payment upon achievement of a certain regulatory milestone and royalties on potential net sales, if any.

SPI-1620: SPI-1620 is a highly selective peptide agonist of endothelin B receptors, which can stimulate receptors on endothelial cells, the innermost layer of cells lining the blood vessels. This technology takes advantage of the fact that the blood supply to tumors is different than the blood supply to healthy organs. Blood vessels in the growing part of tumors are relatively devoid of smooth muscle covering and are rich in endothelial cells. Therefore, by stimulating the endothelial B receptors present on the endothelial cells, SPI-1620 should selectively increase tumor blood flow while sparing healthy tissue.

Chemotherapy is one of the mainstays of therapy for solid carcinomas, including breast, lung, and prostate. Chemotherapy uses drugs called cytotoxic agents that are poisonous to cells and kill cancer cells. Chemotherapy often fails because adequate and uniform distribution of the cytotoxic agents is not achieved in the tumor, and serious side effects can result from toxicity to normal cells. Consequently, any means to increase the delivery of a cytotoxic agent selectively to tumors, while minimizing its concentration in normal tissues may be very beneficial.

SPI-1620 is being developed as an adjunct to chemotherapy. In pre-clinical studies, when anti-cancer drugs, such as paclitaxel injection, are administered shortly after SPI-1620, the anti-cancer drug concentration in the tumor is increased several fold. This results in increased antitumor efficacy at a given dose of a cytotoxic agent, and might allow physicians to maximize efficacy with reduced cytotoxic agent doses with resultant decreased toxicity to the normal organs.

We are currently completing the pre-clinical pharmacology and toxicology studies for SPI-1620 required to file an IND, which we expect to do in 2007. Subsequent to that, we plan to initiate a Phase I study.

The following describes the commercial terms relating to SPI-1620 licensing and development.

In February 2005, we entered into a license agreement with Chicago Labs, Inc., whereby we acquired an exclusive worldwide license to develop and commercialize SPI-1620 for the prevention and treatment of cancer. We paid Chicago Labs an upfront fee of \$100,000, and we are obligated to make future payments contingent upon the successful achievement of certain development and regulatory milestones. In addition we will pay royalties and sales milestones on net sales, if any, after marketing approval is obtained from the FDA and other regulatory authorities. Chicago Labs may terminate the agreement if we do not meet certain development deadlines that may be extended by Chicago Labs upon our request if we demonstrate good faith efforts to meet the deadlines.

RenaZorb[®]: RenaZorb, a second-generation lanthanum-based nanoparticle phosphate binding agent, has the potential to address hyperphosphatemia, or high phosphate levels in blood, in patients with end-stage renal disease and chronic kidney disease. Hyperphosphatemia, or high phosphate levels in blood, affects patients with chronic kidney disease, especially end-stage kidney disease patients on dialysis. It can lead to significant bone disease (including pain and fractures) and cardiovascular disease, and is independently associated with increased mortality. According to the United States Renal Data System's 2005 Annual Report and the National Kidney Foundation, there are an estimated 470,000 patients with end-stage renal disease in the United States. During the past decade, the end-stage renal disease population is estimated to have grown by approximately 8% annually. Treatment of hyperphosphatemia is aimed at lowering blood phosphate levels by: (1) restricting dietary phosphorus intake; and (2) using, on a daily basis, and with each meal, oral phosphate binding drugs that facilitate fecal elimination of dietary phosphate before its absorption from the gastrointestinal tract into the bloodstream. Restricting dietary phosphorus intake has historically not been a successful means of serum phosphate control, and phosphate binders are the mainstay of hyperphosphatemia management.

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Currently marketed therapies for treating hyperphosphatemia include non-calcium, non-aluminum, non-magnesium phosphate binders such as polymer-based and lanthanum-based phosphate binders, aluminum-based phosphate binders, and calcium-based phosphate binders. Under the new National Kidney Foundation K/DOQI guidelines, both calcium-based phosphate binders and non-calcium, non-aluminum, non-magnesium phosphate binders are recommended as first line or long-term therapy for the management of hyperphosphatemia. However, the current therapies require use of a large number of pills or large pills to be chewed or swallowed along with each meal, leading to problems with patient compliance with the treatment regime.

We believe that RenaZorb has the opportunity, because of its potentially higher capacity for binding phosphate on an equal weight basis, to significantly improve patient compliance by offering the lowest-in-class dosage (potentially one or two small tablets per meal) to achieve the same therapeutic benefit as other phosphate binders. We continue to perform preclinical development work on RenaZorb.

SPI-205: SPI-205, a lipid suspension of leteprinim, has demonstrated, in experimental models, benefits in treating chemotherapy induced peripheral neuropathy. Chemotherapy drugs can damage the nervous system, especially the peripheral nervous system which are those nerves that carry motor (movement) information for muscle contraction and those that carry sensory information such as touch, vibration, pain and temperature. Damage to the peripheral nerves is known as neuropathy. Currently, there is no effective treatment for chemotherapy induced neuropathy.

During 2007, we plan to continue preclinical evaluation of SPI-205.

Generic drugs: The Drug Price Competition and Patent Term Restoration Act of 1984 created an ANDA approval process to accelerate the approval of generic drugs and foster generic competition.

In the expectation of a growing U.S. market for generic drugs, we filed several ANDAs with the FDA, including those for sumatriptan injection, as discussed above, and for ciprofloxacin tablets, fluconazole tablets, atenolol tablets, and carboplatin injection, which have received FDA approval. We are currently evaluating the potential economic value of these drugs.

Business Alliances

Strategic business alliances are an important part of the execution of our business strategy. We currently do not own any manufacturing or distribution capabilities. We generally 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 and address our manufacturing and distribution needs, we enter into alliances where we believe 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. We have entered into product development and manufacturing, and sales, marketing and distribution alliances for some of our drug candidates and intend to enter into additional alliances in the future. Key product development and manufacturing alliances are described elsewhere in this report along with the product descriptions.

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Sales, Marketing and Distribution

With the exception of the distribution of the authorized generic versions of GSK's Imitre[®] injection, expected to be launch by Par on our behalf in 2008, we do not currently have any exclusive distribution arrangements.

Based on the progress of our drug candidates through the development and regulatory process, especially LFA and satraplatin, both of which may be approved by the FDA this year, we may hire sales and marketing personnel, as needs dictate. We may also seek alliances with other third parties to assist us in the marketing and sale of our proprietary drug candidates.

Competition

The pharmaceutical industry is characterized by rapidly evolving biotechnology and intense competition. We expect biotechnological developments and improvements in the fields of our business to continue to occur at a rapid rate and, as a result, expect competition to remain intense. Many companies are engaged in research and development of compounds that are similar to our research. Biotechnologies under development by these and other pharmaceutical companies could result in treatments for the diseases and disorders for which we are developing our own treatments. In the event that one or more of those programs are successful, the market for some of our drug candidates could be reduced or eliminated. Any product for which we obtain FDA approval must also compete for market acceptance and market share.

Competition for Proprietary Products

Competing in the branded product business requires us to identify and quickly bring to market new products embodying therapeutic innovations. Successful marketing of branded products depends primarily on the ability to communicate the effectiveness, safety and value of the products to healthcare professionals in private practice, group practices, hospitals and academic institutions, and managed care organizations. Competition for branded drugs is less driven by price and is more focused on innovation in treatment of disease, advanced drug delivery and specific clinical benefits over competitive drug therapies. Unless our proprietary products are shown to have a better safety profile, efficacy and are as cost effective, if not more cost effective, than other alternatives, they may not gain acceptance by medical professionals and may therefore never be successful commercially.

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., Novartis Pharmaceuticals Corporation, Ferring Pharmaceuticals, NeoRx Corporation, Genentech, Inc., Bristol-Myers Squibb Company, GlaxoSmithKline, Biogen-IDEC Pharmaceuticals, Inc., OSI Pharmaceuticals, Inc., Cephalon, Inc., Sanofi-Aventis Inc., Pfizer, Inc., AVI Biopharma, Inc., Genta Inc., Genzyme Corporation, Imclone Systems Incorporated, MGI Pharma, Inc., Millennium Pharmaceuticals, SuperGen, Inc., Shire Pharmaceuticals, TAP Pharmaceuticals, Inc., QLT Inc., Threshold 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.

Competition for Generic Products

The generic drug market is extremely price-competitive and revenues and gross profit derived from the sales of generic drug products tend to follow a pattern based on certain regulatory and competitive factors. As patents and regulatory exclusivity for brand name products expire, if a generic manufacturer has first-to-file status (as described below under Paragraph IV Certification) or has an authorized generic, such generic manufacturer generally enjoys a period of exclusivity with respect to other manufacturers of the generic drug, and can achieve significant market penetration. However, as competing generic manufacturers receive regulatory approvals on similar products, market share, revenues and gross profit typically decline, in some cases, dramatically. Accordingly, the level of market share, revenues and gross profit attributable to a particular generic product is normally related to the number of competitors in that product's market and the timing of that product's regulatory

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approval and launch, in relation to competing approvals and launches. We have observed significant price declines in the marketplace for each of our marketed products, due to the FDA's approval of several competing ANDAs, and the resultant glut of product introduced on and after the generic product launch dates. We have recorded only modest revenues to date from generic product sales, due primarily to our late entry into the market for each of our approved generic drugs. We are unable at this time to reliably estimate recurring revenues or profits from these generic products in the foreseeable future. In addition to competition from other generic drug manufacturers, we face competition from brand name companies in the generic market. Many of these companies seek to participate in sales of generic products by, among other things, collaborating with other generic pharmaceutical companies through authorized generic programs or by marketing their own generic equivalent to their branded products.

Companies that have a significant generic presence include Abraxis Biosciences, Inc., Bedford Laboratories, Mayne, Barr Laboratories, Teva Pharmaceuticals, Par Pharmaceuticals Companies, Dr. Reddy's Laboratories, Ranbaxy Laboratories, Mylan Laboratories, Inc., Sandoz (a division of Novartis), and Watson Pharmaceuticals, Inc.

Please also read our discussion of competition matters in Item 1A "Risk Factors" of this report.

Research and Development

Research and development expenses are comprised of the following types of costs incurred in performing research and development activities: personnel expenses, facility costs, contract services, license fees and milestone payments, costs of clinical trials, laboratory supplies and drug products, and allocations of corporate costs. Research and development expenditures, including related stock-based charges, are expensed as we incur them and were approximately \$23.8 million in 2006, \$13.5 million in 2005, and \$7.6 million in 2004 as follows:

	Years Ended December 31,		
	2006	2005	2004
	(Amounts in thousands)		
Ozarelix	\$ 2,881	\$ 2,288	\$ 1,228
EQquin	2,617	1,422	777
LFA	1,686		
SPI 1620	1,214	412	
Elsamitruicin	870	1,287	496
Other Proprietary drugs	1,004	1,260	652
Generic ANDA development	755	1,708	953
Total - Direct Costs	11,026	8,378	4,105
Indirect Costs	6,846	4,222	2,849
Subtotal	\$ 17,872	\$ 12,600	\$ 6,954
Add: Stock-based charges (non-cash)	5,856	883	634
Total Research & Development	\$ 23,728	\$ 13,483	\$ 7,588

Patents and Proprietary Rights***Our Patents, Proprietary Rights and ANDAs***

We in-license from third parties certain patent and related intellectual property rights related to our proprietary products. In particular, we have licensed patent rights with respect to satraplatin, LFA, EQquin, elsamitruicin, ozarelix, lucanthon, RenaZorb and SPI-1620, in each case for the remaining life of the applicable patents. Except for ozarelix and LFA, our agreements generally provide us with exclusive worldwide rights to, among other things, develop, sublicense, and sell the drug candidates. Under these license arrangements, we are generally responsible for

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all development, patent filing and maintenance costs, sales, marketing and liability insurance costs related to the drug candidates. In addition, these licenses and agreements may require us to make royalty and other payments and to reasonably exploit the underlying technology of applicable patents. If we fail to comply with these and other terms in these licenses and agreements, we could lose the underlying rights to one or more of our potential products, which would adversely affect our product development and harm our business.

The protection, preservation and infringement-free commercial exploitation of these patents and related intellectual property rights is very important to the successful execution of our proprietary drug strategy. However, the issuance of a patent is not conclusive as to its validity nor as to the enforceable scope of the claims of the patent. Accordingly, our patents and the patents we have in-licensed may not prevent other companies from developing similar or functionally equivalent products or from successfully challenging the validity of our patents. If our patent applications are not approved or, even if approved, if our patents or the patents we have in-licensed, are circumvented or not upheld by the courts, our ability to competitively exploit our patented products and technologies may be significantly reduced. Also, such patents may or may not provide competitive advantages for their respective products or they may be challenged or circumvented by competitors, in which case our ability to commercially exploit these products may be diminished.

From time to time, we may need to obtain licenses to patents and other proprietary rights held by third parties to develop, manufacture and market our products. If we are unable to timely obtain these licenses on commercially reasonable terms, our ability to commercially exploit such products may be inhibited or prevented.

