

SPECTRUM PHARMACEUTICALS INC

Form 10-K

March 14, 2008

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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**Form 10-K**

- p ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2007**
- o 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.<sup>tm</sup>**  
*(Exact Name of Registrant as Specified in its Charter)*

**Delaware**  
*(State or other jurisdiction of  
incorporation or organization)*

**157 Technology Drive  
Irvine, California**  
*(Address of principal executive offices)*

**93-0979187**  
*(I.R.S. Employer  
Identification No.)*

**92618**  
*(Zip Code)*

**Registrant's telephone number, including area code:  
(949) 788-6700**

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

<b>Title of Each Class</b>	<b>Name of Each Exchange on Which Registered</b>
Common Stock, \$0.001 par value Common Stock Purchase Warrants Rights to Purchase Series B Junior Participating Preferred Stock	The NASDAQ Global Market

**Securities registered pursuant to Section 12(g) of the Act:**  
**None**

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, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting  
(Do not check if a smaller reporting company)

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, 2007 was \$218,475,000 based on the closing sale price of such common equity on such date.

As of March 10, 2008 there were 31,233,798 shares of the registrant's common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Proxy Statement for the Registrant's 2008 Annual Meeting of Stockholders, to be filed on or before April 29, 2008, 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, including but not limited to, believes, may, will, expects, intends, estimates, anticipates, plans, seeks, or continues, and also contains 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, safety and efficacy of our drug products, product approvals, product sales, revenues, 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. Except as required by law, we do not undertake to update any such forward-looking statements and expressly disclaim any duty to update the information contained in this filing.*

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.

Spectrum Pharmaceuticals, Inc.<sup>tm</sup> and ISO-Vorin<sup>tm</sup> are trademarks owned by Spectrum Pharmaceuticals, Inc., and EOquin<sup>®</sup> is a registered trademark of Spectrum Pharmaceuticals, Inc. RenaZorb<sup>®</sup> is a registered trademark of Altair Nanomaterials, Inc., and licensed to Spectrum Pharmaceuticals, Inc. All other trademarks, tradenames and service marks are the property of their respective owners.

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**PART I**

**Item 1. *Business***

**Overview**

On March 7, 2008, we received approval from the U.S. Food and Drug Administration, or FDA, of our new drug application, or NDA, for our drug product, LEVOleucovorin (formerly, ISO-Vorin<sup>™</sup>). We anticipate launching LEVOleucovorin in the U.S. market in mid-2008. Also, during the fourth quarter of 2008, we will launch sumatriptan injection, the generic form of GlaxoSmithKline's Imitrex<sup>®</sup> injection, through our commercialization partner, Par Pharmaceutical Companies, Inc. We are a biopharmaceutical company that acquires, develops and commercializes a diversified portfolio of drug products, with a focus on oncology, urology and other critical health challenges. We are focused on executing our business strategy, which is comprised of the following four parts:

Acquiring and developing a broad and diverse pipeline of late-stage clinical and commercial products with a focus on oncology and urology.

We acquire and develop multiple novel, late-stage oncology drug products that address niche markets. 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 early clinical process. Our strategy allows us to leverage organizational, collaborative, commercial and scientific efficiencies from a therapeutic focus on oncology and urology.

Establishing a commercial organization for LEVOleucovorin that will be available if and when each of the other drug products in our pipeline are approved. As we transform from a development to a commercial organization, we are building a foundation for successful product launches.

Continuing to build a team with significant drug development and commercialization expertise in our areas of focus and creating a culture of success that allows our people to thrive.

We have built the foundation of a team with significant experience in oncology and urology drug development. We endeavor to leverage the talents of our team and add people who have relevant experience. Our team members have, in the past, been responsible for the development of drugs such as adriamycin, cisplatin, carboplatin, paclitaxel, Etoposide, Buspar, Cialis, Nefazodone and Stadol, among others. We also have, and will continue to bring, commercialization experience to the Company as we build our commercial infrastructure.

Leveraging the expertise of partners around the world in areas of manufacturing, development and commercialization to assist us in the execution of our strategy.

**Recent Developments**

In 2007, we continued to execute on our business strategy, which is described above. Below are some key developments.

For LEVOleucovorin, we filed an amendment to the NDA with the FDA to answer questions surrounding the chemistry manufacturing and control section of the NDA. We recently received approval from the FDA for this drug.

For EOquin<sup>®</sup>, we received concurrence from the FDA for the design of a Phase 3 study protocol for the treatment of non-invasive bladder cancer under a special protocol assessment procedure. The development plan for EOquin calls for two Phase 3 clinical studies. The first study began during the second quarter of 2007, and the second study began during the third quarter of 2007. We recently received scientific advice from the European Medicines Agency, or EMEA, the European equivalent to the FDA, whereby the EMEA agreed that the two Phase 3 studies being conducted at this time, mostly in the United States, should be sufficient for a regulatory decision regarding European registration. We continue to enroll patients in these two studies and plan to add study sites in



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Canada to accelerate patient enrollment since we recently received authorization from the Canadian Health Authorities allowing us to initiate the trials in Canada.

For ozarelix, the FDA accepted our investigational new drug, or IND, application to study ozarelix for the treatment of benign prostatic hypertrophy, or BPH as it is commonly known, and also approved the protocol for a Phase 2b study of ozarelix for the treatment of BPH. We completed patient enrollment in such study and expect that complete data will be available by mid-April 2008. While we wait for the data, we are concurrently working on the design of the protocol for the next study, which we expect to initiate soon thereafter.

For satraplatin, in 2007 we received approximately \$7.7 million in revenues from GPC Biotech AG, our sublicensee for the drug, and we paid Johnson Matthey, our licensor of the drug, an aggregate of \$1 million in milestone payments, in connection with the achievement of certain regulatory milestones by GPC. On October 30, 2007, GPC announced that the Phase 3 trial evaluating satraplatin for the treatment of hormone-refractory prostate cancer failed to meet its primary efficacy endpoint. While the disappointment with satraplatin represents the elimination of one future source of non-dilutive funding for our drug development plans, it should be noted that a marketing authorization application for the treatment of hormone-refractory prostate cancer is still under review in Europe. Also, GPC has stated that it has revised its development plans for satraplatin and has decided to continue certain clinical trials, stop other studies and selectively initiate new trials.

We entered into a worldwide license agreement for ortataxel, a third-generation taxane that has demonstrated oral bioavailability and clinical activity against taxane-refractory tumors. We acquired these rights from Indena S.p.A., the Italian company that discovered ortataxel. Ortataxel belongs to a new generation of taxanes with the potential to be active against tumors resistant to Bristol-Myers Squibb's Taxot® (paclitaxel) and Sanofi-aventis' Taxoter® (docetaxel). While we are optimizing the oral formulation for better bioavailability, we may consider some studies with the parenteral formulation.

We recently initiated an open label, dose-escalation Phase 1 study assessing the safety, tolerability, pharmacokinetics and pharmacodynamics of SPI-1620 in patients with recurrent or progressive carcinoma.

In May 2007, we completed the sale of 5,134,100 shares of our common stock at a price of \$6.25 per share without issuing any warrants. The net proceeds to us from the offering, after placement agent fees and estimated expenses, were approximately \$30 million, providing us with additional capital resources to advance the development of our drug products.

## **Product Portfolio**

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 that requires several phases of clinical trials to demonstrate to the satisfaction of the appropriate regulatory authorities that the products are both safe and effective for their respective indications.

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

While other indications have not yet been identified, some of our drug products may prove to be beneficial in additional disease indications as we continue to study and develop these drug products. 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 products have the potential to be effective therapeutic agents with some advantages over existing therapies. Our goal is to develop and commercialize many of these drug products in the United States and license the rights for outside the United States to global partners (to the extent that we have rights outside the United States).

**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 were expected to be diagnosed in 2008 and over 565,000 persons were expected to die from the disease in 2008. Accordingly, there is significant demand for improved and novel cancer treatments.

Cancer develops when cells in a part of the body begin to grow out of control. Although there are many kinds of cancer, they all start because of out-of-control growth of abnormal cells. Normal body cells grow, divide, and die in an orderly fashion. During the early years of a person's life, normal cells divide more rapidly until the person

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becomes an adult. After that, cells in most parts of the body divide only to replace worn-out or dying cells and to repair injuries. Because cancer cells continue to grow and divide, they are different from normal cells. Instead of dying, they outlive normal cells and continue to form new abnormal cells.

Cancer cells develop because of damage to DNA. Most of the time, when DNA becomes damaged, the body is able to repair it. In cancer cells, the damaged DNA is not repaired. People can inherit damaged DNA, which accounts for inherited cancers. More often, however, a person's DNA becomes damaged by exposure to something in the environment, like smoking.

Cancer usually forms as a tumor. Some cancers, like leukemia, do not form tumors. Instead, these cancer cells involve the blood and blood-forming organs and circulate through other tissues where they grow. Often, cancer cells travel to other parts of the body where they begin to grow and replace normal tissue. This process is called metastasis. Regardless of where a cancer may spread, however, it is always named for the place it began. For instance, breast cancer that spreads to the liver is still called breast cancer, not liver cancer.

Different types of cancer can behave very differently. For example, lung cancer and breast cancer are very different diseases. They grow at different rates and respond to different treatments. That is why people with cancer need treatment that is aimed at their particular kind of cancer. 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 are seeking novel drugs, drug delivery methods and combination therapies that address cancer or cancer related indications with significant unmet medical need, 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 success and commercial potential.

## ***Benign Prostatic Hypertrophy***

The prostate is a walnut-sized gland that forms part of the male reproductive system. The prostate is located in front of the rectum and just below the bladder, where urine is stored. The prostate also surrounds the urethra, the canal through which urine passes out of the body. 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. According to the National Kidney and Urologic Diseases Information Clearinghouse, BPH rarely causes symptoms before age 40, but more than half of men in their sixties and as many as 90 percent in their seventies and eighties have some symptoms of BPH. As life expectancy rises, so does the occurrence of BPH. Treatment options for benign prostatic hypertrophy include surgery and medications to reduce the amount of tissue and increase the flow of urine.

## **Our drug products**

*Levoleucovorin for Injection (formerly, ISO-Vorin<sup>tm</sup>)*: On March 7, 2008, our NDA for our proprietary drug LEVOleucovorin was approved by the FDA. LEVOleucovorin is a novel folate analog formulation and the pharmacologically active isomer (the *levo*-isomer) of the racemic compound, calcium leucovorin. Isomers are compounds with the same molecular formula, but mirror image atomic structures. Leucovorin is a mixture of equal

parts of both isomers: the pharmacologically active *levo*-isomer and the inactive *dextro*-isomer. Preclinical studies have demonstrated that the inactive *dextro*-isomer competes with the active *levo*-isomer for uptake at the cellular level. By removing the inactive *dextro* form, the dosage of LEVOleucovorin is one-half that of leucovorin and patients are spared the administration of an inactive substance.

LEVOleucovorin is indicated after high-dose methotrexate therapy in patients with osteosarcoma, and to diminish the toxicity and counteract the effects of impaired methotrexate elimination or inadvertent overdose of folic acid antagonists. LEVOleucovorin has been designated as an orphan drug for its approved indications.

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Methotrexate is a widely used anti-cancer drug. It is a therapeutic option in the treatment of solid tumors and hematological malignancies, such as Non-Hodgkin's Lymphoma. In addition, methotrexate is also used to treat autoimmune diseases such as rheumatoid arthritis, psoriasis and some rare opportunistic infections.

LEVOleucovorin has been marketed and sold (under different trade names) by Wyeth, Sanofi-aventis, Takeda and others in certain parts of the world, including Europe and Japan.

A tradename for LEVOleucovorin for Injection is currently under review by the FDA.

Our next filing will be an NDA amendment for LEVOleucovorin tablets which is expected by mid-June 2008. Following the tablet submission, we plan to file a supplemental NDA of LEVOleucovorin in combination with 5-FU-containing regimens in the treatment of colorectal cancer.

Calcium leucovorin is currently a standard combination agent with 5-FU in various colorectal cancer treatment regimens. There are peer-reviewed publications wherein LEVOleucovorin is used in place of the leucovorin in combination with 5-FU containing regimens for adjuvant and advanced colorectal cancer and in combination with oxaliplatin and/or irinotecan for advanced disease. LEVOleucovorin is currently listed as a replacement for calcium leucovorin in the National Comprehensive Cancer Network Clinical Practice Guidelines in oncology. The NCCN Drugs and Biologics Compendium is an important reference that has been recognized by United HealthCare as a formal guidance for coverage policy.