As mentioned above, we have in-licensed from third parties certain patent rights related to our proprietary products. We believe that our patents and licenses are important to our business, but that with the exception of the United States and European patents discussed in this paragraph, relating to our proprietary products, no one patent or license is currently of material importance to our business. There are two United States patents covering satraplatin, a compound patent that expires in 2008 and a medical use patent that expires in 2010, and an issued compound patent in Europe that expires in various countries between 2008 and 2009. There is a possibility, under the Hatch-Waxman Act, to obtain up to a 5-year extension of one of the United States patents for the time spent during the FDA regulatory process. There are similar extension possibilities in Europe. For LFA, we have one United States patent that covers LFA for use in methotrexate rescue that expires in 2019 and one United States patent that covers LFA for use in conjunction with 5-fluorouracil for the treatment of colorectal cancer that expires in 2008. As with satraplatin, there is the possibility of a patent term extension. For EOquin, there is a compound patent that expires in 2009 in the United States and in various countries in Europe in 2007. We have filed and will file additional patent applications covering new formulations and/or uses for this product. For elsamitrucin, the United States and Europe patents have already expired, however, we have filed a United States method of use patent application and we anticipate filing future United States and European patent applications covering new formulations and/or uses for this product. For ozarelix, there is a United States compound patent issued that will expire in 2020 and a method of use patent application is on file in the United States. For lucanthone, there is a United States method of use patent that expires in 2019. For RenaZorb, there are patents comprising compositions of matter directed at treating hyperphosphatemia pending in the United States and Europe. For SPI-1620, we have filed method of use patent applications in the United States and Europe. For SPI-205, there is a United States compound patent that expires in 2010 and United States method of use patent that expires in 2021. The United States compound patent's foreign counterpart in Europe expires in various countries in 2011. We are constantly evaluating our patent portfolio and are currently prosecuting patent applications for our drug products and are considering new patent applications in order to maximize the life cycle of each of our products.

While the United States and the European Union are currently the largest potential markets for most of our proprietary product candidates, we also have patents issued and patent applications pending outside of the United States and Europe. Limitations on patent protection in these countries, and the differences in what constitutes patentable subject matter in countries outside the United States, may limit the protection we have on patents issued or licensed to us outside of the United States. In addition, laws of foreign countries may not protect our intellectual property to the same extent as would laws in the United States. To minimize our costs and expenses and to maintain effective protection, we usually focus our patent and licensing activities within the United States, the European Union, Canada and Japan. In determining whether or not to seek a patent or to license any patent in a certain foreign country, we weigh the relevant costs and benefits, and consider, among other things, the market potential and profitability, the scope of patent protection afforded by the law of the jurisdiction and its enforceability, and the nature of terms with any potential licensees. Failure to obtain adequate patent protection for our proprietary drugs and technology would impair our ability to be commercially competitive in these markets.

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In addition to the specific intellectual property subjects discussed above, we have trademark protection for EOquin and RenaZorb. We will likely register trademarks for the branded names of our proprietary drug products if any are approved for marketing.

In conducting our business generally, we rely upon trade secrets, know-how, and licensing arrangements and use customary practices for the protection of our confidential and proprietary information such as confidentiality agreements. It is possible that these agreements will be breached or 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 or know-how will otherwise become known or independently developed by competitors. The protection of know-how is particularly important because the know-how is often the necessary or useful information that allows us to practice the claims in the patents related to our proprietary product candidates.

We may find it necessary to initiate litigation to enforce our patent rights, to protect our trade secrets or know-how or to determine the scope and validity of the proprietary rights of others. Litigation concerning patents, trademarks, copyrights and proprietary technologies can often be protracted and expensive and, as with litigation generally, the outcome is inherently uncertain. See Item 1A Risk Factors for more information.

In connection with ANDAs filed on behalf of J.B. Chemicals & Pharmaceuticals Ltd., or JBCPL, and FDC, Ltd., we have the exclusive license to market and distribute those drugs within the United States, if and when approved by the FDA. We own the ANDAs for carboplatin, sumatriptan succinate injection and our other ANDAs.

The Patent Process

The United States Constitution provides Congress with the authority to provide inventors the exclusive right to their discoveries. Congress codified this right in United States Code Title 35, which gave the U.S. Patent and Trademark Office, or USPTO, the right to grant patents to inventors and defined the process for securing a United States patent. This process involves the filing of a patent application that teaches a person having ordinary skill in the respective art how to make and use the invention in clear and concise terms. The invention must be novel (not previously known) and non-obvious (not an obvious extension of what is already known). The patent application concludes with a series of claims that specifically describe the subject matter that the patent applicant considers his invention.

The USPTO undertakes an examination process that can take from one to five years, or more, depending on the complexity of the patent and the problems encountered during examination. Generally, the less novel an invention is, the longer the examination process will last.

In exchange for disclosing the invention to the public, the successful patent applicant is provided a right to exclude others from making, using or selling the claimed invention for a period of 20 years from the effective filing date of the patent application.

Under certain circumstances, a patent term may be extended. Patent extensions are most frequently granted in the pharmaceutical and medical device industries under the Drug Price Competition and Pricing Term Restoration Act of 1984, or commonly known as the Hatch-Waxman Act, to recover some of the time lost during the FDA regulatory process, subject to a number of limitations and exceptions. The patent term may be extended up to a maximum of five years; however, as a general rule, the average extension period granted for a new drug is approximately three years and approximately 18 months for a new medical device. Only one patent can be extended per FDA approved product, and a patent can only be extended once.

Regulatory Exclusivities

The FDA has provided for certain regulatory exclusivities for products whereby the FDA will not approve of the sale of any generic form of the drug until the end of the prescribed period. The FDA will grant a 5-year period of exclusivity for a product that contains a chemical entity never previously approved by the FDA either alone or in combination with other drugs. In addition, the FDA will grant a 3-year period of exclusivity to a new drug product

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that contains the same active drug substance that has been previously approved such as a new formulation of an old drug product. Also, as an incentive for pharmaceutical companies to research the safety and efficacy of their brand name drugs for use in pediatric populations, Congress enacted the Food & Drug Administration Modernization Act of 1997, which included a pediatric exclusivity for brand name drugs. This pediatric exclusivity protects drug products from generic competition for six months after their patents expire in exchange for research on children. For example, if a pharmaceutical company owns a patent covering a brand name drug they can only exclude third parties from selling generic versions of that drug until that patent expires. However, if the FDA grants a brand named drug pediatric exclusivity the FDA will not approve a generic drug company's ANDA and thus not allow the sale of a generic drug for six months beyond the patent term covering the brand name drug. Thus, the pediatric exclusivity effectively extends the brand named company's patent protection for six months. This extension applies to all dosage forms and uses that the original patent covered.

Paragraph IV Certification

In 1984, Congress enacted the Hatch-Waxman Act in part to establish a streamlined approval process for the FDA to use in approving generic versions of previously approved branded drugs. Under the Hatch-Waxman Act, for each patent listed in the FDA Orange Book, where branded companies are required to list their patents for branded products, for the relevant branded drug, an ANDA applicant must certify one of the following claims: (1) that there is no patent information listed; (2) that such patent has expired; (3) that the proposed drug will not be marketed until expiration of the patent; or (4) that either the proposed generic drug does not infringe the patent or the patent is invalid, otherwise known as paragraph IV certification. If an ANDA applicant files a paragraph IV certification, the Hatch-Waxman Act requires the applicant to provide the patent holder with notice of that certification and provides the patent holder with a 45-day window, during which it may bring suit against the applicant for patent infringement. If patent litigation is initiated during this period, the FDA may not approve the ANDA until the earlier of (1) 30 months from the patent holder's receipt of the notice (the 30-month stay) or (2) the issuance of a final, non-appealed, or non-appealable court decision finding the patent invalid, unenforceable or not infringed. If the patent is found to be infringed by the filing of the ANDA, the patent holder could seek an injunction to block the launch of the generic product until the patent expires.

Often more than one company will file an ANDA that includes a paragraph IV certification. However, the Hatch-Waxman Act provides that such subsequent ANDA applications will not be approved until 180 days after the earlier of (1) the date of the first commercial marketing of the first-filed ANDA applicant's generic drug or (2) the date of a decision of a court in an action holding the relevant patent invalid, unenforceable, or not infringed. Thus, the Hatch-Waxman Act effectively grants the first-filed ANDA holder 180 days of marketing exclusivity for the generic product.

For more information on our ANDA with paragraph IV certification for sumatriptan succinate injection, please see Item 3 Legal Proceedings below.

Please also read our discussion of patent and intellectual property matters in Item 1A Risk Factors section of this report.

Orphan Drug Designation

Some jurisdictions, including Europe and the United States, may designate drugs for relatively small patient populations as orphan drugs. The FDA grants orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. In the United States, orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Also, competitors may receive approval of different drugs or biologics for the indications for which the orphan product has exclusivity.

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Under European Union medicines laws, criteria for designation as an orphan medicine are similar but somewhat different from those in the United States. Orphan medicines are entitled to ten years of market exclusivity, except under certain limited circumstances comparable to United States law. During this period of market exclusivity, no similar product, whether or not supported by full safety and efficacy data, will be approved unless a second applicant can establish that its product is safer, more effective or otherwise clinically superior. This period may be reduced to six years if the conditions that originally justified orphan designation change or the sponsor makes excessive profits.

Our drug product LFA has been granted orphan drug designations for its use in conjunction with high dose methotrexate in the treatment of osteosarcoma and for its use in combination chemotherapy with the approved agent 5-fluorouracil in the treatment of metastatic colorectal cancer.

Governmental Regulation

The production and marketing of our proprietary and generic drug products are subject to regulation for safety, efficacy and quality by numerous governmental authorities in the United States and other countries. In the United States, drugs are subject to rigorous regulation. The Federal Food, Drug and Cosmetics Act, as amended from time to time, and the regulations promulgated there under, as well as other federal and state statutes and regulations, govern, among other things, the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of our proposed products. Product development and approval within this regulatory framework, including for drugs already at a clinical stage of development, can take many years and require the expenditure of substantial resources. In addition to obtaining FDA approval for each product, each drug-manufacturing establishment must be registered with, and approved by, the FDA. Domestic manufacturing establishments are subject to regular inspections by the FDA and must comply with Good Manufacturing Practices, or cGMPs. To supply products for use in the United States, foreign manufacturing establishments must also comply with cGMPs and are subject to periodic inspection by the FDA or by regulatory authorities in certain of such countries under reciprocal agreements with the FDA.

General Information about the Drug Approval Process

The United States system of new drug approval is one of the most rigorous in the world. Only a small percentage of compounds that enter the pre-clinical testing stage are ever approved for commercialization. Our strategy focuses on in-licensing clinical stage drug candidates that are already in or about to enter human clinical trials. This strategic focus on clinical stage drug candidates (those eligible for human trials) is designed to address certain risks of drug development by shortening the timeline to marketability and reducing the risk of failure, both of which are higher with an early stage product.

The following general comments about the drug approval process are relevant to the development activities we are undertaking with our proprietary drugs.

Pre-clinical Testing: During the pre-clinical testing stage, laboratory and animal studies are conducted to show biological activity of a drug compound against the targeted disease and the compound is evaluated for safety.

Investigational New Drug Application: After pre-clinical testing, an Investigational New Drug Application is submitted to the FDA to request the ability to begin human testing of the drug.

Phase 1 Clinical Trials: After an Investigational New Drug Application becomes effective, phase 1 human clinical trials can begin. These trials, typically involving small numbers of healthy volunteers or patients usually define a drug candidate's safety profile, including the safe dosage range.

Phase 2 Clinical Trials: In phase 2 clinical trials, studies of volunteer human patients with the targeted disease are conducted to assess the drug's effectiveness. These studies are designed primarily to determine the appropriate dose levels, dose schedules and route(s) of administration, and to evaluate the effectiveness of the drug on humans, as well as to determine if there are any side effects on humans to expand the safety profile following phase 1.

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Phase 3 Clinical Trials: This phase usually involves large numbers of patients with the targeted disease. During the phase 3 clinical trials, physicians monitor the patients to determine the drug candidate's efficacy and to observe and report any adverse reactions that may result from long-term use of the drug on a large, more widespread, patient population. During the phase 3 clinical trials, typically the drug candidate is compared to either a placebo or a standard treatment for the target disease.

New Drug Application: After completion of all three clinical trial phases, if the data indicates that the drug is safe and effective, a New Drug Application is filed with the FDA requesting FDA approval to market the new drug as a treatment for the target disease.

Fast Track Review: The FDA has established procedures for accelerating the approval of drugs to be marketed for serious life threatening diseases for which the manufacturer can demonstrate the potential to address unmet medical needs. One of our drug candidates, satraplatin, has been given a fast track designation for the hormone refractory prostate cancer indication.

Phase 4 Clinical Trials: After a drug has been approved by the FDA, phase 4 studies are conducted to explore additional patient populations, compare the drug to a competitor, or to further study the risks, benefits and optimal use of a drug. These studies may be a requirement as a condition of the initial approval of the NDA.