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

In April 2006, we acquired all of the oncology drug product assets of Targent, Inc. Pursuant to the terms of the acquisition, we have to date issued to Targent, or its stockholders, an aggregate amount of 725,000 shares of our common stock with an aggregate fair market value of \$3,262,000. Also, due to the recent FDA approval of the NDA, we are obligated to issue to Targent, or its stockholders, an aggregate amount of 125,000 shares of our common stock with a fair market value of \$305,000 as of the date the milestone was achieved. In addition, Targent is eligible to receive additional payments, in the form of our common stock and/or cash, upon achievement of certain additional regulatory and sales milestones. 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. Pursuant to the license agreement, we obtained the exclusive license to use regulatory filings related to LEVOleucovorin and a non-exclusive license under certain patents and know-how related to LEVOleucovorin to develop, make, have made, use, sell and have sold LEVOleucovorin 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 LEVOleucovorin products outside the field of oncology in North America. Under the terms of the license agreement, we will pay Eprova \$100,000 for the achievement of FDA approval of LEVOleucovorin for injection. Eprova is also eligible to receive a payment upon achievement of another regulatory milestone, 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. The license agreement expires in its entirety after the date that we no longer owe any royalties to Eprova. We have the unilateral right to terminate the license agreement, in its entirety or on a product-by-product or country-by-country basis, at any time for any reason and either party may terminate the license agreement due to material breach of the terms of the license agreement by or insolvency of the other party.

In May 2006, we also entered into a manufacturing and supply with Eprova, whereby Eprova shall manufacture the active pharmaceutical ingredient of LEVOleucovorin for us at a set price. 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. Either party may terminate the manufacturing agreement in the event of a material breach by the other party.

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**Sumatriptan injection:** During the fourth quarter of 2008 we will launch sumatriptan injection, the generic form of GlaxoSmithKline's, or GSK, Imitrex® injection, which is currently selling on the market and is indicated for the acute treatment of migraine attacks with or without aura and the acute treatment of cluster headache episodes. We plan to market the product through Par Pharmaceutical Companies, Inc., or Par, our partner for the sale and distribution of the drug. Pursuant to the terms of our agreement with Par, we will receive a majority of the profits from the sale of sumatriptan injection.

In October 2004, we filed an abbreviated new drug application, or ANDA, with paragraph IV certification, with the FDA, for sumatriptan injection. In February 2005, GSK commenced suit against us, alleging that the filing of our ANDA infringes their patent covering Imitrex. In December 2006, the litigation was 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 settlement agreement provide that we may distribute authorized generic versions of sumatriptan injection products in the United States with a launch in the fourth quarter of 2008 during GSK's sumatriptan pediatric exclusivity period. Concurrent with the execution of the settlement agreement, GSK entered into a supply and distribution agreement with Par for certain of the sumatriptan injection products. Pursuant to the terms of such agreement, GSK shall supply Par with the sumatriptan injection products at a price set forth in such agreement. The agreement may be terminated by: (a) either party based upon material breach of the terms of the agreement by the other party or insolvency of the other party, (b) mutual consent by GSK, Par and us, or (c) Par if GSK presents Par with an increase in pricing for the products because the amount of the price paid by Par to GSK for the products reaches a level that is at or below GSK's cost of goods.

In February 2006, we entered into a development and marketing agreement with Par, whereby we granted Par the exclusive right to market our sumatriptan injection product in the United States. We own the ANDA for sumatriptan injection and are responsible for maintaining the appropriate regulatory approvals. At the time we entered in the agreement, Par assumed all the expenses going forward of the litigation between us and GSK regarding sumatriptan injection. In November 2006, we amended the agreement, and pursuant to the amended terms, Par paid us a \$5 million milestone payment related to sumatriptan injection. As mentioned above, pursuant to the terms of the agreement, we will receive a majority of the profits from the sale of sumatriptan injection. The term of the agreement expires ten years after the commercial launch of sumatriptan injection. In addition, the agreement may be terminated by: (a) either party based upon material breach of the terms of the agreement by the other party, (b) mutual consent by both parties, or (c) Par if Par decides to market a competing product, as that term is defined in the agreement.

**EOquin:** EOquin is an anti-cancer agent that becomes activated by certain enzymes often 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 is only in the innermost layer of the bladder and has not spread to deeper layers of the bladder. 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 the 2008 incidence and prevalence of bladder cancer in the United States will be approximately 68,810 and over 500,000, respectively. Based on Globocan data, we estimate that the 2008 incidence and prevalence of bladder cancer in Europe is approximately 149,000 and 944,000, respectively. According to Botteman et al., (PharmacoEconomics 2003), bladder cancer is the most expensive cancer to treat on a lifetime basis.

The initial treatment of this cancer is complete surgical removal of the tumor. However, bladder cancer is a highly recurrent disease with approximately 75% of patients recurring within 5 years, and a majority of patients recurring within 2 years. This high recurrence rate is attributed to: 1) the highly implantable nature of cancer cells that are

dispersed during surgery, 2) incomplete tumor resection, and 3) tumors present in multiple locations in the bladder which may be missed or too small to visualize at the time of resection. Despite evidence in the published literature and guidance from the American and European Urology Associations, instillation of a chemotherapeutic agent immediately following surgery is not a standard clinical practice. Currently, there are no approved drugs for this indication which may, in part, explain the difference between the literature and urology guidelines and actual clinical management of this disease. For more than 30 years no new drugs have been introduced in the market for



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treatment of non-invasive bladder cancer. An immediate instillation of EOquin may help by 1) reducing tumor recurrence by destroying dispersed cancer cells that would otherwise re-implant onto the inner lining of the bladder, 2) by destroying remaining cancer cells at the site of tumor resection (also known as chemo-resection), and 3) by destroying tumors not observed during resection.

EOquin is a bio-reductive prodrug that is activated by enzymes that are over expressed by bladder tumors. A pharmacokinetic study verified that EOquin is not absorbed through the bladder wall into the bloodstream at the current proposed dose when given immediately after surgical resection and thus carries a minimal risk of systemic toxicity. Additionally, the current proposed dose is a fraction of the systemic toxic dose. These features of EOquin are distinct from the other intravesical agents in use for the treatment of recurrent bladder cancer.

A Phase 1 dose-escalation marker lesion study demonstrated that EOquin had no systemic toxicity, and was well tolerated at the dose level being used in the Phase 3 trials. EOquin also demonstrated anti-tumor activity against non-invasive bladder cancer, as evidenced by eight of twelve patients showing a complete response, defined as the complete disappearance of the tumor as confirmed by biopsy, after receiving six treatments with EOquin over a period of six weeks.

Phase 2 data has confirmed anti-tumor activity in patients with multiple, recurrent non-invasive bladder cancer, as evidenced by thirty-one of forty-six patients (67%) showing a complete response after receiving six weekly treatments with 4 mg of EOquin instilled into the urinary bladder in this marker lesion study. EOquin was 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 an open label, multi-center clinical study in Europe in high-risk bladder cancer in 53 patients. Patients with high-risk bladder cancer usually have more aggressive bladder cancer with higher incidence of recurrence and/or progression to a more invasive stage, where the cancer invades the muscle wall of the bladder, which may require total surgical removal of the bladder. Enrollment is almost complete. We plan to follow all patients for twenty-four months or until recurrence or progressive disease is observed.

In 2006, we performed a 20 patient pilot safety study in low-grade non-invasive bladder cancer. In this study, EOquin was found to be well tolerated when a single 4 mg dose is given to patients immediately following surgery. In addition, there was no adverse effect on wound healing and EOquin was not absorbed into the bloodstream from the bladder wall.

In March 2007, we received concurrence from the FDA for the design of a Phase 3 study protocol for the treatment of non-invasive bladder cancer under a special protocol assessment procedure. The development plan for EOquin calls for two randomized, double-blind, placebo-controlled Phase 3 clinical trials, each with 562 patients with T<sub>a</sub>G1-G2 (low grade) non-invasive bladder cancer. Patients will be randomized in a one-to-one ratio to EOquin or placebo. The patients will be given a single 4 mg dose following surgical removal of the tumors. 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. The first study began during the second quarter of 2007, and the second study began during the third quarter of 2007. We recently received scientific advice from the EMEA whereby the EMEA agreed that the two Phase 3 studies as designed should be sufficient for a regulatory decision regarding European registration. We continue to enroll patients in these two studies and plan to add study sites in Canada to accelerate enrollment since we recently received authorization from the Canadian Health Authorities allowing us to initiate one of the trials in Canada.

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 INC Research<sup>®</sup>, formerly NDDO Research Foundation, in the Netherlands, in exchange for an up-front fee of \$100,000, additional payments based upon achievement of certain milestones and a royalty based on net sales, 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

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termination. In addition, the agreement may be terminated earlier by us upon three months notice to INC Research®.

*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 investigated for its targeted indications in hormone dependent prostate cancer, or 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.

Testosterone is considered to play a role in BPH. Unlike LHRH agonists, ozarelix, which is an antagonist of LHRH, has the potential to reduce testosterone thus to decrease the prostate size and improve symptoms without the severe side effects associated with complete reduction in testosterone to castration levels.

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 currently approved 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 need to be dosed daily and 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 144 patients with BPH in a double-blinded, randomized, placebo-controlled, multi-center, dose-ranging study were positive. Statistically significant 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 also found to be safe and well-tolerated in the study. Based on the results of this dose finding study, ozarelix 15 mg, given on day 1 and day 15, was chosen to be developed for this indication.

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, double-blinded, placebo-controlled trial of ozarelix involving approximately 76 men suffering from BPH. In this trial, the men have been dosed by intramuscular injection with 15 mg of ozarelix or placebo on day 1 and day 15 and are being followed for nine months. The study is evaluating safety and assessing the clinical efficacy of ozarelix as a treatment for BPH. The primary endpoint of the study is the improvement of BPH symptoms as measured by the International Prostate Symptom Score, which is designed to assess the severity of BPH. The study is also measuring urine flow, residual urine volume and quality of life. We completed patient enrollment and expect that complete data will be available by mid-April. While we wait for the data, we are concurrently working on the design of the protocol for the next study, which is expected to initiate soon thereafter.

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. 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. We are currently working with our licensor for the drug, Aeterna Zentaris, to develop a longer-acting, commercially feasible depo formulation.

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 painful condition typically affects women during their menstruating years

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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. We believe intermittent administration of ozarelix can be used to treat endometriosis both through transient estrogen suppression and a direct effect on the LHRH receptors present in the endometrial tissue. We are considering a Phase 1 study to study ozarelix as a treatment for endometriosis.

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 Inc., Aeterna Zentaris GmbH, 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. In 2004, we paid an up-front fee of approximately \$1.2 million and issued 251,896 shares of our common stock valued at \$634,000 and in 2006, we paid a development milestone payment of approximately \$1.3 million. We are also contingently obligated to pay additional amounts based upon achievement of milestones and a royalty based on any future net sales. 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 up-front 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 up-front and milestone payments and royalties received from Nippon Kayaku Co. Ltd. by Aeterna Zentaris. In this regard, we received a payment of \$891,000 in 2007. In the event Aeterna 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. Similarly, Aeterna Zentaris is entitled to receive and utilize the results of our development efforts in North America and India. 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. 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 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 days notice to Aeterna Zentaris.

Ortataxel: In July 2007, we entered into an exclusive worldwide license agreement for ortataxel, a third-generation taxane. We acquired these rights from Indena S.p.A., a natural products company. Ortataxel has been shown to be bioavailable when administered orally to patients with solid tumors. In addition, it belongs to a new generation of taxanes with the potential to be active against tumors resistant to paclitaxel (Bristol-Myers Squibb's Taxol®) and docetaxel (Sanofi-Aventis' Taxoterm®). Phase 1 and 2 studies in more than 350 patients with solid tumors have shown responses in patients that were refractory to treatment with the available taxane drugs. The safety profile of ortataxel is comparable to that of paclitaxel and docetaxel.

While we are optimizing the oral formulation for better bioavailability, we are considering some studies with the parenteral formulation.

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

Under the terms of the license agreement with Indena, we gained exclusive worldwide development and commercialization rights to ortataxel. We made an up-front payment to Indena of approximately \$2.8 million,

and will also make additional payments based on the achievement of certain development, regulatory filing and sales milestones. We will also pay Indena single-digit royalties on worldwide sales of ortataxel, if and when the product is approved. The license agreement expires on a product-by-product and country-by-country basis upon the expiration of our obligation to pay royalties applicable to such product in such country. The license agreement shall expire in its entirety after the date on which we no longer owe any royalties to Indena. In addition, the license agreement may be terminated earlier unilaterally by us at any

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time and for any reason, and by either party upon material breach of the terms of the license agreement by or insolvency of the other party. Also, we shall purchase all of our requirements of ortataxel active pharmaceutical ingredient from Indena pursuant to terms to be agreed to in a separate agreement.

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 beneficial.