Abbreviated New Drug Application, or ANDA: An ANDA is the abbreviated review and approval process created by the Drug Price Competition and Patent Term Restoration Act of 1984 signed into law in part for the accelerated approval of generic drugs. When a company files an ANDA, it must make a patent certification if there are any patents covering the branded product listed in the FDA's Orange Book. An ANDA applicant must make one of four certifications: (1) that there is no patent information listed in the Orange Book; (2) that the listed patent has expired; (3) that the listed patent will expire on a stated date and the applicant will not market the product until the patent expires; or (4) that the listed patent is invalid or will not be infringed by the generic product. The ANDA must also demonstrate both chemical equivalence and bio-equivalence (the rate and extent of absorption of the generic drug in the body is substantially equivalent to the brand name product), unless a bio-equivalence waiver is granted by the FDA. The ANDA drug development and approval process generally takes less time than the NDA drug development and approval process since the ANDA process does not require new clinical trials establishing the safety and efficacy of the drug product.

Approval: If the FDA approves the New Drug Application, the drug becomes available for physicians to prescribe to patients for treatment. The marketing of a drug after FDA approval is subject to substantial continuing regulation by the FDA, including regulation of adverse event reporting, manufacturing practices and the advertising and promotion of the drug.

Failure to comply with FDA and other governmental regulations can result in fines, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA's review of NDAs, ANDAs or other product applications enforcement actions, injunctions and criminal prosecution. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals. Although we have internal compliance programs, if these programs do not meet regulatory agency standards or if our compliance is deemed deficient in any significant way, it could have a material adverse effect on our business. See Item 1A Risks Factors. Our failure to comply with governmental regulation may delay or prevent approval of our product candidates and/or subject us to penalties.

The Generic Drug Enforcement Act of 1992 established penalties for wrongdoing in connection with the development or submission of an ANDA. Under this Act, the FDA has the authority to permanently or temporarily bar companies or individuals from submitting or assisting in the submission of an ANDA, and to temporarily deny approval and suspend applications to market generic drugs. The FDA may also suspend the distribution of all drugs approved or developed in connection with certain wrongful conduct and/or withdraw approval of an ANDA and seek civil penalties. The FDA can also significantly delay the approval of any pending NDA, ANDA or other regulatory submissions under its Fraud, Untrue Statements of Material Facts, Bribery and Illegal Gratuities Policy.

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As part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 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.

Continuing studies of the proper utilization, safety and efficacy of pharmaceuticals and other health care products are being conducted by industry, government agencies and others. Such studies, which increasingly employ sophisticated methods and techniques, can call into question the utilization, safety and efficacy of previously marketed products and in some cases have resulted, and may in the future result, in the discontinuance of their marketing.

Foreign Regulation

Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement also vary greatly from country to country.

Under European Union regulatory systems, we may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure which is available for medicines produced by biotechnology or which are highly innovative, provides for the grant of a single marketing authorization that is valid for all European Union member states. This authorization is a marketing authorization approval, or MAA. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization, which is granted by a single European Union member state, may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval. This procedure is referred to as the mutual recognition procedure, or MRP.

In addition, regulatory approval of prices is required in most countries other than the United States. We face the risk that the resulting prices would be insufficient to generate an acceptable return to our collaborators or us.

Third Party Reimbursement and Pricing Controls

In the United States and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third-party payers, such as government and private insurance plans. Third-party payers are increasingly challenging the prices charged for medical products and services. It will be time-consuming and expensive for us to go through the process of seeking reimbursement from Medicare and private payers. Our products may not be considered cost effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis. The passage of the Medicare Prescription Drug and Modernization Act of 2003 imposes new requirements for the distribution and pricing of prescription drugs, which may affect the marketing of our products.

In many foreign markets, including the countries in the European Union, pricing of pharmaceutical products is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental pricing control. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability.

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Employees

The efforts of our employees are critical to our success. We believe that we have assembled a strong management team with the experience and expertise needed to execute our business strategy. We anticipate hiring additional personnel as needs dictate to implement our growth strategy. As of December 31, 2006, we had 50 employees, of which six held a M.D. degree and eight held a Ph.D. degree. We cannot assure you that we will be able to attract and retain qualified personnel in sufficient numbers to meet our needs. Our employees are not subject to any collective bargaining agreements, and we regard our relations with our employees to be good.

Corporate Background and Available Information

Spectrum Pharmaceuticals is a Delaware corporation that was originally incorporated in Colorado as Americus Funding Corporation in December 1987, became NeoTherapeutics, Inc. in August 1996, was reincorporated in Delaware in June 1997, and was renamed Spectrum Pharmaceuticals, Inc. in December 2002.

We also maintain a website located at <http://www.spectrumpharm.com>, and electronic copies of our periodic and current reports, and any amendments to those reports, are available, free of charge, under the Investor Relations link on our website as soon as practicable after such material is filed with, or furnished to, the SEC.

For financial information regarding our business activities, please see Item 8 Financial Statements and Supplementary Data.

Item 1A. Risk Factors

An investment in our common stock involves a high degree of risk. Our business, financial condition, operating results and prospects can be impacted by a number of factors, any one of which could cause our actual results to differ materially from recent results or from our anticipated future results. As a result, the trading price of our common stock could decline, and you could lose a part or all of your investment. You should carefully consider the risks described below with all of the other information included in this Annual Report. Failure to satisfactorily achieve any of our objectives or avoid any of the risks below would likely have a material adverse effect on our business and results of operations.

Risks Related to Our Business

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

Our cumulative losses since our inception in 1987 through December 31, 2006 were in excess of \$200 million. We lost approximately \$23 million in 2006, \$19 million in 2005, and \$12 million in 2004. We expect to continue to incur significant additional losses as we implement our growth strategy of developing marketable drug products for at least the next several years unless they are offset, if at all, by licensing revenues under our out-license agreement with GPC Biotech or from the out-license of any of our other proprietary products and any profits from the sale of generic products. We may never achieve significant revenues from sales of products or become profitable. Even if we eventually generate significant revenues from sales, we will likely continue to incur losses over the next several years.

Our business does not generate the cash needed to finance our ongoing operations and therefore, we will likely 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 we anticipate meaningful revenues in 2007 from milestone payments and royalties from our satraplatin license agreement with GPC Biotech, and in 2008 from distribution of authorized generic versions of certain sumatriptan injection products by Par, we believe that in the near-term we will likely need to continue to raise funds through public or private financings in order to continue future drug product development and acquisition, and to capitalize on growth opportunities.

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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.

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 In multiple trials in other cancer types; in combination with radiation therapy; and in combination with other chemotherapies	NDA submitted February 2007 Phase(s) 1-2
Levofolinic acid, or LFA,	High dose methotrexate rescue in Osteogenic Sarcoma Colorectal Cancer	NDA on file with FDA; CMC responses pending Planned regulatory filing
EOquin	Non-invasive Bladder Cancer	Phase 2 completed; SPA negotiated with FDA; Phase 3 to start in the first half of 2007
Ozarelix	Benign Prostatic Hypertrophy Hormone dependent prostate cancer	Phase 2b initiated first quarter of 2007; Phase 3/Safety Study to initiate late 2007 Phase 2 study completed in 2006; Phase 2b study in progress in Europe
	Endometriosis	Phase 1 study in second half of 2007
Elsamitrucin	Various potential cancers	Phase 1/2

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Lucanthone	Radiation Sensitizer for Glioblastoma Multiforme and other Brain Tumors and Brain Metastases	Phase 1 expected to initiate in second half of 2007
SPI-1620	Adjunct to Chemotherapy	Pre-clinical
RenaZorb	Hyperphosphatemia in End-stage Renal Disease	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 sublicensee, Pharmion. GPC Biotech and its sub licensee may not be successful in the clinical development of the drug, the achievement of any additional milestones such as the acceptance of a 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.

An adverse outcome in the arbitration proceedings with GPC Biotech may hurt our financial and strategic prospects.

We are currently in arbitration with GPC Biotech as described in Item 3 Legal Proceedings. In the arbitration, we seek monetary damages and other relief for GPC Biotech's material breach of our license agreement, including a declaration that GPC Biotech's breaches provide a basis for termination of the license agreement. GPC Biotech has filed counterclaims and is asking for, among other things, a discharge from any obligation to negotiate a co-promotion agreement with us for satraplatin in the U.S. and a perpetual, paid-up, royalty-free worldwide license to develop and market satraplatin. We believe that GPC Biotech's counterclaims are baseless and without merit, however, the arbitration panel may decide otherwise, which could cause us significant financial and strategic harm if we were to lose our co-promotion right and/or our right to receive milestone payments and royalties. In addition, the fact that we are currently in arbitration may make it difficult for us to agree on terms of a co-promotion agreement with GPC Biotech.

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Our 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.

The eventual FDA approval and subsequent marketing and sale of our drug candidate levofolinic acid, or 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.

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.

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 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

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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 may also 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.

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

We currently do not have the capability to market our drug products ourselves. 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 market 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 would be required 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. To the extent that our 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

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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, 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 result 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;

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;

initiation 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.

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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

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distributing or may be developing drug products that directly compete with the 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 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.

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 or maximize profit on the sale of our products.

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. 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 we will not have adequate clinical supplies to timely meet our clinical development objectives or market demand for a particular drug product could outstrip the ability of our supply source to timely manufacture and deliver the product, thereby causing us to lose sales. In addition, our ability to make a profit on the sale of our drug products depends on our ability to obtain transfer price arrangements that ensure a supply of product at favorable prices.

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 adherence to FDA's current 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 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.

We may not be successful in establishing additional active pharmaceutical ingredient or finished dose drug supply relationships, which would limit our ability to develop and market our drug products.

Success in the development and marketing of our 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, or API, or for the manufacture of our finished dose 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 our drugs. In addition, we currently have no capacity to manufacture APIs or finished dose 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 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 development and market our drug products will be harmed.

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

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

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

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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.

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. Our ability to compete effectively in the generic drug market depends largely on our ability to obtain transfer price agreements that ensure a supply of our generic drug products at favorable prices. Even if we obtain regulatory approval to market 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.

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Risks Related to Our Industry

Rapid bio-technological advancement may render our drug candidates obsolete before we are able to 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 who are consequently not available to us for our clinical trials. 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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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

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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.

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. While we believe that we are currently in compliance with applicable FDA regulations, if partners, our contract research organizations, our contract manufacturing 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:

finer;

changes in advertising;

revocation or suspension of regulatory approvals of products;

product recalls or seizures;

delays, interruption, or suspension of product distribution, marketing and sale;

civil or criminal sanctions; and

refusals to approve new products.

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

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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;

changes in the methods of marketing and selling products;

taking FDA-mandated corrective action, which may include placing advertisements or sending letters to physicians, rescinding previous advertisements or promotions; and

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

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

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

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

In both the United States and certain foreign jurisdictions, there have been and may continue to be a number of legislative and regulatory proposals to change the healthcare system and pharmaceutical industry in ways that could impact 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 that 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

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may grant to an ANDA applicant who is the first to file a legal challenge to patents of branded drugs. We recently settled our case with GSK for sumatriptan injection, the generic form of GSK's Imitrex® injection, whereby we acquired the right to exclusively distribute authorized generic versions of certain sumatriptan injectable products in the U.S. Any changes in the Hatch-Waxman Act, FDA regulations, procedures, or interpretations may make ANDA approvals of generic drugs more difficult, limit the benefits available through the granting of 180-day marketing exclusivity or limit the ability for us to market authorized generic versions of branded products. If we are not able to market our authorized generic versions of sumatriptan injection, 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, could adversely affect our business.

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

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.

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

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

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

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

Patent and other intellectual property litigation is becoming more common in the pharmaceutical industry. Litigation is sometimes necessary to defend against or assert claims of infringement, to enforce our patent rights, including those we have licensed from others, to protect trade secrets or to determine the scope and validity of proprietary rights of third parties. Currently no third party is asserting that we are infringing upon their patent rights or other intellectual property, nor are we aware or believe that we are infringing upon any third party's patent rights or other intellectual property. We may, however, be infringing upon a third party's patent rights or other intellectual property, and litigation asserting such claims might be initiated in which we would not prevail, or we would not be able to obtain the necessary licenses on reasonable terms, if at all. All such litigation, whether meritorious or not, as well as litigation initiated by us against third parties, is time-consuming and very expensive to defend or prosecute and to resolve. In addition, if we infringe the intellectual property rights of others, we could lose our right to develop, manufacture or sell our products or could be required to pay monetary damages or royalties to license proprietary rights from third parties. An adverse determination in a judicial or administrative proceeding or a failure to obtain necessary licenses could prevent us from manufacturing or selling our products, which could harm our business, financial condition and prospects.

If our competitors prepare and file patent applications in the United States that claim technology we also claim, we may have to participate in interference proceedings required by the USPTO 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.

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

Risks Related to Our Stock

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

As of March 9, 2007, there were approximately 25.3 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 would receive over \$80 million from the issuance of shares of common stock upon the 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 on file a shelf registration statement 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 5 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 existing 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 2006, the price of our common stock ranged between \$3.36 and \$6.20, and the daily trading volume was as high as 6,624,100 shares and as low as 24,300 shares. During 2007 through March 9, 2007, the price of our common stock has ranged between \$5.27 and \$7.11, and the daily trading volume has been as high as 1,167,200 shares and as low as 66,000 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 and bylaws, both as amended, may make it more difficult for someone to acquire control of us or replace our current management. These provisions include:

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

the inability of stockholders to call special meetings;

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

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

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

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

We have a stockholder rights plan pursuant to which we distributed rights to purchase units of our series B junior participating preferred stock. The rights become exercisable upon the earlier of ten days after a person or group of affiliated or associated persons has acquired 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 on our common stock 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.

Item 1B. *Unresolved Staff Comments*

None.

Item 2. *Properties*

Our corporate administrative offices are located in a two-story 34,320 square foot facility containing office and laboratory space, constructed for us in Irvine, California. The lease on this facility was renewed effective July 1, 2004 for a five-year period through June 30, 2009, at an average base monthly rental rate of approximately \$33,000 over the five-year term, plus taxes, insurance and common area maintenance. At the end of the lease term we have one five-year renewal option. This facility is suitable and adequate to undertake our current and anticipated future operations. We also lease a small administrative office in Zurich, Switzerland on an expense-sharing basis. The financial and other terms of this lease are not material to our business.

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Item 3. *Legal Proceedings* ***Arbitration with GPC Biotech***

On December 12, 2006, we filed a demand for arbitration with the American Arbitration Association to address violations of the letter and spirit of our co-development and license agreement with GPC Biotech AG for satraplatin. Through our demand for arbitration, we seek to enforce our rights under the license agreement. The demand for arbitration is a response to GPC Biotech's intentional and bad faith exclusion of us from our rightful participation in sublicense fee income received by GPC Biotech, and to other non-monetary violations of the License Agreement.

As set forth in our demand for arbitration, GPC Biotech willfully and materially breached the license agreement and the implied covenant of good faith and fair dealing by structuring its co-development and license agreement with Pharmion GmbH to evade financial obligations owed to us under our license agreement. Specifically, GPC Biotech owes us a percentage of fees that GPC Biotech receives from any sublicensee, including Pharmion. GPC Biotech has reported receipt of approximately \$37 million in upfront payments from Pharmion, and a commitment by Pharmion to pay an additional \$22 million. Of this \$59 million, GPC Biotech claims that it owes us nothing. We therefore seek damages and other relief related to GPC Biotech's material breaches of the license agreement. In addition to GPC Biotech's monetary breaches, GPC Biotech has also breached the license agreement through material failure to use commercially reasonable endeavors to obtain regulatory approvals and to promote the distribution of satraplatin in Japan; repeated failure to properly acknowledge our rights to satraplatin in GPC Biotech's literature; failure to provide us with copies of all satraplatin-related correspondence with the FDA, and failure to negotiate a co-promotion agreement, all of which is required by the license agreement.

Our demand for arbitration seeks, in addition to monetary damages, a declaration that GPC Biotech has materially breached the license agreement so that we are entitled to terminate the agreement. If the license agreement is so terminated, GPC Biotech would be required to transfer to us all rights to satraplatin, including its agreement with Pharmion.

On January 2, 2007, GPC Biotech filed an answer denying our claims. They also filed counterclaims alleging that we acted in bad faith, breached the license agreement and the implied covenant of good faith and fair dealing by issuing a notice of default. In addition, GPC claims that our conduct discharges them from any duty to comply with their obligations under the license agreement to negotiate a co-promotion agreement with us. GPC Biotech has asked the arbitration panel, among other things, to declare that it is not in default of any obligation under the license agreement, to discharge it from any obligation to negotiate a co-promotion agreement with us for satraplatin in the U.S. and to grant it a perpetual, paid-up, royalty-free worldwide license to develop and market satraplatin.

The three arbitration panel members have been selected and have met. We are currently in fact discovery. The arbitration hearing has been set for July 6 to July 13, 2007 and will take place in Boston, Massachusetts.

While it is not possible to determine with any degree of certainty the ultimate outcome of the arbitration, we believe that we have a meritorious basis for our claims and that GPC Biotech's counterclaims are baseless and without merit.

Sumatriptan injection paragraph IV litigation

In October 2004, we filed with the FDA an abbreviated new drug application for sumatriptan injection, GlaxoSmithKline's Imitrex® injection, seeking approval to engage in the commercial manufacture, sale and use of the sumatriptan injection product in the United States. On February 18, 2005, GSK filed a lawsuit against us in the United States District Court for the District of Delaware, alleging infringement of the patent on Imitrex® injection.

On November 10, 2006, we reached a settlement agreement with GSK and on December 20, 2006, the District Court dismissed the case. The terms of the settlement agreement 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.

Other

We are party to various other legal proceedings arising from the ordinary course of business. Although the ultimate resolution of these various proceedings cannot be determined at this time, we do not believe that such proceedings, individually or in the aggregate, will have a material adverse effect on our future consolidated results of operations, cash flows or financial condition.

Item 4. *Submission of Matters to a Vote of Security Holders*

No matters were submitted to a vote of security holders during the quarter ended December 31, 2006.

Table of Contents**PART II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities**
Common Stock

As of March 9, 2007 there were 25,325,683 shares of common stock outstanding and 363 shareholders of record. On March 9, 2007, the closing sale price of our common stock was \$5.81 per share.

Market for Securities

Our common stock is traded on the NASDAQ Global Market under the symbol SPPI. The high and low sale prices of our common stock reported by NASDAQ during each quarter ended in 2006 and 2005 were as follows:

	High	Low
Year 2006		
Quarter Ended		
March 31	\$ 5.69	\$ 4.14
June 30	\$ 4.98	\$ 3.37
September 30	\$ 5.30	\$ 3.36
December 31	\$ 6.20	\$ 5.10
Year 2005		
Quarter Ended		
March 31	\$ 7.50	\$ 5.78
June 30	\$ 6.50	\$ 4.06
September 30	\$ 5.73	\$ 4.12
December 31	\$ 5.07	\$ 3.51

The high and low sales prices of our common stock reported by NASDAQ reflect inter-dealer prices, without retail mark-ups, markdowns or commissions, and may not represent actual transactions.

Dividends

We have never paid cash dividends on our common stock and we do not intend to pay cash dividends of our common stock in the foreseeable future. We currently intend to retain our earnings, if any, to finance future growth.

Unregistered Sales of Equity Securities

On January 23, 2007, a warrant was exercised for the purchase of 12,500 shares of our common stock for cash consideration of \$59,375. We believe the sale of the shares was exempt from registration under the Securities Act of 1933, or the Act, pursuant to Section 4(2) of the Act. We made no solicitation in connection with the exercise of the warrant; we obtained representations from the holder regarding its status as an accredited investor; and the holder had access to adequate information about us in order to make an informed investment decision. No underwriting discounts or commissions were paid in conjunction with the issuance.

Table of Contents**Item 6. Selected Financial Data**

The following table presents our selected financial data. Financial data for the years ended December 31, 2006, 2005 and 2004 and as of December 31, 2006 and 2005 has been derived from our audited financial statements included elsewhere in this Form 10-K, and should be read in conjunction with those financial statements and accompanying notes and with Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations. Financial data for the years ended December 31, 2003 and 2002 and as of December 31, 2004, 2003 and 2002 has been derived from our audited financial statements not included herein.

CONSOLIDATED FINANCIAL INFORMATION

(In thousands, except Share data)

Statement of Operations Data for the Years Ended December 31:	2006	2005	2004	2003	2002
Revenues	\$ 5,673	\$ 577	\$ 258	\$ 1,000	\$ 2,371
Operating expenses:					
Cost of product sold	\$ 97	\$ 397	\$ 123	\$	\$
Research and development	17,872	12,600	6,954	3,683	11,706
General and administrative	6,330	6,490	5,096	5,049	3,691
Stock-based charges (see supplement below)	7,267	1,012	885	2,573	1,431
Restructuring expenses				163	3,050
Loss from operations	(25,893)	(19,922)	(12,800)	(10,468)	(17,507)
Other income (expense)	2,609	1,280	514	78	(127)
Net loss	\$ (23,284)	\$ (18,642)	\$ (12,286)	\$ (10,390)	\$ (17,634)
Basic and diluted net loss per share	\$ (0.96)	\$ (1.06)	\$ (0.98)	\$ (4.83)	\$ (12.34)
Cash Dividends on common stock	\$	\$	\$	\$	\$
Supplemental Information					
Stock-based charges - Components:					
Research and development	\$ 5,856	\$ 883	\$ 634	\$ 1,000	\$ 1,020
General and administrative	1,411	129	251	1,573	411
Total stock based charges	\$ 7,267	\$ 1,012	\$ 885	\$ 2,573	\$ 1,431
Balance Sheet Data at December 31:					
Cash, cash equivalents and marketable securities	\$ 50,697	\$ 63,667	\$ 39,206	\$ 26,351	\$ 1,578
Property and equipment, net	\$ 625	\$ 562	\$ 687	\$ 560	\$ 802
Total assets	\$ 53,117	\$ 65,075	\$ 40,758	\$ 27,389	\$ 3,453
Current liabilities	\$ 6,233	\$ 3,828	\$ 2,666	\$ 3,108	\$ 2,522
Long-term debt, less current portion	\$	\$	\$	\$	\$ 158
Other non-current liabilities	\$ 1,035	\$ 241	\$ 178	\$	\$ 101
Minority interest in consolidated subsidiaries	\$ 20	\$ 23	\$ 24	\$	\$
Total stockholders' equity	\$ 45,829	\$ 60,983	\$ 37,890	\$ 24,281	\$ 672

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Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations*

You should read the following discussion of the financial condition, changes in financial condition and results of our operations in conjunction with the financial statements and the notes to those statements included elsewhere in this report. The discussion in this report contains forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. Reference is made in particular to forward-looking statements regarding the success of our drug candidates, product approvals, product sales, revenue development timelines, product acquisitions, liquidity and capital resources and trends. Our actual results could differ materially from those discussed here. Factors that might cause such a difference include, but are not limited to, those discussed below and elsewhere, including under Item 1A "Risk Factors" of this report. The cautionary statements made in this report should be read as applying to all related forward-looking statements wherever they appear in this report.

Overview

We are a biopharmaceutical company that acquires and advances a diversified portfolio of drug candidates, with a focus on oncology, urology and other critical health challenges for which there are few other treatment options. Our expertise lies in identifying undervalued drugs with demonstrated safety and efficacy, and adding value through further clinical development and selection of the most viable and low-risk methods of commercialization. We currently have ten drugs in development, including five in late stage clinical development. We expect to have two drugs approved by the FDA, and begin two registrational Phase 3 clinical trials in 2007. Additionally, we expect to launch another drug in 2008.

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.

Business Outlook

Our primary business focus for 2007, 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. Key developments anticipated in the next 12 to 18 months are:

Satraplatin: In February 2007, submission of an NDA with the FDA was completed. Acceptance of the NDA by the FDA will trigger a milestone payment from GPC Biotech to us of \$4 million. We paid Johnson Matthey \$500,000 upon submission of the complete NDA filing and are obligated to pay an additional \$500,000 upon acceptance of the NDA by the FDA. A European marketing application is expected to be filed in the first half of 2007. GPC Biotech has initiated additional studies in other indications. At December 31, 2006, we were in dispute with GPC Biotech. We had filed a demand for arbitration to address violations of the letter and spirit of our agreement with GPC Biotech, and GPC Biotech has counterclaimed. While we believe that we have a meritorious basis for our claims, and that GPC Biotech's counterclaims are baseless and without merit, due to the early stage of discovery, it is not possible to determine with any degree of certainty the ultimate outcome of the arbitration. We believe that an adverse outcome is remote; accordingly, no loss contingency has been recorded in the accompanying financial statements. Conversely, no gain contingency has been recorded in the event we are successful in our demands. However, in the event we were successful in our demand that the Agreement be terminated and that GPC Biotech be required to transfer to us all rights to satraplatin, including its December 2005 agreement with Pharmion, we would likely seek additional capital in order to successfully launch satraplatin in the marketplace.

Levofolinic acid, or LFA: We expect to respond in early 2007 to certain chemistry and manufacturing questions raised by the FDA during the review of the NDA for LFA.

EOquin[®]: In February 2007, we completed patient accrual in the pilot safety study that was requested by the FDA. In this study, EOquin was found to be well-tolerated when administered to patients immediately following surgery for noninvasive bladder cancer in clinical results to date. We recently reached agreement with the FDA for a Special Protocol Assessment for noninvasive bladder cancer and we expect to initiate the Phase 3 studies before mid 2007. Also, apaziquone, the drug substance in EOquin, is being evaluated as a radiation sensitizer.