SPI-1620 is being developed as an adjunct to chemotherapy. In pre-clinical studies, when anti-cancer drugs, such as paclitaxel, are administered shortly after SPI-1620, the anti-cancer drug concentration in the tumor is increased several fold. This results in increased anti-tumor 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 recently initiated an open label, dose-escalation Phase 1 study assessing the safety, tolerability, pharmacokinetics and pharmacodynamics of SPI-1620 in patients with recurrent or progressive carcinoma.

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 up-front 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, after marketing approval is obtained from the FDA and other regulatory authorities. The term of the license agreement shall endure on a product-by-product and country-by-country basis until the expiration of the obligation by us to pay royalties applicable to such product in such country. The license agreement shall expire in its entirety after the date that we no longer owe any royalties to Chicago Labs. Chicago Labs may terminate the license 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. We have the unilateral right to terminate the license agreement, in its entirety or on a product-by-product or country-by-country basis, at any time for any reason. In addition, either party may terminate the license agreement if the other party materially breaches the agreement or becomes insolvent.

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.

On the basis of previous studies conducted by our licensor, Bristol-Myers Squibb, or BMS, elsamitrucin has been shown to have minimal toxicity to bone marrow while demonstrating promising anti-tumor activity.

We conducted a Phase 2, single agent study in heavily pre-treated patients with non-Hodgkins lymphoma. The level of activity seen did not justify further development for this indication as a single agent. However, since elsamitrucin appears to have synergy with taxane and platinum derivatives in experimental models, a Phase I dose-escalation study of elsamitrucin in combination with paclitaxel in patients with advanced solid tumors is being planned. Minimal toxicity to bone marrow may allow combinations with other drugs without a need to significantly



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reduce doses, which may result in improved therapeutic effects. After the phase 1 study is completed we will consider initiating phase 2 studies with this combination in selected solid tumors.

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

We in-licensed exclusive worldwide rights to elsamitrucin from its developer, BMS, in 2001, in exchange for an up-front fee of \$100,000, additional payments based upon achievement of development and regulatory milestones and a royalty based on net sales, if and when a commercial drug is approved and sales are initiated. The term of the agreement shall terminate as to each product in each country upon the expiration of the royalty term (the period of time commencing on the effective date of the agreement and ending on the date that is the latest of (i) ten years from the date of the first commercial sale of such product in such country, or (ii) the expiration of the last to expire of the valid claims in a patent necessary for the manufacture, use and sale of such product in such country). The agreement shall terminate in its entirety upon its termination in all countries. We have the right to terminate the agreement in its entirety at any time by giving written notice to BMS. Either party may terminate the agreement upon material breach of the terms of the agreement by the other party. The agreement shall terminate automatically in the event that we fail to maintain all insurance coverage that we are required to maintain under the agreement.

**Lucanthone:** Lucanthone is an orally administered small-molecule which inhibits Topoisomerase II and AP endonuclease. In preclinical tests, lucanthone was shown to enhance the sensitivity of animals to an anticancer agent in a time dependent and reversible manner.

Lucanthone 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 anti-parasitic medications became available. A Phase I Dose-Escalation Study of Lucanthone in Patients With Recurrent Malignant Gliomas Receiving Temozolomide is being planned.

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

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 license agreement, we made an up-front payment of \$20,000 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. The term of the license agreement shall endure on a product-by-product and country-by-country basis until the expiration of the obligation by us to pay royalties applicable to such product in such country. The license agreement shall expire in its entirety after the date that we no longer owe any royalties to Dr. Bases. We have the unilateral right to terminate the license agreement, in its entirety or on a product-by-product or country-by-country basis, at any time for any reason. In addition, either party may terminate the license agreement if the other party materially breaches the license agreement or becomes insolvent.

**RenaZorb:** RenaZorb, a second-generation lanthanum-based nanoparticle phosphate binding agent, has the potential to address hyperphosphatemia, (high phosphate levels in blood), in patients with stage 5 chronic kidney disease (end-stage renal disease). Hyperphosphatemia 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 National Kidney Foundation, in 2008 there will be an estimated 600,000 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, therefore phosphate binders are the mainstay of hyperphosphatemia management.

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Currently marketed therapies for treating hyperphosphatemia include polymer-based and lanthanum-based phosphate binders, aluminum-based phosphate binders, and calcium-based phosphate binders. Under the 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 regimen.

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 to achieve the same therapeutic benefit as other phosphate binders. We continue to perform preclinical development work on RenaZorb.

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

On January 28, 2005, we entered into a license agreement with Altair Nanomaterials, Inc. and its parent Altair Nanotechnologies, Inc., or Altair, whereby we acquired an exclusive worldwide right to develop and commercialize RenaZorb for all human therapeutic and diagnostic uses. Under the terms of the license agreement, we issued to Altair 100,000 shares of our common stock valued at \$594,000 as an upfront payment and made an equity investment of \$200,000 in 38,314 shares of Altair's common stock. In 2006, we also issued Altair 140,000 shares of our common stock valued at \$574,000 in connection with this payment of a milestone and for transfer of technology related to formulation improvements to RenaZorb developed by Altair. In addition, Altair is eligible to receive payments upon achievement of a clinical development and certain regulatory and sales milestones, in addition to royalties on potential net sales. The term of the license agreement shall expire on a product-by-product and country-by-country basis upon the later to occur of (a) expiration or final rejection without right of appeal of the last-to-expire patent that covers such product in such country; or (b) the entry of generic competition in such country. We have the unilateral right to terminate the license agreement, in its entirety or on a product-by-product or country-by-country basis, at any time for any reason. In addition, either party may terminate the license agreement if the other party materially breaches the license agreement or becomes insolvent.

**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 2008, we plan to continue preclinical evaluation of SPI-205.

**Satraplatin:** Satraplatin, an orally administered platinum-derived chemotherapy agent, is being developed by our sublicensee, GPC Biotech AG. On October 30, 2007, GPC announced that the Phase 3 trial evaluating satraplatin for the treatment of hormone-refractory prostate cancer failed to meet its primary efficacy endpoint and, as a result, GPC did not refile the NDA with the FDA seeking approval for satraplatin. However, a marketing authorization application for the same indication is still under review in Europe. GPC has stated that it has revised its development plans for satraplatin and has decided to continue certain trials, stop other studies and selectively initiate new trials.

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 up-front fee, additional payments to be made based upon achievement of

certain milestones and royalties based on any net sales, if and when a commercial drug is approved and sales are initiated. The term of the license 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 license 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 terms of the license agreement

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by or commencement of bankruptcy or insolvency proceedings involving the other party. We paid to Johnson Matthey \$1,000,000 upon achievement by GPC of certain regulatory milestones in 2007. Each of our contingent future cash payment milestone obligations to Johnson Matthey is generally matched by a corresponding, greater milestone receivable from GPC (see below).

In 2002, in exchange for an up-front license fee and future milestones and royalties, we entered into a Co-Development and License Agreement with GPC for worldwide rights for further development and commercialization of satraplatin. Under the terms of this agreement, GPC agreed to fully fund the development expenses for satraplatin. In December 2005, GPC licensed commercialization rights for Europe, Turkey, the Middle East, Australia and New Zealand to Pharmion Corporation. To date, we have received \$10,200,000 in up-front and milestone payments and approximately \$550,000 in commissions on the sale of satraplatin product to GPC. In addition, during 2003, pursuant to the license agreement, GPC made an equity investment of \$1,000,000 to purchase 128,370 shares of our common stock at \$7.79 per share. We are entitled to additional revenues upon: achievement of specified milestones by GPC and Pharmion, which are generally based on regulatory and sales milestones; and royalties on worldwide sales, if any, of the product. The term of the license 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 of the terms of the license agreement by or the commencement of bankruptcy or insolvency proceedings involving the other party, or by GPC upon six months' notice to us.

*Generic drugs:* We hold the rights to certain ANDAs that we filed with the FDA for several tablet and injectable generic products. We are currently working on selling these assets.

## **Business Alliances**

Strategic business alliances are an important part of the execution of our business strategy. We currently do not have 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 products 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. Please see Item 1A Risk Factors for a discussion of risks associated with our reliance on business alliances to enhance our capabilities.

## **Sales, Marketing and Distribution**

With the exception of the distribution of sumatriptan injection, expected to be launched by Par on our behalf in 2008, we do not currently have any exclusive distribution arrangements.

We are in the process of building a sales and marketing infrastructure to prepare for the launch of LEVOleucovorin, which was approved by the FDA on March 7, 2008. However, we are also exploring strategic opportunities with third parties to assist us in the sales, marketing and distribution of LEVOleucovorin.

## **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

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developing our own treatments. In the event that one or more of those programs are successful, the market for some of our drug products 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 cost-effectiveness as compared to 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, Neurocrine Biosciences, Abraxis Bioscience, Inc., 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, Millennium Pharmaceuticals, Shire Pharmaceuticals, TAP Pharmaceuticals, Inc., QLT Inc., Abbott Laboratories, Poniard Pharmaceuticals, Inc., Roche Pharmaceuticals, Schering-Plough, Johnson & Johnson and others who may be more advanced in development of competing drug products or are more established and are currently marketing products for the treatment of various indications that our drug products 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.

As noted above, we plan to launch our proprietary product, LEVOleucovorin, in mid-2008, LEVOleucovorin is the levo isomeric form of the racemic compound calcium leucovorin, a product already approved for the same indications our product is approved for. 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. 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 LEVOleucovorin in a cost-effective manner or at a cost below the generic leucovorin cost price. Also, LEVOleucovorin will be offered as part of a treatment regimen, and that regimen may change to exclude LEVOleucovorin.

### ***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 approval and launch, in relation to competing approvals and launches.

Companies that have a significant generic presence include Par Pharmaceutical Companies, Inc. Abraxis Biosciences, Inc., Bedford Laboratories, Mayne, Barr Laboratories, Teva Pharmaceuticals, Dr. Reddy's



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Laboratories, Ranbaxy Laboratories, Mylan Laboratories, Inc., Sandoz (a division of Novartis), and Watson Pharmaceuticals, Inc.

As noted above, we have the right to market authorized generic versions of sumatriptan injection products in the United States. We expect to launch our products in the fourth quarter of 2008 prior to the expiration of the pediatric exclusivity period associated with sumatriptan injection.

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 \$33.3 million in 2007, \$23.8 million in 2006, and \$13.5 million in 2005 as follows:

	<b>Years Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(Amounts in thousands)</b>		
LEVOleucovorin	\$ 1,368	\$ 4,428	\$
EOquin	6,348	2,617	1,422
Ozarelix	6,217	2,881	2,883
Ortataxel	3,719		
Other drugs	3,452	4,457	4,667
Total Direct Costs	21,104	14,383	8,972
Indirect Costs	12,181	9,345	4,511
Total Research & Development	\$ 33,285	\$ 23,728	\$ 13,483

**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 LEVOleucovorin, EOquin, ozarelix, ortataxel, satraplatin, elsamitrucin, lucanthone, RenaZorb and SPI-1620, in each case for the remaining life of the applicable patents. Except for ozarelix and LEVOleucovorin, our agreements generally provide us with exclusive worldwide rights to, among other things, develop, sublicense, and commercialize the drug products. Under these license arrangements, we are generally responsible for all development, patent filing and maintenance costs, sales, marketing and liability insurance costs related to the drug products. 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 allowed or, even if allowed and issued as patents, if such 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.

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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. For LEVOleucovorin, we have one United States formulation patent that covers LEVOleucovorin that expires in 2019. For EOquin, there is a composition patent that has already expired in 2007 in various countries in Europe and that will expire in 2009 in the United States. We have filed and plan to file additional United States and foreign patent applications covering new formulations and/or uses for this product. For ozarelix, there is a United States composition patent that will expire in 2020, and method of use and formulation patent applications on file in the United States. For ortataxel, there are two United States composition patents that will expire in 2013, and the corresponding European patents will expire in 2014. We anticipate filing new method of use and formulation patent applications for the ortataxel product in the future. There are two United States patents covering satraplatin, a composition patent that expires in 2008 and a method of use patent that expires in 2010, and foreign composition patents in Europe that will expire in various countries between 2008 and 2009. For elsamitucin, we have filed United States and foreign formulation and method of use patent applications, and we anticipate filing future United States and foreign patent applications covering new formulations and/or uses for this product. For lucanthone, there is a United States method of use patent that expires in 2019, and we anticipate filing future United States and foreign patent applications covering new formulations and/or uses for this product. For RenaZorb, there are pending United States and foreign patent applications covering compositions of matter directed to treating hyperphosphatemia. 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 composition and method of use patent that expires in 2010. This patent expires in certain European countries in 2011. We also have a United States method of use patent that expires in 2021 and there is ongoing prosecution for its European counterparts. We have also filed another method of use patent application in the United States and Europe and anticipate filing future patent applications pending the continued development of new methods of use and new formulations. 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 drug products, 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.

In addition to the specific intellectual property subjects discussed above, we have trademark protection in the United States for EOquin and RenaZorb. We will likely register trademarks for the branded names of our proprietary drug products if any are approved for marketing. Spectrum Pharmaceuticals, Inc.<sup>tm</sup> and ISO-Vorin<sup>tm</sup> are trademarks owned by Spectrum Pharmaceuticals, Inc., and EOquin<sup>®</sup> is registered trademark of Spectrum Pharmaceuticals, Inc. RenaZorb<sup>®</sup> is a registered trademark of Altair Nanomaterials, Inc., and licensed to Spectrum Pharmaceuticals, Inc. All

other trademarks, tradenames and service marks are the property of their respective owners.

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

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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 drug products.

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., 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 injection, sumatriptan 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.

In exchange for disclosing the invention to the public, the successful patent applicant is currently 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. 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 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.

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### ***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.

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.

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 LEVOleucorvin 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 palliative treatment of metastatic adenocarcinoma of the colon and rectum (colorectal cancer). Final approval of orphan drug status is granted after approval of the product in the applicable indication.



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### **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 current 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 products that are already in or about to enter human clinical trials. A late-stage focus helps us to effectively manage the high cost of drug development by focusing on compounds that have already passed the many hurdles in the pre-clinical and early clinical process.

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 is accepted by the FDA, 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 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.

*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 or NDA:* 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.

*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.

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*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 regarding the 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 NDA or the ANDA, 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 products 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. If fraud or discrepancies are discovered, the FDA may significantly delay or suspend substantive scientific review of a pending application during validity assessment or remove approved products from the market until the assessment is complete and questions regarding reliability of the data are resolved. To approve an application, the FDA generally must determine that the applicant is capable of producing a safe and, for some types of applications, an effective or functional product based on, among other things, testing and other data provided by the applicant and the adequacy of the applicant's manufacturing processes and controls. The principal basis for this determination is the data in the application; therefore, the reliability of data is of critical importance. If the agency determines that the criteria for approval cannot be met because of unresolved questions regarding reliability of data, the agency will not approve the application. If an application is denied, a new application will be accepted after completion of corrective action and sanction against individuals involved in the fraudulent activity.

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.

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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 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.

### ***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, 2007, we had 61 employees, of which 6 held a M.D. degree and 9 held a Ph.D. degree. We cannot be sure 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.

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### **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 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, 2007 were in excess of \$240 million. We lost approximately \$34 million in 2007, \$23 million in 2006 and \$19 million in 2005. We expect to continue to incur significant additional losses as we implement our growth strategy of developing our drug products for at least the next several years unless they are offset, if at all, from the out-license of any of our other proprietary products and any profits from the sale of LEVOleucovorin and sumatriptan injection. 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 all our drug products, to establish a sales force and commercialization capabilities and to capitalize on growth opportunities. We have historically relied primarily on raising capital through the sale of our securities and out-licensing our drug products to meet our financial needs. While we anticipate revenues in 2008 from the sale of ISO-Vorin and sumatriptan injection, 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 drug product development and acquisition.

We may not be able to raise additional capital on favorable terms, if at all, particularly with the current volatile market conditions. 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 materially impact our ability to expand operations.

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

Prior to receiving approval to commercialize any of our drug products, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA and other regulatory authorities in



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the United States and other countries, that each of the products is both safe and effective. For each drug product, 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 drug products are prone to the risks of failure inherent in drug development. Clinical trials of new drug products sufficient to obtain regulatory marketing approval are expensive and take years to complete. We cannot be certain of successfully completing clinical testing within the time frame we have planned, or at all. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent us from receiving regulatory approval or commercializing our drug products. In addition, the results of pre-clinical studies and early-stage clinical trials of our drug products do not necessarily predict the results of later-stage clinical trials. Later-stage clinical trials may fail to demonstrate that a drug product is safe and effective despite having progressed through initial clinical testing. Even if we believe the data collected from clinical trials of our drug products is 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. As an example, despite promising Phase 2 and 3 data, on October 30, 2007, GPC announced that the Phase 3 trial evaluating satraplatin for the treatment of hormone-refractory prostate cancer failed to meet its primary efficacy endpoint.

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 products. Any failure or significant delay in completing clinical trials for our drug products, or in receiving regulatory approval for the sale of any drugs resulting from our drug products, may severely harm our business and reputation. Even if we receive FDA and other regulatory approvals, our drug products 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 drug products from the market.

### ***If we are unable to establish sales and marketing capabilities, we may be unable to successfully commercialize LEVOleucovorin.***

We are building our own sales force to market LEVOleucovorin in the United States. We currently have little internal experience in selling, marketing or distributing pharmaceutical products and are just now building a sales force of our own to do so. Before we can commercialize LEVOleucovorin, we must further develop our sales, marketing and distribution capabilities, which is an expensive and time consuming process and our failure to do this successfully, could delay the product launch. Our efforts to develop internal sales and marketing capabilities could face a number of risks, including;

we may not be able to attract a sufficient number of qualified sales and marketing personnel;

the cost of establishing a marketing or sales force may not be justifiable in light of the potential revenues for LEVOleucovorin; and

our internal sales and marketing efforts may not be effective in generating sales of LEVOleucovorin.

### ***We may need a third party to assist us with the marketing of LEVOleucovorin. If required, and we are not able to secure a favorable arrangement with a third party, our business and financial condition could be harmed, including the successful commercialization of LEVOleucovorin.***

Due to the cost and resources necessary to launch a product, we may need to secure a favorable arrangement with a third party to help us promote and market LEVOleucovorin. If we need to, and are not able to secure favorable

commercial terms with a third party for the marketing and promotion of LEVOleucovorin, we will have to incur all the expenses necessary to successfully launch and market the product ourselves. If we are not able to secure a favorable partnering arrangement, or are unable to provide the necessary resources for the successful commercialization of LEVOleucovorin, our business and financial condition could be harmed.

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In addition, dependence on a collaborative arrangement will subject us to a number of risks, including:

we may not be able to control the amount or timing of resources that our collaborator may devote to LEVOleucovorin;

we may be required to relinquish important rights, including intellectual property, marketing and distribution rights;

we may have lower revenues than if we were to market and distribute LEVOleucovorin ourselves;

should a collaborator fail to commercialize LEVOleucovorin successfully, we may not receive future milestone payments or royalties;

our collaborator may experience financial difficulties;

business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement; and

our collaborator may operate in countries where its operations could be adversely affected by changes in the local regulatory environment or by political unrest.

***We are dependent on a third party to market, sell and distribute our generic product sumatriptan injection and they may not be successful in doing so.***

We have a development and marketing agreement with Par Pharmaceutical Companies, Inc., or Par, whereby Par has agreed to market, sell and distribute our sumatriptan injection 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 sumatriptan injection products, and, therefore, the success of our sumatriptan injection 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.

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

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

***The development of our drug product, 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 for the worldwide development and commercialization of our drug product, satraplatin. GPC 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 this product depends upon the efforts of GPC and its sublicensee, Pharmion Corporation. GPC and Pharmion may not be successful in the clinical development of the drug, obtaining approval of the product by regulatory authorities, or the eventual commercialization of satraplatin. On October 30, 2007, GPC announced that the Phase 3 trial evaluating satraplatin for the treatment of hormone-refractory prostate cancer failed to meet its primary

endpoint. It should be noted that a marketing authorization application for the treatment of hormone-refractory prostate cancer is still under review in Europe.

***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

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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 drug products. 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, 2008, with automatic one-year renewals thereafter unless we, or Dr. Shrotriya, give notice of intent not to renew at least 90 days in advance of the renewal date. Dr. Lenaz has an employment agreement with us that will expire on July 1, 2008, 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 sales, 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.

***As we evolve from a company primarily involved in development to a company also involved in commercialization, we may encounter difficulties in managing our growth and expanding our operations successfully.***

As we advance our drug products through clinical trials, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with such third parties, as well as additional collaborators and suppliers. Maintaining these relationships and managing our future growth will impose significant added responsibilities on members of our management. We must be able to: manage our development efforts effectively; manage our clinical trials effectively; hire, train and integrate additional management, development, administrative and sales and marketing personnel; improve our managerial, development, operational and finance systems and expand our facilities, all of which may impose a strain on our administrative and operational infrastructure.

Furthermore, we may acquire additional businesses that complement or augment our existing business. To date, we have no experience in acquiring and integrating other businesses. Integrating any newly acquired business could be expensive and time-consuming. We may not be able to integrate any acquired business successfully or operate any acquired business profitably. Our future financial performance will depend, in part, on our ability to manage any future growth effectively and our ability to integrate any acquired businesses. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

***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.

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

We may rely, in full or in part, on third parties to conduct our clinical trials. In such situations, we have less control over the conduct of our clinical trials, the timing and completion of the trials, the required reporting of adverse events and the management of data developed through the trial than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may have staffing difficulties, may undergo changes in priorities or may become financially distressed, adversely affecting their willingness or ability to conduct our trials. We may

experience unexpected cost increases that are beyond our control. Problems with the timeliness or quality of the work of a contract research organization may lead us to seek to terminate the relationship and use an alternative service provider. However, making this change may be costly and may delay our trials, and

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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 are subject to risks associated with doing business internationally.***

Since we conduct clinical trials and manufacture our drug products internationally, our business is subject to certain risks inherent in international business, many of which are beyond our control. These risks include, among other things:

maintaining compliance with foreign legal requirements, including employment law;

unexpected changes in foreign regulatory requirements, including quality standards and other certification requirements;

tariffs, customs, duties and other trade barriers;

changing economic conditions in countries where our products are manufactured;

exchange rate risks;

product liability, intellectual property and other claims;

political instability;

new export license requirements; and

difficulties in coordinating and managing foreign operations.

Any of these factors could have an adverse effect on our business, financial condition and results of operations. We may not be able to successfully manage these risks or avoid their effects.

***We may have conflicts with our partners that could delay or prevent the development or commercialization of our drug products.***

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 drug product, and in turn prevent us from generating revenues:

unwillingness on the part of a partner to pay us milestone payments or royalties that 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 collaboration.

***Our efforts to acquire or in-license and develop additional drug products may fail, which might limit our ability to grow our business.***

Our long-term strategy includes the acquisition or in-license of additional drug products. We are actively seeking to acquire, or in-license, additional commercial drug products as well as drug products that have demonstrated positive



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pre-clinical and/or clinical data. We have certain criteria that we are looking for in any drug product acquisition and we may not be successful in locating and acquiring, or in-licensing, additional desirable drug products 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 drug products 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 portfolio through the in-license or acquisition of compounds. Moreover, while it is not feasible to predict the actual cost of acquiring additional drug products, that cost could be substantial and we may need to raise additional financing, which may further dilute existing stockholders, in order to acquire new drug products.

***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.

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

Many companies, both public and private, including well-known pharmaceutical companies and smaller niche-focused companies, are developing products to treat many, if not all, of the diseases we are pursuing or are currently distributing 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 the treatment of disease, advanced drug delivery and specific clinical benefits over competitive drug therapies. We may not be successful in any or all of our current clinical studies; or if successful, and if one or more of our drug products 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 products. Companies that have products on the market or in research and development that target the same indications as our products target include Ardana Bioscience, Neurocrine Biosciences, Abraxis Bioscience, Inc., 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, Millennium Pharmaceuticals, Shire Pharmaceuticals, TAP Pharmaceuticals, Inc., QLT Inc., Abbott Laboratories, Poniard Pharmaceuticals, Inc., Roche Pharmaceuticals, Schering-Plough, Johnson & Johnson and others who may be more advanced in the development of competing drug products or are more established. 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.

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***Our supply of drug products will be dependent upon the production capabilities of contract manufacturing organizations, or CMOs, and component and packaging supply sources, and, if such CMOs are not able to meet our demands, we may be limited in our ability to meet demand for our products, ensure regulatory compliance or maximize profit on the sale of our products.***

We have no internal manufacturing capacity for our drug products, and, therefore, we have entered into agreements with CMOs to supply us with active pharmaceutical ingredients and our finished dose 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 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 cGMP requirements, the possible breach of the manufacturing agreement by the CMO 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 drug products, 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. In addition, our CMOs will be subject to on-going periodic inspection by the FDA and corresponding state and foreign agencies for compliance with cGMP regulations, similar foreign regulations and other regulatory standards. We do not have control over our CMOs' compliance with these regulations and standards. 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 them or us, including warning letters, 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 APIs or manufacturing of finished 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 APIs and finished dose 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 develop and market our drug products could be harmed.

***Our drug products may not be more effective, safer or more cost-efficient than a competing drug and otherwise may not have any competitive advantage, which could hinder our ability to successfully commercialize our drug***

*products.*

Any drug 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 products ultimately receives FDA approval, our drug products 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

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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 products, they may not gain acceptance by the medical field or become commercially successful.

In addition, many of our competitor companies have substantially greater financial resources and marketing and sales experience than us. As a result, we may not be able to successfully compete against these companies.