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Ozarelix: In January 2007, the FDA accepted our IND application for ozarelix in BPH and also approved the protocol for a Phase 2b study of ozarelix for the treatment of BPH. The Phase 2b study is a randomized, placebo-controlled trial of ozarelix involving approximately 75 men suffering from BPH. In this trial, the men will be dosed with 15 mg of ozarelix or placebo on day 1 and day 15 and will be followed for efficacy for a minimum of twelve weeks. The study will evaluate safety and assess the clinical efficacy of

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ozarelix as a treatment for BPH. The primary endpoint of the study will be the improvement of BPH symptoms as measured by the IPSS, the standard method of assessing BPH symptoms. The study will also measure urine flow, residual urine volume and quality of life. Data from this trial is expected to be available in the second half of 2007. Safety and efficacy data from this trial will be used to support a NDA for ozarelix. We anticipate commencing a Phase 3 clinical trial in BPH in 2007, or soon thereafter.

- ***Sumatriptan injection:*** In November 2006, we reached an agreement with GSK to settle the patent litigation relating to sumatriptan injection. The terms of the agreement 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, our partner for the sale and distribution of the drug.

We plan to continue to fund the development, including clinical trials, of lucanthon, elsamitruicin, RenaZorb, SPI-1620 and SPI-205.

We expect to continue to evaluate additional promising drug product candidates for acquisition or license.

Financial Condition

Liquidity and Capital Resources

Our current business operations do not generate sufficient operating cash to finance the clinical development of our drug product candidates. Our cumulative losses, since inception in 1987 through December 30, 2006, have exceeded \$200 million. We expect to continue to incur significant additional losses as we implement our growth strategy of developing marketable drug products for at least the next several years unless they are offset, if at all, by licensing revenues under our out-license agreement with GPC Biotech or from the out-license of any of our other proprietary products and any profits from the sale of generic products.

We believe that the approximately \$50 million in cash, cash equivalents and marketable securities that we had on hand as of December 31, 2006, will allow us to fund our current planned operations for at least the next twelve months. In the near-term we are likely to seek additional capital in order to develop our portfolio of drugs. Our long-term strategy is to generate profits from the sale and licensing of our proprietary drug products. In the next several years, we anticipate supplementing our cash position with licensing and royalties revenues under our out-license agreement with GPC Biotech, licensing revenues from out-licensing our other proprietary products and profits from the sale by Par of the authorized generic versions of certain sumatriptan injection products.

However, if we are unable to generate the revenues necessary to finance our operations long-term, we may have to seek additional capital through the sale of our equity. Our operations have historically been financed by the issuance of capital stock. To this effect, we have on file a shelf registration statement with approximately \$31 million available for the sale of our securities. In addition, we could receive a significant amount of cash from the exercise of outstanding warrants and options, if the price of our common stock appreciates. It is generally difficult to fund pharmaceutical research and development via borrowings due to the significant expenses involved, lack of revenues sufficient to service debt and the significant inherent uncertainty as to results of research and the timing of those results.

As described elsewhere in this report, including in Item 1A **Risk Factors**, our drug development efforts are subject to the considerable uncertainty inherent in any new drug development. Due to the uncertainties involved in progressing through clinical trials, and the time and cost involved in obtaining regulatory approval and in establishing collaborative arrangements, among other factors, we cannot reasonably estimate the timing and ultimate aggregate cost of developing each of our drug product candidates, and are similarly unable to reasonably estimate when, if ever, we will realize material net cash inflows from our proprietary drug product candidates. Accordingly, the following discussion of our current assessment of the need for cash to fund our operations may prove too optimistic and our assessment of expenditures may prove inadequate.

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Our expenditures for research and development consist of direct product specific costs (such as upfront license fees, milestone payments, active pharmaceutical ingredients, clinical trials, patent related legal costs, and product liability insurance, among others) and non-product specific, or indirect, costs. The following summarizes our research and development expenses for the periods indicated (in thousands) To the extent that costs, including personnel costs, are not tracked to a specific product development program, they are included in the Indirect Costs category in the table below. We charge all research and development expenses to operations as incurred.

	Years Ended December 31,		
	2006	2005	2004
	(Amounts in thousands)		
Ozarelix	\$ 2,881	\$ 2,288	\$ 1,228
EOquin	2,617	1,422	777
LFA	1,686		
SPI-1620	1,214	412	
Elsamitruicin	870	1,287	496
Other Proprietary drugs	1,004	1,260	652
Generic ANDA development	755	1,708	953
Total - Direct Costs	11,026	8,378	4,105
Indirect Costs	6,846	4,222	2,849
Total Research & Development	\$ 17,872	\$ 12,600	\$ 6,954

While we are currently focused on advancing each of our product development programs, we anticipate that we will make determinations as to which programs, if any, to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success of each product candidate, as well as an ongoing assessment as to the product candidate's commercial potential.

Our anticipated use of cash for operations in fiscal 2007, excluding the cost of in-licensing additional drugs, if any, is expected to approximate \$25 million. This estimate is subject to considerable uncertainty, and is dependent on the following key factors: approval of satraplatin by FDA, and subsequent successful launch by GPC Biotech, continued positive results from our preclinical studies, the final results from current phase 2 study data, the outcome of discussions with the FDA regarding our planned phase 3 clinical trials and the initiation of clinical trials as anticipated. Further, while we do not receive any funding from third parties for research and development that we conduct, our estimated costs could be mitigated should we enter into co-development agreements for any of our drug product candidates.

In addition to our present portfolio of drug product candidates, we continually evaluate proprietary products for acquisition. If we are successful in acquiring rights to additional products, we may pay up-front licensing fees in cash and our research and development expenditures would likely increase.

Under our various existing licensing agreements, we are contingently obligated to make milestone payments. In connection with the development of certain in-licensed drug products, we anticipate the occurrence of certain of these milestones over the next twelve months. Upon successful achievement of these milestones, we will likely become obligated to pay up to approximately \$4 million in cash and issue up to 375,000 shares of our common stock during 2007 and will simultaneously have the right to receive approximately \$10 million from the same milestones.

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Net Cash used in Operating Activities

During the year ended December 31, 2006, the net cash used in operations was approximately \$13.5 million, net of interest income of approximately \$2.6 million.

During the years ended December 31, 2006 and 2005, the net cash used in operations was approximately \$13.5 million and \$16.0 million, respectively. The decrease of approximately \$2.5 million in cash required for operations is primarily due to the receipt of a \$5 million milestone payment from Par for sumatriptan injection, and an increase of \$1.3 million in 2006 interest income. As a result of the aforementioned factors, during the fourth quarter of 2006, the cash used in operations was only approximately \$0.2 million.

Net Cash provided by and used for Investing Activities

While cash preservation is our primary investment goal, in order to maximize the interest yield on our investments, we invest our cash in a variety of investments pending its use in our business. During the year ended December 31, 2006, we reinvested our funds with Lehman Brothers acting as primary cash manager. This reinvestment resulted in the net conversion of approximately \$15 million of cash and cash equivalents into marketable securities.

Net Cash provided by and used for Financing Activities

During the year ended December 31, 2006, we received approximately \$56,000 from the exercise of stock options and warrants; and paid \$26,000 preferred stock dividends in cash. In addition, during 2006, we received \$1 million pursuant to the purchase by JBCPL of 120,000 shares of our common stock and the modification of a supply agreement. The fair value of the common stock on the effective date was \$419,000. The remainder of the proceeds, \$581,000, has been recorded as a component of revenue for 2006, and representing the consideration for the modification of the supply agreement.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. The estimation process requires assumptions to be made about future events and conditions, and as such, is inherently subjective and uncertain. Actual results could differ materially from our estimates. On an on-going basis, we evaluate our estimates, including cash requirements, by assessing: planned research and development activities and general and administrative requirements, required clinical trial activity, market need for our drug candidates and other major business assumptions.

The SEC defines critical accounting policies as those that are, in management's view, most important to the portrayal of our financial condition and results of operations and most demanding of our judgment. We consider the following policies to be critical to an understanding of our consolidated financial statements and the uncertainties associated with the complex judgments made by us that could impact our results of operations, financial position and cash flows.

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities primarily consist of bank checking deposits, short-term treasury securities, and institutional money market funds, corporate debt and equity, municipal obligations, including market auction debt securities, government agency notes, and certificates of deposit. We classify highly liquid short-term investments, with insignificant interest rate risk and maturities of 90 days or less at the time of acquisition, as cash

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and cash equivalents. Other investments, which do not meet the above definition of cash equivalents, are classified as either held-to-maturity or available-for-sale marketable securities, in accordance with the provisions of Financial Accounting Standards Board, or FASB, Statement, or SFAS, No. 115, Accounting for Certain Investments in Debt and Equity Securities. Investments that we intend to hold for more than one year are classified as long-term investments.

Patents and Licenses

We own or license all the intellectual property that forms the basis of our business model. We expense all licensing and patent application costs as they are incurred.

Revenue Recognition

We follow the provisions as set forth by current accounting rules, which primarily include Staff Accounting Bulletin (SAB) 104, *Revenue Recognition*, and Emerging Issues Task Force (EITF) No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*. Generally, revenue is recognized when evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed and determinable, and collectibility is reasonably assured.

Up-front fees representing non-refundable payments received upon the execution of licensing or other agreements are recognized as revenue upon execution of the agreements where we have no significant future performance obligations and collectibility of the fees is reasonably assured. Milestone payments, which are generally based on developmental or regulatory events, are recognized as revenue when the milestones are achieved, collectibility is reasonably assured, and we have no significant future performance obligations in connection with the milestone. In those instances where we have collected fees or milestone payments but have significant future performance obligations related to the development of the drug product, we record deferred revenue and recognize it over the period of our future obligations.

Revenue from sales of product is recognized upon shipment of product when title and risk of loss have transferred to the customer, and provisions for estimates, including promotional adjustments, price adjustments, returns, and other potential adjustments are reasonably determinable. Such revenue is recorded, net of such estimated provisions, at the minimum amount of the customer's obligation to us. We state the related accounts receivable at net realizable value, with any allowance for doubtful accounts charged to general operating expenses.

Research and Development

Research and development expenses are comprised of the following types of costs incurred in performing research and development activities: personnel expenses, facility costs, contract services, license fees and milestone payments, costs of clinical trials, laboratory supplies and drug products, and allocations of corporate costs. We expense all research and development activity costs in the period incurred. We review and accrue clinical study expenses based on factors such as estimates of work performed, patient enrollment, completion of patient studies and other events. Accrued clinical study costs are subject to revisions as trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known.

Accounting for Stock-Based Employee Compensation

In December 2004, FASB issued SFAS No. 123(R), Share-Based Payment. This pronouncement amended SFAS No. 123, Accounting for Stock-Based Compensation, and supersedes Accounting Principles Board, or APB, Opinion No. 25, Accounting for Stock Issued to Employees. SFAS No. 123(R) requires that companies account for awards of equity instruments issued to employees under the fair value method of accounting and recognize such amounts in their statements of operations. We adopted SFAS No. 123(R) on January 1, 2006, using the modified prospective method and, accordingly, have not restated the consolidated statements of operations for periods prior to January 1, 2006. Under SFAS No. 123(R), we are required to measure compensation cost for all stock-based awards at fair value on the date of grant and recognize compensation expense in our consolidated statements of operations over the service period that the awards are expected to vest. As permitted under SFAS No. 123(R), we have elected to recognize compensation cost for all options with graded vesting on a straight-line basis over the vesting period of the entire option.

In estimating the fair value of stock-based compensation, we use the quoted market price of our common stock for stock awards, and the Black Scholes Option Pricing Model for stock options and warrants. We estimate future volatility based on past volatility of our common stock; and we estimate the expected length of the option on several criteria, including the vesting period of the grant, and the expected volatility.

Prior to January 1, 2006, we accounted for stock-based compensation, as permitted by FASB Statement No. 123, Accounting for Stock-Based Compensation, under the intrinsic value method described in APB Opinion No. 25, Accounting for Stock Issued to Employees, and related

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Interpretations. Under the intrinsic value method, no stock-based employee compensation cost is recorded when the exercise price is equal to, or higher than, the market value of the underlying common stock on the date of grant. We recognized stock-based compensation expense for all grants to consultants and for those grants to employees where the exercise prices were below the market price of the underlying stock at the measurement date of the grant.

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New Accounting Pronouncements

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109* (FIN 48). FIN 48 clarifies the accounting for uncertainty in income taxes by prescribing the recognition threshold a tax position is required to meet before being recognized in the financial statements. It also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006 and is required to be adopted in 2007. We do not expect the adoption of FIN 48 to have a material impact on our financial statements.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors' requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 applies whenever other standards required (or permit) assets or liabilities to be measured at fair value, and does not expand the use of fair value in any new circumstances. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We are currently evaluating the effect that the adoption of SFAS 157 will have on our consolidated results of operations and financial condition and are not yet in a position to determine such effects.

In September 2006, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 108 (SAB 108), *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*. SAB 108 provides guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of a materiality assessment. SAB 108 establishes an approach that requires quantification of financial statement errors based on the effects on the Company's balance sheet and statement of operations and the related financial statement disclosures. SAB 108 is effective for 2007. We do not expect the adoption of SAB 108 to have a material impact on our financial statements.