***Our drug product LEVOleucovorin may not be more cost efficient than competing drugs and otherwise may not have any competitive advantage, which could hinder our ability to successfully commercialize it.***

LEVOleucovorin is a novel folate analog formulation and the pharmacologically active isomer (the levo-isomer) of the racemic compound calcium leucovorin, a product already approved for the same indications our product is approved for. 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. 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 LEVOleucovorin in a cost efficient manner or at a cost below the generic leucovorin cost price. Also, LEVOleucovorin will be offered as part of a treatment regimen, and that regimen may change to exclude LEVOleucovorin. Accordingly, it may not gain acceptance by the medical field or become commercially successful.

***The marketing and sale of our drug product LEVOleucovorin, may be adversely affected by the marketing and sales efforts of third parties who sell LEVOleucovorin outside North America.***

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

***The size of the market for our potential products is uncertain.***

We often provide estimates of the number of people who suffer from the diseases that our drugs are targeting. However, there is limited information available regarding the actual size of these patient populations. In addition, it is uncertain whether the results from previous or future clinical trials of drug products will be observed in broader patient populations, and the number of patients who may benefit from our drug products may be significantly smaller than the estimated patient populations.

***Intense competition from a large number of generic companies may make the marketing and sale of our sumatriptan injection product and any of our other 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. We will be competing against generic companies such as Teva Pharmaceuticals, Sandoz, Barr Laboratories, Mylan Laboratories Inc., Watson Pharmaceuticals, Inc., Genpharm, Dr. Reddy's, Ranbaxy, American Pharmaceutical Partners, Bedford Laboratories, Mayne Pharmaceuticals and others. In addition, we anticipate that many foreign manufacturers will continue to enter the generic market due to low barriers to entry. These companies may have greater economies of scale in the production of their products and, in certain cases, may produce their own product supplies, such as active pharmaceutical ingredients, or can procure product supplies on more favorable terms which may provide significant cost and supply advantages to customers in the retail prescription market. We expect that the generic market will be competitive and will be largely dominated by the competitors listed above who may target the same products as us.



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**Risks Related to Our Industry**

***If third-party payors do not adequately reimburse providers for any of our product candidates, if approved for marketing, we may not be successful in selling them.***

Our ability to commercialize any products successfully will depend in part on the extent to which reimbursement will be available from governmental and other third-party payors, both in the United States and in foreign markets. Even if we succeed in bringing one or more products to the market, the amount reimbursed for our products may be insufficient to allow us to compete effectively and could adversely affect our profitability.

Reimbursement by a governmental and other third-party payor may depend upon a number of factors, including a governmental or other third-party payor's determination that use of a product is:

a covered benefit under its health plan;

safe, effective and medically necessary;

appropriate for the specific patient;

cost-effective; and

neither experimental nor investigational.

Obtaining reimbursement approval for a product from each third-party and governmental payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payor. We may not be able to provide data sufficient to obtain reimbursement.

Eligibility for coverage does not imply that any drug product will be reimbursed in all cases or at a rate that allows us to make a profit. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not become permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower-cost drugs that are already reimbursed, may be incorporated into existing payments for other products or services, and may reflect budgetary constraints and/or Medicare or Medicaid data used to calculate these rates. Net prices for products also may be reduced by mandatory discounts or rebates required by government health care programs or by any future relaxation of laws that restrict imports of certain medical products from countries where they may be sold at lower prices than in the United States.

***Rapid bio-technological advancement may render our drug products 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 products and thereby cause our drug products to become commercially obsolete. Some of our drug products may become obsolete before we recover the expenses incurred in their development. As a result, such products may never become profitable.

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

Many pharmaceutical companies are conducting clinical trials in patients with the disease indications that our drug products 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



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patient population, the nature of the trial protocol, the proximity of patients to clinical sites and the eligibility criteria for the study. The delay or inability to meet planned patient enrollment may result in increased costs and delays or termination of the trial, which could have a harmful effect on our ability to develop products.

***We may not be successful in obtaining regulatory approval to market and sell our drug products.***

Before our drug products 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 drug products satisfy rigorous standards of safety and efficacy. We need to conduct significant research, pre-clinical testing and clinical testing, before we can file applications with the FDA for approval of our drug products. 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 product 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 products.

***Failure to obtain regulatory approval outside the United States will prevent us from marketing our product candidates abroad.***

We intend to market certain of our existing and future product candidates in non-U.S. markets. In order to market our existing and future product candidates in the European Union and many other non-U.S. jurisdictions, we must obtain separate regulatory approvals. We have had limited interactions with non-U.S. regulatory authorities, and the approval procedures vary among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more non-U.S. regulatory authorities does not ensure approval by regulatory authorities in other countries or by the FDA. The non-U.S. regulatory approval process may include all of the risks associated with obtaining FDA approval as well as other risks specific to the jurisdictions in which we may seek approval. We may not obtain non-U.S. regulatory approvals on a timely basis, if at all. We may not be able to file for non-U.S. regulatory approvals and may not receive necessary approvals to commercialize our existing and future product candidates in any market.

***Even after we receive regulatory approval to market our drug products, the market may not be receptive to our drug products upon their commercial introduction, which would negatively affect our ability to achieve profitability.***

Our drug products may not gain market acceptance among physicians, patients, healthcare payors and the medical community. The degree of market acceptance of any approved drug products will depend on a number of factors, including:

the effectiveness of the drug product;

the prevalence and severity of any side effects;

potential advantages or disadvantages over alternative treatments;

relative convenience and ease of administration;

the strength of marketing and distribution support;

the price of the drug product, both in absolute terms and relative to alternative treatments; and

sufficient third-party coverage or reimbursement.

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If our drug products receive regulatory approval but do not achieve an adequate level of acceptance by physicians, healthcare payors and patients, we may not generate drug product revenues sufficient to attain profitability.

***Our failure to comply with governmental regulations may delay or prevent approval of our drug products 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 our 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 drug product 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 product 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 drug products, 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:

warning letters;

fines;

changes in advertising;

revocation or suspension of regulatory approvals of products;

product recalls or seizures;

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

civil or criminal sanctions; and

refusals to approve new products.

***The 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 drug product, including withdrawal from the market. In addition, the FDA may revisit and change its prior determinations with

regard to the safety and efficacy of our 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 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, which may include substantial fines.

***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 payors 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 provided a new Medicare prescription drug benefit beginning in 2006 and mandated other reforms. Also, the passage of the Medicare Modernization Act reduced reimbursement for certain drugs used in the treatment of cancer. The new benefit, which is 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.

The Medicare Modernization Act also made adjustments to the physician fee schedule and the measure by which prescription drugs are presently paid, changing from average wholesale price to average sales price. The effects of

these changes are unknown but may include decreased utilization of new medicines in physician prescribing patterns, and further pressure on drug company sponsors to provide discount programs and reimbursement support programs. We expect that there will continue to be federal and state proposals to constrain expenditures for medical products and services, which may affect reimbursement levels for our future products. In addition, the Centers for Medicare and Medicaid Services frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payors often follow

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Medicare coverage policy and payment limitations in setting their own reimbursement rates and may have sufficient market power to demand significant price reductions.

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 payors 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. Also, third-party payors are refusing, in some cases, to provide coverage when an approved product is used for disease indications in a way that has not received FDA marketing approval. Our products may not be considered cost-effective, or adequate third party reimbursement may not be available to enable us to maintain price levels sufficient to realize a return on our investments.

In addition, new court decisions, FDA interpretations, and legislative changes have modified the rules governing eligibility for and the timing of 180-day market exclusivity periods, a period of marketing exclusivity that the FDA may grant to an ANDA applicant who is the first to file a legal challenge to patents of branded drugs. We recently settled our case with GSK for sumatriptan injection, the generic form of GSK's Imitre® injection, whereby we acquired the right to distribute authorized generic versions of 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.

In some foreign countries, particularly in the European Union, prescription drug pricing is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our profitability will be negatively affected.

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

***If we market products in a manner that violates health care fraud and abuse laws, we may be subject to civil or criminal penalties.***

The Federal health care program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for

the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid or other federally financed health care programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers and formulary managers, on the other hand. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve



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remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to Medicaid for non-covered off-label uses; and submitting inflated best price information to the Medicaid Rebate Program.

HIPAA created two new federal crimes: health care fraud, and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services.

The majority of states also have statutes or regulations similar to these federal laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. In addition, some states have laws that require pharmaceutical companies to adopt comprehensive compliance programs. For example, under California law, pharmaceutical companies must comply with both the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and the July 2002 PhRMA Code on Interactions with Healthcare Professionals. We have adopted and implemented a compliance program which we believe satisfies the applicable requirements of California law.

Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines and imprisonment. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our past, present or future operations are found to be in violation of any of the laws described above or other similar governmental regulations to which we are subject, we may be subject to the applicable penalty associated with the violation which could adversely affect our ability to operate our business and our financial results.

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

Our success with the drug products that we develop will depend, in part, on our ability and the ability of our licensors 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. Our license agreements 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 allowed or, if allowed and issued into patents, if such patents and the patents we have licensed are not upheld in a court of law, our ability to competitively exploit our drug 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.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in biotechnology patents has

emerged to date in the United States. The laws of many countries may not protect intellectual property rights to the same extent as United States laws, and those countries may lack adequate rules and procedures for defending our intellectual property rights. Filing, prosecuting and defending patents on all our products or product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions and may not be covered by any of our patent claims or other intellectual property rights.

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Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. We do not know whether any of our patent applications will result in the issuance of any patents, and we cannot predict the breadth of claims that may be allowed in our patent applications or in the patent applications we license from others.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

we or our licensors might not have been the first to make the inventions covered by each of our or our licensors pending patent applications and issued patents, and we may have to participate in expensive and protracted interference proceedings to determine priority of invention;

we or our licensors might not have been the first to file patent applications for these inventions;

others may independently develop similar or alternative product candidates or duplicate any of our or our licensors product candidates;

our or our licensors pending patent applications may not result in issued patents;

our or our licensors issued patents may not provide a basis for commercially viable products or may not provide us with any competitive advantages or may be challenged by third parties;

others may design around our or our licensors patent claims to produce competitive products that fall outside the scope of our or our licensors patents;

we may not develop or in-license additional patentable proprietary technologies related to our product candidates; or

the patents of others may prevent us from marketing one or more of our product candidates for one or more indications that may be valuable to our business strategy.

Moreover, an issued patent does not guarantee us the right to practice the patented technology or commercialize the patented product. Third parties may have blocking patents that could be used to prevent us from commercializing our patented products and practicing our patented technology. Our issued patents and those that may be issued in the future may be challenged, invalidated or circumvented, which could limit our ability to prevent competitors from marketing related product candidates or could limit the length of the term of patent protection of our product candidates. In addition, our competitors may independently develop similar technologies. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

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

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

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

The patent positions related to our drug products are inherently uncertain and involve complex legal and factual issues. Although we are not aware of any infringement by any of our drug products on the rights of any third party, there may be third party patents or other intellectual property rights relevant to our drug products of which we are not aware. Third parties may assert patent or other intellectual property infringement claims against us with

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respect to our 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 products.

***We may be subject to damages resulting from claims that we, or our employees, have wrongfully used or disclosed alleged trade secrets of our employees' former employers.***

Many of our employees were previously employed at universities or biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we have not received any claim to date, we may be subject to claims that these employees through their employment inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel.

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

We may be exposed to product liability claims from patients who participate in our clinical trials or from consumers of our products. Although we currently carry product liability insurance in the amount of at least \$10 million in the aggregate, it is possible that this coverage will be insufficient to protect us from future claims.

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

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

Our research and development efforts 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

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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; however, future claims may exceed the amount of our coverage. Also, we do not have insurance coverage for pollution clean up and removal. 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 7, 2008, there were approximately 31 million shares of our common stock outstanding, and in addition, security holders held options, warrants and preferred stock which, if vested, exercised or converted, would obligate us to issue up to approximately 16.5 million additional shares of common stock. However, we would receive over \$101 million from the issuance of shares of common stock upon the exercise of all of the options 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 may have to file a shelf registration statement to raise additional funds that allows us to sell our securities, some or all of which may be shares of our common stock or securities convertible into or exercisable for shares of our common stock, and all of which would be available for resale in the market. The market price of our common stock could fall as a result of sales 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 increase 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:

adverse results or delays in our clinical trials;

fluctuations in our results of operations, timing and announcements of our bio-technological innovations or new products or those of our competitors;

developments concerning any strategic alliances or acquisitions we may enter into;

announcements of FDA non-approval of our drug products, or delays in the FDA or other foreign regulatory review process or actions;

adverse actions taken by regulatory agencies with respect to our drug products, clinical trials, manufacturing processes or sales and marketing activities;

any lawsuit involving us or our drug products;

developments with respect to our patents and proprietary rights;



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announcements of technological innovations or new products by our competitors;

public concern as to the safety of products developed by us or others;

regulatory developments in the United States and in foreign countries;

changes in stock market analyst recommendations regarding our common stock or lack of analyst coverage;

the pharmaceutical industry generally and general market conditions;

failure of our results of operations to meet the expectations of stock market analysts and investors;

sales of our common stock by our executive officers, directors and five percent stockholders or sales of substantial amounts of our common stock.

changes in accounting principles; and

loss of any of our key scientific or management personnel.

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 2007, the price of our common stock ranged between \$2.58 and \$7.88, and the daily trading volume was as high as 8,208,500 shares and as low as 34,200 shares. During 2008 through March 10, 2008, the price of our common stock has ranged between \$2.32 and \$2.93, and the daily trading volume has been as high as 4,369,800 shares and as low as 36,900 shares.

Following periods of volatility in the market price of a company's securities, securities class action litigation may be instituted against companies. These types of lawsuits generally result in substantial legal fees and management's attention and resources being diverted from the operations of a business to the litigation.

***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.

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*Our publicly-filed SEC reports are reviewed by the SEC from time to time and any significant changes required as a result of any such review may result in material liability to us and have a material adverse impact on the trading price of our common stock.*

The reports of publicly-traded companies are subject to review by the Securities and Exchange Commission from time to time for the purpose of assisting companies in complying with applicable disclosure requirements and to enhance the overall effectiveness of companies' public filings, and reviews of such reports are now required at least every three years under the Sarbanes-Oxley Act of 2002. SEC reviews may be initiated at any time. While we believe that our previously filed SEC reports comply, and we intend that all future reports will comply, in all material respects with the published rules and regulations of the SEC, we could be required to modify or reformulate information contained in prior filings as a result of an SEC review. Any modification or reformulation of information contained in such reports could be significant and could result in material liability to us and have a material adverse impact on the trading price 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.

**Item 3. *Legal Proceedings***

**Arbitration with GPC Biotech**

In December 2006, we filed a demand for arbitration with the American Arbitration Association to address our exclusion from participating in nearly \$70 million in sublicense income received by GPC Biotech AG, and to address other non-monetary material violations of our license agreement with GPC, and GPC answered and counterclaimed and demanded a royalty-free license among other demands. The arbitration hearing was conducted in Boston, Massachusetts, between July 6 and July 13, 2007, and final arguments were presented on August 21. On November 5, 2007, the arbitration panel issued a ruling whereby it dismissed all claims of each party against the other. The panel's ruling is binding according to the terms of the license agreement between us and GPC.

**Other**

We are involved with various other legal matters arising from the ordinary course of business. Although the ultimate resolution of these various matters cannot be determined at this time, we do not believe that such matters, 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, 2007.

**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 10, 2008 there were 31,233,798 shares of common stock outstanding and 389 shareholders of record. On March 10, 2008, the closing sale price of our common stock was \$2.93 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 2007 and 2006 were as follows:

	<b>High</b>	<b>Low</b>
<b>Year 2007</b>		
Quarter Ended		
March 31	\$ 7.11	\$ 5.27
June 30	\$ 7.75	\$ 6.18
September 30	\$ 7.88	\$ 3.48
December 31	\$ 4.73	\$ 2.58
<b>Year 2006</b>		
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

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.

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**CUMULATIVE TOTAL RETURN**  
**Based upon an initial investment of \$100 on December 31, 2002**  
**with dividends reinvested**

	<b>Dec-02</b>	<b>Dec-03</b>	<b>Dec-04</b>	<b>Dec-05</b>	<b>Dec-06</b>	<b>Dec-07</b>
Spectrum Pharmaceuticals Inc.	\$ 100	\$ 465	\$ 370	\$ 235	\$ 307	\$ 151
Custom Composite Index (15 Stocks)	\$ 100	\$ 139	\$ 78	\$ 58	\$ 65	\$ 64
S&P SmallCap 600	\$ 100	\$ 139	\$ 170	\$ 183	\$ 211	\$ 210
Russell 2000® Index	\$ 100	\$ 147	\$ 174	\$ 182	\$ 216	\$ 227

The Custom Composite Index consists of Allos Therapeutics Inc., AVI Biopharma, Inc., Avigen Inc., Cortex Pharmaceuticals Inc., Genta Inc., Immunomedics Inc., Kosan Biosciences Inc., La Jolla Pharmaceutial Co., Maxim Pharmaceuticals Inc. (through 4Q05), Neurobiological Technologies Inc., Sangamo BioSciences Inc., Seattle Genetics Inc., SuperGen Inc., Targeted Genetics Corp., and Vical Inc.

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**Table of Contents****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**

None.

**Item 6. Selected Financial Data**

The following table presents our selected financial data. Financial data for the years ended December 31, 2007, 2006, and 2005 and as of December 31, 2007 and 2006 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, 2004 and 2003 and as of December 31, 2005, 2004 and 2003 and has been derived from our audited financial statements not included herein.

**CONSOLIDATED FINANCIAL INFORMATION**

	<b>2007</b>	<b>2006</b>	<b>2005</b>	<b>2004</b>	<b>2003</b>
	<b>(In thousands, except per share data)</b>				
<b>Statement of Operations Data for the Years Ended December 31:</b>					
Revenues	\$ 7,672	\$ 5,673	\$ 577	\$ 258	\$ 1,000
Operating expenses:					
Cost of product sold		97	397	123	
Research and development	33,285	23,728	13,483	7,588	4,683
General and administrative	11,582	7,741	6,619	5,347	6,622
Restructuring expenses					163
Loss from operations	(37,195)	(25,893)	(19,922)	(12,800)	(10,468)
Other income, net	3,159	2,609	1,280	514	78
Net loss	\$ (34,036)	\$ (23,284)	\$ (18,642)	\$ (12,286)	\$ (10,390)
Basic and diluted net loss per share	\$ (1.17)	\$ (0.96)	\$ (1.06)	\$ (0.98)	\$ (4.83)
Cash Dividends on common stock	\$	\$	\$	\$	\$
<b>Balance Sheet Data at December 31:</b>					
Cash, cash equivalents and marketable securities	\$ 55,659	\$ 50,697	\$ 63,667	\$ 39,206	\$ 26,351
Property and equipment, net	\$ 716	\$ 625	\$ 562	\$ 687	\$ 560
Total assets	\$ 57,540	\$ 53,117	\$ 65,075	\$ 40,758	\$ 27,389
Current liabilities	\$ 7,799	\$ 6,233	\$ 3,828	\$ 2,666	\$ 3,108
Other non-current-liabilities	\$ 992	\$ 1,035	\$ 241	\$ 178	\$

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Minority interest in consolidated subsidiary	\$	\$	20	\$	23	\$	24	\$		
Total stockholders equity	\$	48,749	\$	45,829	\$	60,983	\$	37,890	\$	24,281



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

The following discussion and analysis should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. 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, the safety and efficacy 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**

On March 7, 2008, we received approval from the U.S. Food and Drug Administration, or FDA, of our new drug application, or NDA, for our drug product, LEVOleucovorin (formerly, ISO-Vorin<sup>tm</sup>). We anticipate launching LEVOleucovorin in the U.S. market in mid-2008. Also, during the fourth quarter of 2008, we will launch sumatriptan injection, the generic form of GlaxoSmithKline's Imitre<sup>®</sup> injection, through our commercialization partner, Par Pharmaceutical Companies, Inc. We are a biopharmaceutical company that acquires, develops and commercializes a diversified portfolio of drug products, with a focus on oncology, urology and other critical health challenges. We are focused on executing our business strategy, which is comprised of the following four parts:

Acquiring and developing a broad and diverse pipeline of late-stage clinical and commercial products with a focus on oncology and urology.

We acquire and develop multiple novel, late-stage oncology drug products that address niche markets. 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 early clinical process. Our strategy allows us to leverage organizational, collaborative, commercial and scientific efficiencies from a therapeutic focus on oncology and urology.

Establishing a commercial organization for LEVOleucovorin that will be available if and when each of the other drug products in our pipeline are approved. As we transform from a development to a commercial organization, we are building a foundation for successful product launches.

Continuing to build a team with significant drug development and commercialization expertise in our areas of focus and creating a culture of success that allows our people to thrive.

We have built the foundation of a team with significant experience in oncology and urology drug development. We endeavor to leverage the talents of our team and add people who have relevant experience. Our team members have, in the past, been responsible for the development of drugs such as adriamycin, cisplatin, carboplatin, paclitaxel, Etoposide, Buspar, Cialis, Nefazodone and Stadol, among others. We also have, and will continue to bring, commercialization experience to the Company as we build our commercial infrastructure.

Leveraging the expertise of partners around the world in areas of manufacturing, development and commercialization to assist us in the execution of our strategy.

#### **Business Outlook**

Our primary business focus for 2008, and beyond, will be to continue to acquire, develop and commercialize a portfolio of 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:

LEVOleucovorin: On March 7, 2008, we received approval from the FDA for LEVOleucovorin and we expect to commercially launch LEVOleucovorin in mid-2008. Also, we plan to file a supplemental NDA for the colorectal cancer indication and to file an NDA amendment for the tablet formulation. LEVOleucovorin

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is currently marketed and sold (under different trade names) by Wyeth, Sanofi-aventis, Inc. and others in certain parts of the world, including Europe and Japan.

*Sumatriptan injection:* In November 2006, we reached an agreement with GlaxoSmithKline, or GSK, to settle the patent litigation relating to sumatriptan injection. The terms of the agreement provide that we may distribute authorized generic versions of sumatriptan injection products in the United States with an expected launch in the fourth quarter during GSK's sumatriptan pediatric exclusivity period. We will launch sumatriptan injection through Par Pharmaceutical Companies, Inc., or Par, our partner for the sale and distribution of the drug. Pursuant to the terms of our agreement with Par, we will receive a majority of the profits from the sale of sumatriptan injection.

*EOquin:* Pursuant to a special protocol assessment procedure, in 2007, we initiated two Phase 3 clinical studies in the United States for EOquin in non-invasive bladder cancer. We recently received scientific advice from the European Medicines Agency, or EMEA, the European equivalent to the FDA, whereby the EMEA agreed that the two Phase 3 studies being conducted at this time, mostly in the United States, should be sufficient for a regulatory decision regarding European registration. We have enrolled nearly 300 patients into the two trials, and in early 2008, we anticipate expanding one of the clinical studies to sites in Canada since we recently received authorization from the Canadian Health Authorities allowing us to initiate the trial in Canada. The first Phase 3 study is currently expected to complete enrollment by the end of 2008, and the second Phase 3 trial to be fully enrolled by mid-2009. We are also investigating the out-licensing of EOquin ex-USA.

*Ozarelix:* In January 2007, we initiated a Phase 2b study of ozarelix for the treatment of benign prostatic hypertrophy, or BPH, following a European study in 144 patients in BPH. The 9-month study concludes in the first quarter of 2008. We completed patient enrollment and expect that complete data will be available mid-April 2008. While we wait for the data, we are concurrently working on the design of the protocol for the next study, which we expect to initiate soon thereafter.

*Ortataxel:* In July 2007, we entered into a worldwide license agreement for ortataxel, a third-generation taxane that has demonstrated clinical activity against taxane-refractory tumors. We acquired these rights from Indena S.p.A., the Italian company that discovered ortataxel. While we are optimizing the oral formulation for better bioavailability, we may consider some studies with the parenteral formulation.

We plan to continue to fund the development, including clinical trials of SPI-1620.

We expect to continue to evaluate additional promising drug product candidates for opportunistic 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 31, 2007, have exceeded \$240 million. We expect to continue to incur significant additional losses as we implement our growth strategy of developing drug products for at least the next several years, unless they are offset, if at all, by the out-license or product sales of any of our drugs.

We believe that the approximately \$55 million in cash, cash equivalents and marketable securities that we had as of December 31, 2007 will allow us to fund our current planned operations for at least the next twelve months. Our

long-term strategy is to generate profits from the sale and licensing of our drug products. In the next several years, we expect to supplement our cash position with: sales of LEVOleucovorin; licensing revenues from out-licensing our other drug products; and profits from the sale by Par of our sumatriptan injection products.

However, it is unlikely that we will be able to generate the revenues necessary to finance our operations near-term, therefore, we will likely have to seek additional capital through the sale of our equity. Our operations have historically been financed by the issuance of capital stock. In May 2007, we received net proceeds of approximately \$30 million from the sale of 5,134,100 shares of our common stock at a price of \$6.25 with no warrants in an

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offering pursuant to a shelf registration statement. We may file another shelf registration statement in 2008, to facilitate a future financing, if necessary.