Results of Operations

Results of Operations for Fiscal 2006 Compared to Fiscal 2005

In 2006, we incurred a net loss of approximately \$23.3 million compared to a net loss of approximately \$18.6 million in 2005. The increase of approximately \$4.7 million in the net loss was primarily due to an increase of approximately \$5.3 million in research and development expense, an increase of approximately \$6.3 million in non-cash, stock-based charges resulting from the January 1, 2006 adoption of SFAS 123(R), and from the issuance of common stock for the acquisition and licensing of drug products, partially offset by an increase in revenue of approximately \$5.1 million, and an increase of approximately \$1.3 million in interest income.

During the year ended December 31, 2006, we recorded milestone and other fee revenue of approximately \$5.6 million as follows: a \$5 million milestone payment from Par related to sumatriptan injection; and a \$581,000 premium received in connection with the modification of a supply agreement with JBCPL, and the related purchase by JBCPL of 120,000 shares of our common stock for \$1 million. In 2005, we recorded \$56,000 of revenues received from GPC Biotech representing commissions on drug products used by GPC Biotech in clinical trials of satraplatin. No such commissions were received in 2006. The timing and amount of future commissions is neither predictable nor assured, however if satraplatin is approved by the FDA, we would expect to receive commissions on commercial drug product used by GPC Biotech. Generic product sales in 2006 and 2005 were \$92,000 and \$521,000, respectively. In view of the extremely competitive market for each of our currently approved generic products and products for which ANDAs are pending with the FDA, we are unable to assess the future revenue potential from sales of generic products. We do anticipate, however, that pursuant to our settlement agreement with GSK, we will launch, through our distribution partner Par, 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.

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Research and development expenses increased by approximately \$5.3 million, from approximately \$12.6 million in 2005 to approximately \$17.9 million in 2006. During 2006, we continued to advance the development of projects initiated prior to 2006, including EOquin and ozarelix, and reduced the investment in generic drugs. In addition we incurred increased costs in advancing the development of newly-acquired compounds, LFA, SPI-1620 and Lucanthone. We expect continued increases in research and development expenses in 2007 and beyond as we develop and expand our proprietary drug product portfolio. Principal components of the increase in 2006 were:

An increase of approximately \$2.6 million in direct development expenses, resulting from an expansion in the number and scope of our clinical trials and other research and development activity, net of a approximately \$1 million reduction in the development of generic drugs.

An increase of approximately \$2.1 million in R&D personnel costs and approximately \$0.5 million in other indirect R&D expenses. General and administrative expenses decreased by approximately \$0.2 million, from approximately \$6.5 million in 2005 to approximately \$6.3 million in 2006. Modest increases in general operating expenses were more than offset by a decrease in legal expense in connection with our patent challenge of GSK's Imitre[®] injection. As described elsewhere in this report, the agreement with Par for the distribution of our generic products obligated Par to provide financial and legal support, including the payment of all legal expenses for the patent challenge of sumatriptan injection, which lawsuit was dismissed in late 2006, subsequent to a settlement agreement with GSK.

Stock-based charges increased by approximately \$6.3 million, from approximately \$1.0 million in 2005 to approximately \$7.3 million in 2006, primarily as follows:

Approximately \$3.5 million due to our adoption of SFAS 123(R), effective January 1, 2006; and

In connection with the acquisition of the oncology assets of Targent, Inc., we recorded a stock-based charge of approximately \$2.7 million in 2006.

Other income consisted of interest income of approximately \$2.6 million for 2006 and approximately \$1.3 million for 2005. The increase of approximately \$1.3 million is attributable to significantly higher average interest rates and balances of investable funds in 2006.

Results of Operations for Fiscal 2005 Compared to Fiscal 2004

In 2005, we incurred a net loss of approximately \$18.6 million compared to a net loss of approximately \$12.3 million in 2004. The increase of approximately \$6.3 million in the net loss was primarily due to an increase of approximately \$5.6 million in research and development expense.

As of December 31, 2005, the FDA had approved three of our generic products, ciprofloxacin tablets, fluconazole tablets and carboplatin injection, for sale in the United States. We recorded \$521,000 and \$185,000 of product sales during the years ended December 31, 2005 and 2004, respectively, with cost of product sold being approximately \$397,000 and \$123,000, respectively. Also, during 2005 and 2004, we recorded \$56,000 and \$73,000, respectively, of revenues representing amounts received from GPC Biotech under our license agreement for commissions on drug products used by GPC Biotech in clinical trials. We had no performance obligations or incurred costs in connection with this revenue.

Research and development expenses increased by approximately \$5.6 million, from approximately \$7.0 million in 2004 to approximately \$12.6 million in 2005, primarily due to the increasing scope of our drug development activities. During 2004, the principal clinical study costs related to a Phase 2 trial on EOquin. In 2005, we incurred

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costs related to multiple Phase 2 clinical trials on EOquin, elsamitucin and ozarelix, and costs in advancing the development of SPI-205 and newly acquired compounds, RenaZorb, SPI-1620 and Lucanthone. Principal components of the increase in 2005 are:

An increase of approximately \$4.5 million in direct development expenses, resulting from an expansion in the number and scope of our clinical trials and other research and development activity.

An increase of approximately \$0.9 million in R&D personnel costs, and an increase of approximately \$0.2 million in patent-related legal expenses.

General and administrative expenses increased by approximately \$1.4 million, from approximately \$5.1 million in 2004 to approximately \$6.5 million in 2005, primarily due to an increase in legal expense in connection with the litigation regarding our patent challenge of GSK's Imitrex® injection, described elsewhere in this report.

Stock-based charges increased by approximately \$127,000, from \$885,000 in 2004 to \$1,012,000 in 2005, primarily due to an increase in the amortization of stock-based deferred compensation.

Other income consisted of net interest income of approximately \$1.3 million for 2005 and approximately \$0.5 million for 2004. The increase of approximately \$0.8 million is attributable to significantly higher investable funds and increasing interest rates in 2005.

Off-Balance Sheet Arrangements

None.

Contractual and Commercial Obligations

The following table summarizes our contractual and other commitments, including obligations under a facility lease and equipment leases, as of December 31, 2006:

	Total	Payment Due by Period			After 5 Years
		Less than 1 Year	1-3 Years	3-5 Years	
Amounts In Thousands					
Contractual Obligations (1)					
Capital Lease Obligations (2)	\$	\$	\$	\$	\$
Operating Lease Obligations (3)	\$ 1,226	\$ 474	\$ 747	\$ 5	\$
Purchase Obligations (4)	\$ 3,847	\$ 3,195	\$ 555	\$ 98	\$
Contingent Milestone Obligations (5)	\$ 48,302	\$ 4,272	\$ 3,205	\$ 19,725	\$ 21,100
Total	\$ 53,375	\$ 7,941	\$ 4,507	\$ 19,828	\$ 21,100

- (1) The table of contractual and commercial obligations excludes contingent payments that we may become obligated to pay upon the occurrence of future events whose outcome is not readily predictable. Such significant contingent obligations are described below under Employment Agreements.
- (2) As of December 31, 2006, we had no capital lease obligations.
- (3) The operating lease obligations are primarily related to the facility lease for our corporate office, which extends through June 2009.

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- (4) Purchase Obligations represent the amount of open purchase orders and contractual commitments to vendors, for products and services that have not been delivered, or rendered, as of December 31, 2006.
- (5) Milestone Obligations are payable contingent upon successfully reaching certain development and regulatory milestones as further described below under *Licensing Agreements* . While the amounts included in the table above represent all of our potential cash development and regulatory milestone obligations as of December 31, 2006, given the unpredictability of the drug development process, and the impossibility of predicting the success of current and future clinical trials, the timelines estimated above do not represent a forecast of when payment milestones will actually be reached, if at all. Rather, they assume that all development and regulatory milestones under all of our license agreements are successfully met, and represent our best estimates of the timelines. In the event that the milestones are met, we believe it is likely that the increase in the potential value of the related drug product will significantly exceed the amount of the milestone obligation.

Licensing Agreements

Almost all of our proprietary drug product candidates are being developed pursuant to license agreements, which provide us with rights to certain territories to, among other things, develop, sublicense, and sell the drugs. With regard to one of our proprietary drug product candidates, satraplatin, we have out-licensed our rights to GPC Biotech. We are required to use commercially reasonable efforts to develop the drugs, are generally responsible for all development, patent filing and maintenance costs, sales, marketing and liability insurance costs, and are generally contingently obligated to make milestone payments to the licensors if we successfully reach development and regulatory milestones specified in the agreements. In addition, we are obligated to pay royalties and, in some cases, milestone payments based on net sales, if any, after marketing approval is obtained from regulatory authorities. We have no similar milestone or other payment obligations in connection with our generic drug products, however, Par is responsible for marketing our generic sumatriptan injection product and we share the profits.

The potential contingent development and regulatory milestone obligations under all our licensing agreements are generally tied to progress through the FDA approval process, which approval significantly depends on positive clinical trial results. The following list is typical of milestone events: conclusion of Phase 2 or commencement of Phase 3 clinical trials, filing of new drug applications in each of the United States, Europe and Japan, and approvals from each of the regulatory agencies in those jurisdictions.

Given the uncertainty of the drug development process, we are unable to predict with any certainty when any of the milestones will occur. Accordingly, the milestone payments represent contingent obligations that will be recorded as expense when the milestone is achieved. In connection with the development of in-licensed drug products, we anticipate certain milestones will be achieved over the next twelve months. If the anticipated milestones are achieved, we will likely become obligated to issue up to 375,000 shares of our common stock and pay up to approximately \$4 million in cash during the twelve-month period and will simultaneously have the right to receive approximately \$10 million from the same milestones. If all of our contingent milestones were achieved, our potential contingent cash development and regulatory milestone obligations, aggregating approximately \$48 million as of December 31, 2006, would be due approximately as follows: \$4 million in less than 1 year; \$3 million between 1 and 3 years; \$20 million between 3 and 5 years; and \$21 million after 5 years.

Service Agreements

In connection with the research and development of our drug products, we have entered into contracts with numerous third party service providers, such as clinical trial centers, clinical research organizations, data monitoring centers, and with drug formulation, development and testing laboratories. The financial terms of these agreements are varied and generally obligate us to pay in stages, depending on achievement of certain events specified in the agreements, such as contract execution, reservation of service or production capacity, actual performance of service, or the successful accrual and dosing of patients. As of each period end, we accrue for all non-cancelable installment amounts that we are likely to become obligated to pay.

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Employment Agreements

We have entered into employment agreements with two of our Executive Officers, Dr. Shrotriya, Chief Executive Officer, and Dr. Lenaz, Chief Scientific Officer, expiring December 31, 2007 and July 1, 2007, respectively. The employment agreements automatically renew for a one-year term unless either party gives written notice at least 90 days prior to the commencement of the next year of such party's intent not to renew the agreement. The agreements require each executive to devote his full working time and effort to the business and affairs of the Company during the term of the agreement. The agreements provide for an annual base salary with annual increases, periodic bonuses and option grants as determined by the Compensation Committee of our Board of Directors.

Each officer's employment may be terminated by us with or without cause, as defined in the agreement. The agreements provide for certain guaranteed severance payments and benefits if the officer's employment is terminated without cause, if the officer's employment is terminated due to a change in control or is adversely affected due to a change in control and the officer resigns or if the officer decides to terminate his employment due to a disposition of a significant amount of assets or business units. The guaranteed severance payment includes a payment equal to the officer's annual base salary and other cash compensation, and approved bonus. The officer is also entitled to two years medical, dental and other benefits following termination. In addition, all options held by the officer shall immediately vest and will be exercisable for one year from the date of termination; provided, however, if the Board determines that the officer's employment is being terminated for the reason that the shared expectations of the officer and the Board are not being met, in the Board's judgment, then the options currently held by the officer will vest in accordance with their terms for up to one year after the date of termination, with the right to exercise those options, when they vest, for approximately thirteen (13) months after the date of termination. The agreements also provide that, upon his retirement, all options held by the officer will become fully vested.

Item 7A. *Quantitative and Qualitative Disclosures About Market Risk*

We are exposed to certain market risks associated with interest rate fluctuations and credit risk on our cash equivalents and marketable securities, which investments are entered into for purposes other than trading. The primary objective of our investment activities is to preserve principal, while at the same time maximizing yields without significantly increasing risk. We do not utilize hedging contracts or similar instruments.

Our primary exposures relate to (1) interest rate risk on our investment portfolio, and (2) credit risk of the companies' bonds in which we invest. We manage interest rate risk on our investment portfolio by matching scheduled investment maturities with our cash requirements.

Our investments as of December 31, 2006 are primarily in floating rate securities, short-term government securities and money market accounts. Because of our ability to redeem these investments at par with short notice, changes in interest rates would have an immaterial effect on the fair value of these investments. If a 10% change in interest rates were to have occurred on December 31, 2006, any decline in the fair value of our investments would not be material. In addition, we are exposed to certain market risks associated with credit ratings of corporations whose corporate bonds we may purchase from time to time. If these companies were to experience a significant detrimental change in their credit ratings, the fair market value of such corporate bonds may significantly decrease. If these companies were to default on these corporate bonds, we may lose part or all of our principal. We believe that we effectively manage this market risk by diversifying our investments, and selecting securities that generally have third party insurance coverage in the event of default by the issuer.