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, completion dates, and ultimate aggregate cost of developing each of our drug product candidates. In addition, while we expect revenues in 2008 from sales of LEVOleucovorin and from sales of sumatriptan injection, we are unable to reasonably estimate when, if ever, we will realize net profit from sales of these two products or any of our other products, if they are approved by the FDA. 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.

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.

	<b>Years Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(Amounts in thousands)</b>		
LEVOleucovorin	\$ 1,368	\$ 4,428	\$
EOquin	6,348	2,617	1,422
Ozarelix	6,217	2,881	2,883
Ortataxel	3,719		
Other drugs	3,452	4,457	4,667
<b>Total Direct Costs</b>	<b>21,104</b>	<b>14,383</b>	<b>8,972</b>
Indirect Costs (including non-cash share-based compensation of \$3,555, \$2,540, and \$289, respectively)	12,181	9,345	4,511
<b>Total Research &amp; Development</b>	<b>\$ 33,285</b>	<b>\$ 23,728</b>	<b>\$ 13,483</b>

While we are currently focused on advancing our key product development programs, we anticipate that we will make regular determinations as to which other 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 net use of cash for operations in the fiscal year ending December 31, 2008, excluding the cost of in-licensing additional drugs, if any, is expected to range between approximately \$30 and \$35 million. While our primary focus in 2008 and the programs that will represent a significant part of our expenditures are the on-going clinical study of EQquin and ozarelix, and the commercial launch of LEVOleucovorin, key factors we will monitor as we determine the funding of other development projects are:

the success of the commercial launch of LEVOleucovorin in mid 2008; we estimate launch expenses in the range of approximately \$5 million;

success of the launch of sumatriptan injection in the fourth quarter of 2008; we will receive a majority of the profits from the sale of sumatriptan injection;

the timing of the initiation of a new study for ozarelix in 2008;

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continued patient enrollment in our EOquin clinical trials at anticipated rates; and

continued positive results from our preclinical studies and clinical trials.

Further, while we do not receive any funding from third parties for research and development that we conduct, co-development and out-licensing agreements with other companies for any of our drug products may reduce our expenses. In this regard, we are investigating the out-licensing of ex-USA rights for EOquin. The success of such out-license would mitigate the use of cash or enable accelerated development of other drug development projects.

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/or common stock 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 during 2008. Upon successful achievement of these milestones, we will likely become obligated to pay up to approximately \$880,000 in cash and issue up to 250,000 shares of our common stock during 2008. In this regard, the FDA approval of our NDA for LEVOleucovorin on March 7, 2008, triggered a payment of \$100,000 to Eprova and issuance of an aggregate of 125,000 shares of our common stock to Targent, or its stockholders, with a fair market value of \$305,000.

*Net Cash used in Operating Activities*

During the year ended December 31, 2007 and 2006, net cash used in operations was approximately \$25.4 million and \$13.5 million, respectively. The increase of approximately \$11.8 million in cash required for operations is primarily due to an increase of approximately \$11.2 million in cash used for research and development costs.

*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 place our cash in a variety of investments pending its use in our business. Net cash used for investing activities was approximately \$4.6 million during the year ended December 31, 2007, and resulted from the disinvestment of marketable securities, of approximately \$25.7 million, which were initially invested from our available cash balances and the net \$30 million proceeds from the May 2007 financing, and the cash used in capital expenditures of approximately \$346,000 to support operations.

*Net Cash provided by and used for Financing Activities*

Net cash provided by financing activities totaled approximately \$30.6 million for the year ended December 31, 2007. Approximately \$30 million derived from the sale of 5,134,100 shares of common stock, and approximately \$639,000 derived from the exercise of outstanding warrants for 161,145 shares of our common stock and the exercise of stock options for 81,438 shares of our common stock.

**Results of Operations**

*Results of Operations for Fiscal 2007 Compared to Fiscal 2006*

In 2007, we incurred a net loss of approximately \$34 million compared to a net loss of approximately \$23.3 million in 2006. The principal components of the year to year changes in line items are discussed below.

During 2007, we recognized approximately \$7.7 million in licensing milestone and related revenues, pursuant to our agreement with GPC Biotech for satraplatin. Of this amount, \$7.2 million in milestone payments related to the acceptance by the FDA of an NDA filing by GPC, and the filing and acceptance of a Marketing Authorization Application with the EMEA. Approximately \$0.5 million of the recorded revenues represented amounts received from GPC under our agreement for commissions on drug products used by GPC in clinical trials and for anticipated commercial launch. In comparison, we recorded milestone and other fees during 2006 as follows: a \$5 million milestone payment from Par related to sumatriptan injection; and approximately \$581,000 premium received in



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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. Generic product sales in 2006 were approximately \$92,000. No product sales were recorded in 2007. We do anticipate, however, we will generate revenues from product sales in 2008 from the launch of LEVOleucovorin, and profits from the launch in the fourth quarter of 2008 of sumatriptan injection products in the United States through our distribution partner Par.

Research and development expenses increased by approximately \$9.6 million, from approximately \$23.7 million in 2006 to approximately \$33.3 million in 2007. During 2007, we continued to advance the development of all of our proprietary drugs. Primary components of cost increases related to the two Phase 3 trials for EOquin, which initiated during 2007, a Phase 2b and toxicological study of ozarelix, and the acquisition of ortataxel. Principal components of the increase in 2007 were as follows. Approximately:

\$3.7 million related to the manufacture of clinical supplies and the clinical costs of two Phase 3 trials for EOquin;

\$3.7 million related to the acquisition of ortataxel and manufacture of clinical supplies;

\$3.2 million related to the manufacture of clinical supplies and clinical costs for the ozarelix phase 2b trial, and for toxicological studies;

\$1.0 million related to the payment of milestones upon the filing and acceptance of the NDA for satraplatin;

\$1.4 million increase in cash compensation to employees; and an increase of \$1.0 million in non-cash share-based employee compensation; and

off set by a decrease of \$4.1 million in the development costs of other drugs, primarily LEVOleucovorin, which was acquired for \$2.7 million in 2006.

We anticipate research and development expense in 2008 to remain roughly the same as 2007, with a substantial part of the expenses attributed to the clinical trials of EOquin and ozarelix.

General and administrative expenses increased by approximately \$3.9 million, from approximately \$7.7 million in 2006 to approximately \$11.6 million in 2007, primarily due to increased legal expenses resulting from the arbitration against GPC Biotech, described elsewhere in this report. We expect an significant increase in general and administrative expenses for 2008 related to sales and marketing of LEVOleucovorin.

Other income of approximately \$3.1 million consisted primarily of interest income, and the increase in fiscal year 2007 from fiscal year 2006 is attributable to higher average interest rates and balances of investable funds in 2007.

***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 principal components of the year to year changes in line items are discussed below.

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 approximately \$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 approximately \$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. Generic product sales in 2006 and 2005 were approximately \$92,000 and \$521,000, respectively.

Research and development expenses increased by approximately \$10.2 million, from approximately \$13.5 million in 2005 to approximately \$23.7 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

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addition, we incurred increased costs in advancing the development of newly-acquired compounds, ISO-Vorin, SPI-1620 and Lucanthone. 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 an approximately \$1 million reduction in the development of generic drugs.

An increase of approximately \$2.1 million in cash compensation to employees and approximately \$2.3 million in non-cash share-based employee compensation due to our adoption of SFAS 123(R), effective January 1, 2006.

Also 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.

General and administrative expenses increased by approximately \$1.1 million, from approximately \$6.6 million in 2005 to approximately \$7.7 million in 2006, primarily due to an increase in non-cash share-based employee compensation recorded, respectively, due to our adoption of SFAS 123(R), effective January 1, 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.

**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, 2007, approximately:

	<b>Total</b>	<b>Less than 1 Year</b>	<b>1-3 Years</b>	<b>4-5 Years</b>	<b>After 5 Years</b>
<b>Contractual Obligations(1)</b>					
Capital Lease Obligations(2)	\$	\$	\$	\$	\$
Operating Lease Obligations(3)	752	494	258		
Purchase Obligations(4)	15,628	9,019	4,817	1,792	
Contingent Milestone Obligations(5)	70,750	880	6,840	14,170	48,860
<b>Total</b>	<b>\$ 87,130</b>	<b>\$ 10,393</b>	<b>\$ 11,915</b>	<b>\$ 15,962</b>	<b>\$ 48,860</b>

- (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, 2007, 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.
- (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, 2007. Over 80% of the purchase obligations consist of expenses associated with clinical trials and related costs for EOquin and ozarelix for each of the periods presented. Please see [Service Agreements](#) below for further information.
- (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, 2007, 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

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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 drug candidates are being developed pursuant to license agreements that provide us with rights to certain territories to, among other things, develop, sublicense, and sell the drugs. We have out-licensed development and commercialization rights to satraplatin, one of our drug product candidates, to GPC Biotech AG in exchange for up-front and milestone payments and royalties on sales of product. 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. Par Pharmaceutical Companies, Inc. is responsible for marketing our generic sumatriptan injection product and we will 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, if at all. Accordingly, the milestone payments represent contingent obligations that will be recorded as expense when the milestone is achieved. Our potential contingent cash development and regulatory milestone obligations aggregate approximately \$70.8 million as of December 31, 2007, assuming such milestones are achieved. We may achieve certain milestones over the next twelve months, thereby obligating us to issue up to 250,000 shares of our common stock and to pay up to approximately \$880,000 in cash. In this regard, the FDA approval of our NDA for LEVOleucovorin on March 7, 2008, triggered a payment of \$100,000 to Eprova and issuance of an aggregate of 125,000 shares of our common stock to Targent, or its stock holders, with a fair market value of \$305,000.

### ***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. We are in a position to accelerate, slow-down or discontinue any or all of the projects that we are working on at any given point in time. Should we decide to discontinue and/or slow-down the work on any project, the associated costs for those projects would get limited to the extent of the work completed. Generally, we are able to terminate these agreements due to the discontinuance of the related project(s) and thus avoid paying for the services that have not yet been rendered and our future purchase obligations would reduce accordingly. As of each period end, we accrue for installment amounts that we are likely to become obligated to pay, on the presumption that all the projects will be completed as planned, and hence all the related costs are considered as obligated to be paid, based on current outstanding purchase obligations.

***Employment Agreements***

We have entered into employment agreements with two of our named executive officers, Dr. Shrotriya, President and Chief Executive Officer, and Dr. Lenaz, Chief Scientific Officer, expiring December 31, 2008 and July 1, 2008, respectively. The employment agreements automatically renew for a one-year term unless either party

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gives written notice of such party's intent not to renew the agreement at least 90 days prior to the commencement of the next year. The employment agreements require each officer to devote his full working time and effort to the business and affairs of the Company during the term of the agreement. The employment agreements provide for a minimum annual base salary with annual increases, periodic bonuses and option grants as determined by the Compensation Committee of the Board of Directors.

Under the employment agreements, each officer is entitled to receive additional employment benefits, including the right to participate in any pension or profit sharing plan and to receive life, medical, dental or other benefits. Each officer is also entitled to receive not less than four weeks per year of paid vacation. The employment agreements also provide for reimbursements of expenses incurred in performing duties for the Company, including: entertaining business prospects; maintaining and improving professional skills through continuing education; and business related travel, costs and entertainment. In addition, Dr. Shrotriya is entitled to a monthly vehicle allowance and reimbursements for automobile related expenses (including insurance and maintenance expenses).

Each officer's employment may be terminated due to expiration of the term of his employment agreement, mutual agreement, death or disability, or by us for cause (as that term is defined in the respective employment agreements) or without cause, or by the officer at any time upon ninety days' notice. The employment agreements provide for certain guaranteed severance payments and benefits if the officer's employment is terminated by us at the expiration of the term of the agreement, the officer is terminated without cause, if the officer's employment is terminated (other than by the officer) due to a change in control, or the officer is adversely affected (as described below) in connection with a change in control and the officer resigns. However, if the officer terminates his employment at any time upon ninety days' notice, or death or disability, he shall not be entitled to any severance.

If the officer is terminated without cause or at the expiration of the term of the employment agreement, the guaranteed severance payments include the right to receive base salary for two years after termination. The officer is also entitled to two years of medical, dental and other employee benefits following termination. The officer may elect to receive a lump sum payment representing the aggregate cash compensation (including salary, bonus, auto allowance and any other cash or equivalent compensation, other than continued vacation accrual). In the event of such lump sum election, all insurance and other non-cash benefits shall cease.

Pursuant to the terms of the employment agreement, all options held by the officer shall immediately vest and will be exercisable for up to one year from the date of termination; provided, however, that 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 up to approximately thirteen (13) months after the date of termination.