In addition, we are exposed to foreign currency exchange rate fluctuations relating to payments we make to vendors, suppliers and license partners using foreign currencies. In particular, we have foreign expenses associated with our ongoing clinical studies in Europe, where some of our obligations are incurred in Euros. We mitigate such risk by maintaining a limited portion of our cash in Euros. Although fluctuations in exchange rates have an effect on our payment obligations, such fluctuations have not had a material impact on our financial condition or results of operations as of or for the years ended December 31, 2006, 2005 and 2004.

Item 8. *Financial Statements and Supplementary Data*

Our annual consolidated financial statements are included in Item 15 of this report.

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Item 9. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure*

None.

Item 9A. *Controls and Procedures.*

(i) Disclosure Controls and Procedures.

We have established disclosure controls and procedures (as such terms are defined in Rules 13a-15(e) and 15d-15(e)) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer (our principal executive officer) and Vice President Finance (our principal financial officer), as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide a reasonable level of assurance of reaching our desired disclosure control objectives.

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Vice President Finance, of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2006, the end of the period covered by this report (Evaluation Date). Based on the foregoing, our Chief Executive Officer and Vice President Finance concluded that our disclosure controls and procedures were effective and were operating at the reasonable assurance level as of the Evaluation Date.

(ii) Internal Control Over Financial Reporting.

(a) *Management's annual report on internal control over financial reporting.*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f).

Our internal control system was designed to provide reasonable assurance to our management and board of directors regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Due to the small size of our company and the limited number of employees, it is not possible for us to fully segregate duties associated with the financial reporting process; accordingly, we rely on mitigating controls to reduce the risks from such lack of segregation of duties. Further, all internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Because of such inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO. Based on our evaluation under the framework in COSO, our management concluded that our internal control over financial reporting was effective as of the Evaluation Date.

Our management's assessment of the effectiveness of our internal control over financial reporting as of the Evaluation Date has been audited by Kelly & Company, an independent registered public accounting firm, as stated in their report which is included herein.

(b) *Changes in internal control over financial reporting.*

During the fourth quarter ended December 31, 2006, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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(c) Attestation report of the registered public accounting firm.

The integrated attestation report of Kelly & Company, the Company's independent registered public accounting firm, is set forth on page F-3. Presented below is an extract from that attestation report as to their audit of management's assessment of the effectiveness of our internal control over financial reporting and their independent assessment of our internal control over financial reporting:

We have completed integrated audits of the 2006 and 2005 consolidated financial statements of Spectrum Pharmaceuticals, Inc. and Subsidiaries (the Company) and of its annual report on internal control over financial reporting as of December 31, 2006 and an audit of its 2004 consolidated financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

Internal Control Over Financial Reporting

... in our opinion, management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting appearing in Item 9A, that the Company maintained effective internal control over financial reporting as of December 31, 2006 based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, based on criteria established in *Internal Control - Integrated Framework* issued by COSO. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management's assessment and on the effectiveness of the Company's internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A Company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A Company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Item 9B. *Other Information*

None.

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PART III

Item 10. *Directors, Executive Officers and Corporate Governance*

The information concerning our directors and executive officers required under this item is incorporated by reference from our definitive proxy statement related to our 2007 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A, on or before April 30, 2007, or the 2007 Proxy Statement.

Item 11. *Executive Compensation*

The information required under this item is incorporated by reference from our 2007 Proxy Statement.

Item 12. *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*

The information required under this item is incorporated by reference from our 2007 Proxy Statement.

Item 13. *Certain Relationships and Related Transactions, and Director Independence*

The information required under this item is incorporated by reference from our 2007 Proxy Statement.

Item 14. *Principal Accountant Fees and Services*

The information required under this item is incorporated by reference from our 2007 Proxy Statement.

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PART IV

Item 15. Exhibits and Financial Statement Schedules

(a)(1) *Consolidated Financial Statements:*

	Page
Report of Independent Registered Public Accounting Firm	F-3
Consolidated Balance Sheets as of December 31, 2006 and 2005	F-5
Consolidated Statements of Operations for the years ended December 31, 2006, 2005 and 2004	F-6
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2006, 2005 and 2004	F-7
Consolidated Statements of Cash Flow for the years ended December 31, 2006, 2005 and 2004	F-8
Notes to Consolidated Financial Statements	F-10

(a)(2) *Financial Statement Schedules:* All financial statement schedules are omitted because they are not applicable or the required information is included in the Consolidated Financial Statements or notes thereto.

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(a)(3) Exhibits.

Exhibit No.	Description
2.1 #	Asset Purchase Agreement by and between the Registrant, Targent Inc. and Certain Stockholders of Targent, Inc., dated March 17 2006. (Filed as Exhibit 2.1 to Form 10-K/A, Amendment No. 1, as filed with the Securities and Exchange Commission on May 1, 2006, and incorporated herein by reference.)
3.1	Amended Certificate of Incorporation, as filed. (Filed as Exhibit 3.1 to Form 10-Q, as filed with the Securities and Exchange Commission on August 8, 2006, and incorporated herein by reference.)
3.2	Form of Amended and Restated Bylaws of the Registrant. (Filed as Exhibit 3.1 to Form 10-Q, as filed with the Securities and Exchange Commission on August 16, 2004, and incorporated herein by reference.)
4.1	Rights Agreement, dated as of December 13, 2000, between the Registrant and U.S. Stock Transfer Corporation, as Rights Agent, which includes as Exhibit A thereto the form of Certificate of Designation for the Series B Junior Participating Preferred Stock, as Exhibit B thereto the Form of Rights Certificate and as Exhibit C thereto a Summary of Terms of Stockholder Rights Plan. (Filed as Exhibit 4.1 to Form 8-A12G, as filed with the Securities and Exchange Commission on December 26, 2000, and incorporated herein by reference.)
4.2	Form of Warrant issued by the Registrant to certain purchasers, dated as of June 5, 2002. (Filed as Exhibit 4.1 to Form 8-K, as filed with the Securities and Exchange Commission on June 7, 2002, and incorporated herein by reference.)
4.3	Form of Warrant issued by the Registrant to certain purchasers, dated as of June 7, 2002. (Filed as Exhibit 4.1 to Form 8-K, as filed with the Securities and Exchange Commission on June 19, 2002, and incorporated herein by reference.)
4.4	Warrant Repurchase Agreement by and between the Registrant and BNC Bach International, Ltd., dated as of July 31, 2002. (Filed as Exhibit 10.3 to Form 10-Q for the quarterly period ended September 30, 2002, as filed with the Securities and Exchange Commission on November 13, 2002, and incorporated herein by reference.)
4.5*	Form of Warrant issued by the Registrant to five purchasers, dated as of November 21, 2002, to purchase up to an aggregate of 107,870 shares of our common stock. (Filed as Exhibit 4.1 to Form 8-K, as filed with the Securities and Exchange Commission on November 26, 2002, and incorporated herein by reference.)
4.6	Form of Warrant issued by the Registrant to certain purchasers, dated as of December 13, 2002, to purchase up to an aggregate of 65,550 shares of our common stock. (Filed as Exhibit 4.1 to Form 8-K, as filed with the Securities and Exchange Commission on December 23, 2002, and incorporated herein by reference.)
4.7	Form of Warrant issued by the Registrant to three purchasers, dated as of January 16, 2003, to purchase up to an aggregate of 55,555 shares of our common stock. (Filed as Exhibit 4.1 to Form 8-K, as filed with the Securities and Exchange Commission on January 17, 2003, and incorporated herein by reference.)
4.8	Form of Series D-1 Warrant. (Filed as Exhibit 4.1 to Form 8-K, as filed with the Securities and Exchange Commission on May 16, 2003, and incorporated herein by reference.)
4.9	Form of Series D-2 Warrant. (Filed as Exhibit 4.2 to Form 8-K, as filed with the Securities and Exchange Commission on May 16, 2003, and incorporated herein by reference.)

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Exhibit No.	Description
4.10	Form of Series D-3 Warrant. (Filed as Exhibit 4.3 to Form 8-K, as filed with the Securities and Exchange Commission on May 16, 2003, and incorporated herein by reference.)
4.11	Registration Rights Agreement dated as of May 7, 2003, by and among the Registrant and the persons listed on Schedule 1 attached thereto. (Filed as Exhibit 4.4 to Form 8-K, as filed with the Securities and Exchange Commission on May 16, 2003, and incorporated herein by reference.)
4.12	Amendment No. 1 to the Rights Agreement dated as of December 13, 2000 by and between the Registrant and U.S. Stock Transfer Corporation. (Filed as Exhibit 4.1 to Form 10-Q, as filed with the Securities and Exchange Commission on August 14, 2003, and incorporated herein by reference.)
4.13*	Registration Rights Agreement dated as of August 13, 2003, by and among the Registrant and the persons listed on Schedule 1 attached thereto. (Filed as Exhibit 4.1 to Form 8-K, as filed with the Securities and Exchange Commission on August 15, 2003, and incorporated herein by reference.)
4.14*	Form of Series 2003-1 Warrant (Filed as Exhibit 4.2 to Form 8-K, as filed with the Securities and Exchange Commission on August 15, 2003, and incorporated herein by reference.)
4.15	Form of Series E-1 Warrant (Filed as Exhibit 4.1 to Form 8-K, as filed with the Securities and Exchange Commission on September 30, 2003, and incorporated herein by reference.)
4.16	Form of Series E-2 Warrant (Filed as Exhibit 4.2 to Form 8-K, as filed with the Securities and Exchange Commission on September 30, 2003, and incorporated herein by reference.)
4.17	Form of Series E-3 Warrant (Filed as Exhibit 4.3 to Form 8-K, as filed with the Securities and Exchange Commission on September 30, 2003, and incorporated herein by reference.)
4.18	Registration Rights Agreement dated as of September 26, 2003, by and among the Registrant and the persons listed on Schedule 1 attached thereto. (Filed as Exhibit 4.4 to Form 8-K, as filed with the Securities and Exchange Commission on September 30, 2003, and incorporated herein by reference.)
4.19	Investor Rights Agreement, dated as of April 20, 2004, by and among the Registrant and the persons listed on Schedule 1 attached thereto. (Filed as Exhibit 4.1 to Form 8-K, as filed with the Securities and Exchange Commission on April 23, 2004, and incorporated herein by reference.)
4.20	Form of Warrant, dated as of April 21, 2004. (Filed as Exhibit 4.2 to Form 8-K, as filed with the Securities and Exchange Commission on April 23, 2004, and incorporated herein by reference.)
4.21	Amendment No. 2 to the Rights Agreement dated as of December 13, 2000 by and between the Registrant and U.S. Stock Transfer Corporation. (Filed as Exhibit 4.1 to Form 10-Q, as filed with the Securities and Exchange Commission on May 17, 2004, and incorporated herein by reference.)
4.22	Amendment No. 3 to the Rights Agreement dated as of December 13, 2000 by and between the Registrant and U.S. Stock Transfer Corporation. (Filed as Exhibit 4.2 to Form 10-Q, as filed with the Securities and Exchange Commission on May 17, 2004, and incorporated herein by reference.)
4.23	Warrant issued by the Registrant to a Consultant, dated as of September 17, 2003. (Filed as Exhibit 4.3 to Form 10-Q, as filed with the Securities and Exchange Commission on May 17, 2004, and incorporated herein by reference.)

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Exhibit No.	Description
4.24	Warrant issued by the Registrant to a Consultant, dated as of April 21, 2004. (Filed as Exhibit 4.4 to Form 10-Q, as filed with the Securities and Exchange Commission on May 17, 2004, and incorporated herein by reference.)
4.25	Form of Warrant, dated as of September 30, 2004. (Filed as Exhibit 4.1 to Form 10-Q, as filed with the Securities and Exchange Commission on November 15, 2004, and incorporated herein by reference.)
4.26	Amendment No. 1 dated as of November 2, 2005, to Warrant issued by the Registrant to a consultant, dated as of September 17, 2003. (Filed as Exhibit 4.2 to Form 10-Q, as filed with the Securities and Exchange Commission on November 4, 2005, and incorporated herein by reference.)
4.27	Warrant issued by the Registrant to a Consultant, dated as of September 20, 2005. (Filed as Exhibit 4.3 to Form 10-Q, as filed with the Securities and Exchange Commission on November 4, 2005, and incorporated herein by reference.)
4.28	Form of Warrant dated September 15, 2005. (Filed as Exhibit 4.35 to Form 10-K, as filed with the Securities and Exchange Commission on March 15, 2006, and incorporated herein by reference.)
4.29	Registration Rights Agreement dated as of April 20, 2006, by and among the Registrant and Targent, Inc. (Filed as Exhibit 4.2 to Form 10-Q, as filed with the Securities and Exchange Commission on May 8, 2006, and incorporated herein by reference.)
4.30	Fourth Amendment to Rights Agreement dated July 7, 2006. (Filed as Exhibit 4.1 to Form 8-K, as filed with the Securities and Exchange Commission on July 12, 2006, and incorporated herein by reference.)
4.31	Amendment No. 5 to the Rights Agreement dated as of December 13, 2000 by and between the Registrant and U.S. Stock Transfer Corporation. (Filed as Exhibit 4.2 to Form 10-Q, as filed with the Securities and Exchange Commission on November 3, 2006, and incorporated herein by reference.)
10.1	Industrial Lease Agreement dated as of January 16, 1997, between the Registrant and the Irvine Company. (Filed as Exhibit 10.11 to the Form 10-KSB for the fiscal year ended December 31, 1996, as filed with the Securities and Exchange Commission on March 31, 1997, and incorporated herein by reference.)
10.2*	Employee Stock Purchase Plan. (Filed as Exhibit 4.1 to the Registrant's Registration Statement on Form S-8 (No. 333-54246), and incorporated herein by reference.)
10.3*	Amendment 2001-1 to the Employee Stock Purchase Plan effective as of June 21, 2001. (Filed as Exhibit 10.22 to the Annual Report on Form 10-K, as amended, as filed with the Securities and Exchange Commission on April 25, 2001, and incorporated herein by reference.)
10.4*	Executive Employment Agreement for Rajesh C. Shrotriya, M.D., dated as of December 1, 2000. (Filed as Exhibit 10.35 to Form 10-K, as filed with the Securities and Exchange Commission on April 2, 2002, and incorporated herein by reference.)
10.5	License Agreement dated as of June 29, 2001, by and between the Registrant and NDDO Research Foundation. (Filed as Exhibit 10.4 to Form 10-Q, as filed with the Securities and Exchange Commission on November 14, 2001, and incorporated herein by reference.)
10.6	License Agreement dated as of August 28, 2001, by and between the Registrant and Johnson Matthey PLC. (Filed as Exhibit 10.5 to Form 10-Q, as filed with the Securities and Exchange Commission on November 14, 2001, and incorporated herein by reference.)

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Exhibit No.	Description
10.7	License Agreement dated as of October 24, 2001, by and between the Registrant and Bristol-Myers Squibb Company. (Filed as Exhibit 10.6 to Form 10-Q, as filed with the Securities and Exchange Commission on November 14, 2001, and incorporated herein by reference.)
10.8	Settlement Agreement and Release by and between the Registrant and Merck Eprova AG dated as of September 30, 2002. (Filed as Exhibit 10.7 to Form 10-Q for the quarterly period ended September 30, 2002, as filed with the Securities and Exchange Commission on November 13, 2002, and incorporated herein by reference.)
10.9#	First Amendment to License Agreement dated August 28, 2001 by and between the Registrant and Johnson Matthey PLC dated as of September 30, 2002. (Filed as Exhibit 10.8 to Form 10-Q for the quarterly period ended September 30, 2002, as filed with the Securities and Exchange Commission on November 13, 2002, and incorporated herein by reference.)
10.10	Preferred Stock and Warrant Purchase Agreement dated as of April 29, 2003, by and among the Registrant and the purchasers listed on Schedule 1 attached thereto. (Filed as Exhibit 10.1 to Form 8-K, as filed with the Securities and Exchange Commission on May 16, 2003, and incorporated herein by reference.)
10.11	Amendment No. 1 of the Preferred Stock and Warrant Purchase Agreement and Registration Rights Agreement dated as of May 13, 2003 by and among the Registrant and the persons listed on Schedule 1B attached thereto. (Filed as Exhibit 10.2 to Form 8-K, as filed with the Securities and Exchange Commission on May 16, 2003, and incorporated herein by reference.)
10.12*	Common Stock and Warrant Purchase Agreement dated as of August 13, 2003, by and among the Registrant and the purchasers listed on Schedule 1 attached thereto. (Filed as Exhibit 10.1 to Form 8-K, as filed with the Securities and Exchange Commission on August 15, 2003, and incorporated herein by reference.)
10.13	Preferred Stock and Warrant Purchase Agreement dated as of September 26, 2003, by and among the Registrant and the purchasers listed on Schedule 1 attached thereto. (Filed as Exhibit 10.1 to Form 8-K, as filed with the Securities and Exchange Commission on September 30, 2003, and incorporated herein by reference.)
10.14*	Executive Employment Agreement for Luigi Lenaz, M.D., dated as of October 22, 2001. (Filed as Exhibit 10.45 to Form 10-K, as filed with the Securities and Exchange Commission on March 29, 2004, and incorporated herein by reference.)
10.15	First Amendment dated March 25, 2004 to Industrial Lease Agreement dated as of January 16, 1997 by and between the Registrant and the Irvine Company. (Filed as Exhibit 10.1 to Form 10-Q, as filed with the Securities and Exchange Commission on May 17, 2004, and incorporated herein by reference.)
10.16*	2003 Amended and Restated Incentive Award Plan. (Filed as Exhibit 10.2 to Form 10-Q, as filed with the Securities and Exchange Commission on May 17, 2004, and incorporated herein by reference.)
10.17*	Form of Indemnity Agreement of the Registrant. (Filed as Exhibit 10.1 to Form 10-Q, as filed with the Securities and Exchange Commission on August 16, 2004, and incorporated herein by reference.)
10.18	Common Stock and Warrant Purchase Agreement, dated as of April 20, 2004, by and among Spectrum and the purchasers listed on Schedule 1 attached thereto. (Filed as Exhibit 10.1 to Form 8-K, as filed with the Securities and Exchange Commission on April 23, 2004, and incorporated by reference.)

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Exhibit No.	Description
10.19#	Co-Development and License Agreement by and between the Registrant and GPC Biotech AG, dated as of September 30, 2002. (Filed as Exhibit 10.1 to Form 10-Q, as filed with the Securities and Exchange Commission on November 15, 2004, and incorporated by reference.)
10.20#	Diagnostic and Drug Product Manufacturing, Supply and Marketing Agreement dated as of May 10, 2004 by and between the Registrant and Shantha Biotechnics Pvt. Ltd. (Filed as Exhibit 10.2 to Form 10-Q, as filed with the Securities and Exchange Commission on November 15, 2004, and incorporated by reference.)
10.21#	License and Collaboration Agreement by and between the Registrant and Zentaris GmbH, dated as of August 12, 2004. (Filed as Exhibit 10.1 to Form S-3/A, as filed with the Securities and Exchange Commission on January 21, 2005, and incorporated by reference.)
10.22	Settlement Agreement and Release by and between the Registrant and SCO Financial Group, LLC, dated as of September 30, 2004. (Filed as Exhibit 10.4 to Form 10-Q, as filed with the Securities and Exchange Commission on November 15, 2004, and incorporated by reference.)
10.23*	Form of Stock Option Agreement under the 2003 Amended and Restated Incentive Award Plan. (As filed as Exhibit 10.1 to Form 8-K, as filed with the Securities and Exchange Commission on December 17, 2004, and incorporated herein by reference.)
10.24#	License Agreement by and between the Registrant and Altair Nanomaterials, Inc. and Altair Nanotechnologies, Inc. (Filed as Exhibit 10.1 to Form 8-K, as filed with the Securities and Exchange Commission on February 3, 2005, and incorporated herein by reference.)
10.25#	License Agreement by and between the Registrant and Chicago Labs, Inc. (Filed as Exhibit 10.1 to Form 8-K, as filed with the Securities and Exchange Commission on February 25, 2005, and incorporated herein by reference.)
10.26*	Form of Non-Employee Director Stock Option Agreement under the 2003 Amended and Restated Incentive Award Plan. (Filed as Exhibit 10.5 to Form 10-Q with the Securities and Exchange Commission on May 10, 2005, and incorporated herein by reference.)
10.27#	License Agreement between Registrant and Dr. Robert Bases. (Filed as Exhibit 10.1 to Form 8-K, as filed with the Securities and Exchange Commission on May 20, 2005, and incorporated herein by reference.)
10.28	Form Securities Purchase Agreement dated September 14, 2005. (Filed as Exhibit 10.1 to Form 8-K, as filed with the Securities and Exchange Commission on September 15, 2005, and incorporated herein by reference.)
10.29	Letter Agreement between the Registrant and Rodman and Renshaw, LLC. (Filed as Exhibit 10.2 to Form 8-K, as filed with the Securities and Exchange Commission on September 15, 2005, and incorporated herein by reference.)
10.30*	Restricted Stock Award Grant Notice and Restricted Stock Award Agreement under the Amended and Restated Incentive Award Plan. (Filed as Exhibit 10.44 to Form 10-K, as filed with the Securities and Exchange Commission on March 15, 2006, and incorporated herein by reference.)
10.31#	Development and Marketing Agreement between the Registrant and Par Pharmaceutical, Inc. dated February 22, 2006. (Filed as Exhibit 10.1 to Form 10-K/A, Amendment No. 1, as filed with the Securities and Exchange Commission on May 1, 2006, and incorporated herein by reference.)

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Exhibit No.	Description
10.32	Voting Agreement by and Among the Registrant and Certain Stockholders of Targent, Inc. dated March 17, 2006. (Filed as Exhibit 10.2 to Form 10-K/A, Amendment No. 1, as filed with the Securities and Exchange Commission on May 1, 2006, and incorporated herein by reference.)
10.33*	Summary of Director Compensation. (Filed as Exhibit 10.3 to Form 10-K/A, Amendment No. 1, as filed with the Securities and Exchange Commission on May 1, 2006, and incorporated herein by reference.)
10.34#	License Agreement between Registrant and Merck Eprova AG dated May 23, 2006. (Filed as Exhibit 10.1 to Form 10-Q, as filed with the Securities and Exchange Commission on August 8, 2006, and incorporated herein by reference.)
10.35#	Manufacturing and Supply Agreement between Registrant and Merck Eprova AG dated May 23, 2006. (Filed as Exhibit 10.2 to Form 10-Q, as filed with the Securities and Exchange Commission on August 8, 2006, and incorporated herein by reference.)
10.36#	Share Subscription Agreement by and between the Registrant and J B Chemicals & Pharmaceuticals Limited dated as of August 4, 2006. (Filed as Exhibit 10.1 to Form 10-Q, as filed with the Securities and Exchange Commission on November 3, 2006, and incorporated herein by reference.)
10.37*	Third Amended and Restated 1997 Stock Incentive Plan. (Filed as Exhibit 10.2 to Form 10-Q, as filed with the Securities and Exchange Commission on November 3, 2006, and incorporated herein by reference.)
10.38# +	Agreement by and between Registrant and Glaxo Group Limited (d/b/a GlaxoSmithKline) dated November 10, 2006.
10.39# +	First Amendment to the Development and Marketing Agreement by and between Registrant and Par Pharmaceutical Companies, Inc. dated November 10, 2006.
10.40# +	Supply and Distribution Agreement among Glaxo Group Limited, Glaxo Wellcome Manufacturing PTE Limited and Par Pharmaceutical, Inc. dated November 10, 2006.
10.41	Second Amendment to the License Agreement by and between Registrant and Johnson Matthey PLC dated February 23, 2007. (Filed as Exhibit 10.1 to Form 8-K, as filed with the Securities and Exchange Commission on March 2, 2007, and incorporated herein by reference.)
21+	Subsidiaries of Registrant.
23.1+	Consent of Kelly & Company.
31.1+	Certification of Chief Executive Officer, pursuant to Rule 13a-14 promulgated under the Exchange Act, as created by Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification of Vice President Finance, pursuant to Rule 13a-14 promulgated under the Exchange Act, as created by Section 302 of the Sarbanes-Oxley Act of 2002.
32.1+	Certification of Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002.
32.2+	Certification of Vice President Finance, pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002.

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- * Indicates a management contract or compensatory plan or arrangement.

- + Filed herewith

- # Confidential portions omitted and filed separately with the U.S. Securities and Exchange Commission pursuant to Rule 24b-2 promulgated under the Securities Exchange Act of 1934, as amended.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

SPECTRUM PHARMACEUTICALS, INC.

By: /s/ RAJESH C. SHROTRIYA, M.D.
Rajesh C. Shrotriya, M.D.
Chief Executive Officer and President

Date: March 13, 2007

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ RAJESH C. SHROTRIYA, M.D. Rajesh C. Shrotriya, M.D.	Chairman of the Board, Chief Executive Officer President and Director (Principal Executive Officer)	March 13, 2007
/s/ SHYAM K. KUMARIA Shyam K. Kumaria	Vice President Finance (Principal Financial and Accounting Officer)	March 13, 2007
/s/ RICHARD D. FULMER Richard D. Fulmer	Director	March 13, 2007
/s/ STUART M. KRASSNER, Sc.D., Psy.D. Stuart M. Krassner, Sc.D., Psy.D.	Director	March 13, 2007
/s/ ANTHONY E. MAIDA, III Anthony E. Maida, III	Director	March 13, 2007
/s/ DILIP J. MEHTA, M.D., Ph.D. Dilip J. Mehta, M.D., Ph.D.	Director	March 13, 2007
/s/ JULIUS A. VIDA, Ph.D. Julius A. Vida, Ph.D.	Director	