If there is change of control of the Company, and (1) the officer's employment is involuntarily terminated or (2) the officer is adversely affected in terms of overall compensation, benefits, title, authority, reporting relationships, location of employment or similar matters and the officer elects to resign from full service to the Company, the officer shall be provided with senior executive outplacement services at an outplacement or executive search firm, and the cash compensation and all benefits to which the officer is entitled hereunder shall be discontinued twenty-four (24) months after the date of election (or earlier, if a lump sum payment of cash compensation is specified). The officer, at his election, shall have the right to request and, if requested, shall be paid the full cash value of all amounts of cash compensation due for the 24-month period (including salary, approved bonus, auto allowance, and any other cash or equivalent compensation) in a lump sum. In the event of such election, all insurance and noncash benefits shall cease.

Pursuant to the terms of the employment agreement, all options granted to officer shall vest to the same extent as provided in the case of a termination without cause. Also, if an acquirer of 100% of the Company's stock is itself a publicly held company, the Company shall make reasonable efforts to negotiate that the officer shall have the right, but not the obligation, to convert all of his vested options into options to purchase the acquirer's stock and shall have two (2) years to exercise those options, but the Company shall have no obligation to the officer if it fails to secure such rights or concludes that pursuing such rights would materially prejudice the interest of the stockholders of the Company.



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The employment agreements also provide that, upon the officer's retirement (voluntary termination after reaching the Company's retirement age or age 65, whichever occurs first), all options held by the officer will become fully vested.

Notwithstanding the terms of the executive employment agreements as discussed above, the executive's options are subject to the terms of the respective stock incentive plans and individual agreements governing such options.

In the event of the death of the officer, all compensation shall be paid based on value at time of death.

Each officer agrees during the term of his employment by the Company and thereafter that he will not disclose, other than to an authorized employee, officer, director or agent of the Company, any information relating to the Company's business, trade, practices, trade secrets or know-how or proprietary information without the Company's prior express written consent. Following termination of the officer's employment, the officer shall be permitted to continue in his usual occupation and shall not be prohibited from competing with the Company except during the two (2) year severance period and in the specific industry market segments in which the Company competes and which represent twenty percent (20%) or more of the Company's revenues. For a period of one (1) year following the termination of the officer's employment with the Company for any reason, the officer shall not directly or indirectly solicit, induce, recruit or encourage any of the Company's employees to leave their employment.

## **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 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.

### ***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

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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 Share-Based Employee Compensation***

In December 2004, the 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 equity 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 share-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 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 September 2006, FASB Statement No. 157 Fair Value Measurement, or SFAS 157, was issued. This Statement defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, or GAAP, and expands disclosures about fair value measurements. The Statement is effective January 1, 2008. We do not expect the implementation of SFAS 157 to have a material impact on our financial statements.

In February 2007, FASB Statement No. 159, The Fair Value Option for Financial Assets and Financial Liabilities, including an amendment of FASB Statement No. 115, or SFAS 159, was issued. This Statement permits us to choose to measure many financial instruments and certain other items at fair value. It also establishes presentation and disclosure requirements. This Statement is effective January 1, 2008. We are currently evaluating the impact, if any, this standard will have on our financial statements.

In June 2007, EITF 07-3 Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities, or EITF 07-3, was issued. EITF 07-3 provides that nonrefundable advance payments made for goods or services to be used in future research and development activities should be deferred and capitalized until the related goods or services are delivered or are performed, when the amounts would be recognized as an expense. This standard is effective for new contracts entered into after January 1, 2008. We are currently evaluating the impact, if any, this standard will have on our financial statements.

In December 2007, the EITF of the FASB reached a consensus on Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). The EITF concluded on the definition of a collaborative arrangement and that revenues and costs incurred with third parties in connection with collaborative arrangements would be presented gross or net based on the criteria in EITF 99-19 and other accounting literature. Based on the nature of the arrangement, payments to or from collaborators would be evaluated and its terms, the nature of the entity's business, and whether those payments are within the scope of other accounting literature would be presented. Companies are also required to disclose the nature and purpose of collaborative arrangements along with the accounting policies and the classification and amounts of significant financial-statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other accounting literature; however required disclosure under EITF 07-1 applies to the entire collaborative agreement. This Issue is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, and is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. We do not expect this will have a significant impact on our financial statements.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations* (SFAS No. 141(R)), which replaces SFAS No. 141, *Business Combinations*, requires an acquirer to recognize the assets acquired, the liabilities assumed, and any non-controlling interest in the acquiree at the acquisition date, measured at their fair values as of that date, with limited exceptions. This Statement also requires the acquirer in a business combination achieved in stages to recognize the identifiable assets and liabilities, as well as the non-controlling interest in the acquiree, at the full amounts of their fair values. SFAS No. 141(R) makes various other amendments to authoritative literature intended to provide additional guidance or to confirm the guidance in that literature to that provided in this Statement. This Statement applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. We do not expect this will have a significant impact on our financial statements.

In December 2007, FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements* (SFAS No. 160), which amends Accounting Research Bulletin No. 51, *Consolidated Financial Statements*, to improve the relevance, comparability, and transparency of the financial information that a reporting entity provides in its consolidated financial statements. SFAS No. 160 establishes accounting and reporting standards that require the

ownership interests in subsidiaries not held by the parent to be clearly identified, labeled and presented in the consolidated statement of financial position within equity, but separate from the parent's equity. This statement also requires the amount of consolidated net income attributable to the parent and to the non-controlling interest to be clearly identified and presented on the face of the consolidated statement of income. Changes in a parent's ownership interest while the parent retains its controlling financial interest must be accounted for consistently, and when a subsidiary is deconsolidated, any retained non-controlling equity investment in the former subsidiary must

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be initially measured at fair value. The gain or loss on the deconsolidation of the subsidiary is measured using the fair value of any non-controlling equity investment. The Statement also requires entities to provide sufficient disclosures that clearly identify and distinguish between the interests of the parent and the interests of the non-controlling owners. This Statement applies prospectively to all entities that prepare consolidated financial statements and applies prospectively for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. We do not expect this will have a significant impact on our financial statements.

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

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.

We are exposed to certain market risks. Our primary exposures relate to (1) interest rate risk on our investment portfolio, (2) credit risk of the companies' bonds in which we invest, and (3) general credit market risks as existed during late 2007 and early 2008. We manage interest rate risk on our investment portfolio by matching scheduled investment maturities with our cash requirements.

Our investments as of December 31, 2007 are primarily in money market accounts, short-term corporate bonds and floating auction rate securities. Because of our ability to generally 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, 2007, any decline in the fair value of our investments would not be material in the context of our financial statements. 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 investing in highly rated securities that often have third party insurance coverage in the event of default by the issuer. At the end of 2007 and early 2008, there was significant dislocation in the credit markets, beginning with the sub-prime mortgage section and spreading across a variety of credit instruments, potentially affecting the liquidity of our investments. Consequently subsequent to December 31, 2007, we converted substantially all of our investments, including all of our market auction debt securities, into highly liquid investments.

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, 2007, 2006 and 2005.

**Item 8. *Financial Statements and Supplementary Data***

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

**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



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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, 2007, 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.

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

During the fourth quarter ended December 31, 2007, 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.

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

Kelly and Company, the Company's independent registered public accounting firm, has audited the consolidated financial statements included in this Annual Report and has issued an attestation report in our internal control over financial reporting, as set forth on page F-2. Presented below is an extract from that attestation report as to their independent assessment of our internal control over financial reporting: . . . in our opinion, Spectrum Pharmaceuticals, Inc. and Subsidiaries maintained, in all material respects, effective internal control over financial reporting as of

December 31, 2007, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

**Item 9B. Other Information**

None.

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**PART III**

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

The information required under this item is incorporated by reference from our definitive proxy statement related to our 2008 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A, on or before April 29, 2008, or the 2008 Proxy Statement.

**Item 11. *Executive Compensation***

The information required under this item is incorporated by reference from our 2008 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 2008 Proxy Statement.

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

The information required under this item is incorporated by reference from our 2008 Proxy Statement.

**Item 14. *Principal Accountant Fees and Services***

The information required under this item is incorporated by reference from our 2008 Proxy Statement.

**PART IV**

**Item 15. *Exhibits and Financial Statement Schedules***

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

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Balance Sheets as of December 31, 2007 and 2006</u>	F-3
<u>Consolidated Statements of Operations for the years ended December 31, 2007, 2006 and 2005</u>	F-4
<u>Consolidated Statements of Stockholders' Equity for the years ended December 31, 2007, 2006 and 2005</u>	F-5
<u>Consolidated Statements of Cash Flow for the years ended December 31, 2007, 2006 and 2005</u>	F-6
<u>Notes to Consolidated Financial Statements</u>	F-7

(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.

(a)(3) *Exhibits.*

**Exhibit**

<b>No.</b>	<b>Description</b>
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.)

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<b>Exhibit No.</b>	<b>Description</b>
4.2	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.)
4.3	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.)
4.4	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.)
4.5	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.)
4.5*	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.)
4.6*	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.)
4.7	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.)
4.8	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.)
4.9	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.)
4.10	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.)
4.11	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.)
4.12	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.)
4.13	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.)
4.14	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.)
4.15	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.)
4.16	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.)
4.17	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.)
4.18	

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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.)

- 4.19 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.)

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<b>Exhibit No.</b>	<b>Description</b>
4.20	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.)
4.21	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.)
4.22	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.)
4.23	Amendment No. 2 dated as of March 26, 2007, to Warrant issued by the Registrant to a consultant, dated as of September 17, 2003. (Filed as Exhibit 4.1 to Form 10-K/A, as filed with the Securities and Exchange Commission on April 30, 2007, 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.)
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	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.)
10.9	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.)
10.10*	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.)
10.11	

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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.)

- 10.12\* 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).



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<b>Exhibit No.</b>	<b>Description</b>
10.13	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.)
10.14*	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.)
10.15	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.)
10.16#	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.)
10.17#	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.)
10.18	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.)
10.19*	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.)
10.20#	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.)
10.21#	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.)
10.22*	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.)
10.23#	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.)
10.24	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.)
10.25*	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.)
10.26#	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.)
10.27	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.)
10.28#	

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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.)

10.29# 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.)

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<b>Exhibit No.</b>	<b>Description</b>
10.30#	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.)
10.31*	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.)
10.32#	Agreement by and between Registrant and Glaxo Group Limited (d/b/a GlaxoSmithKline) dated November 10, 2006. (Filed as Exhibit 10.38 to Form 10-K, as filed with the Securities and Exchange Commission on March 14, 2007, and incorporated herein by reference.)
10.33#	First Amendment to the Development and Marketing Agreement by and between Registrant and Par Pharmaceutical Companies, Inc. dated November 10, 2006. (Filed as Exhibit 10.39 to Form 10-K, as filed with the Securities and Exchange Commission on March 14, 2007, and incorporated herein by reference.)
10.34#	Supply and Distribution Agreement among Glaxo Group Limited, Glaxo Wellcome Manufacturing PTE Limited and Par Pharmaceutical, Inc. dated November 10, 2006. (Filed as Exhibit 10.40 to Form 10-K, as filed with the Securities and Exchange Commission on March 14, 2007, and incorporated herein by reference.)
10.35	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.)
10.36	Placement Agreement dated as of May 4, 2007, between the Registrant, Oppenheimer & Co. Inc., and Capital Markets LLC, Rodman & Renshaw, LLC, and Think Equity Partners, LLC. (Filed as Exhibit 1.1 to Form 8-K, as filed with the Securities and Exchange Commission on May 4, 2007, and incorporated herein by reference.)
10.37	Form of Subscription Agreement. (Filed as Exhibit 10.1 to Form 8-K, as filed with the Securities and Exchange Commission on May 4, 2007, and incorporated herein by reference.)
10.38*	2003 Amended and Restated Incentive Award Plan. (Filed as Exhibit 10.3 to Form 10-Q, as filed with the Securities and Exchange Commission on August 9, 2007, and incorporated herein by reference.)
10.39*	Summary of Director Compensation. (Filed as Exhibit 10.4 to Form 10-Q, as filed with the Securities and Exchange Commission on August 9, 2007, and incorporated herein by reference.)
10.40#	First Amendment to License Agreement Dated August 28, 2001 between Johnson Matthey PLC and Registrant dated September 30, 2002. (Filed as Exhibit 10.3 to Form 10-Q, as filed with the Securities and Exchange Commission on November 9, 2007.)
10.41#	License Agreement by and between the Registrant and Indena, S.p.A. dated as of July 17, 2007. (Filed as Exhibit 10.4 to Form 10-Q, as filed with the Securities and Exchange Commission on November 9, 2007.)
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+	

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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.

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

# 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.

+ Filed herewith.

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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 14, 2008

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:

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Rajesh C. Shrotriya, M.D.  Rajesh C. Shrotriya, M.D.	Chairman of the Board, Chief Executive Officer, and President (Principal Executive Officer)	March 14, 2008
/s/ Shyam K. Kumaria  Shyam K. Kumaria	Vice President Finance (Principal Financial and Accounting Officer)	March 14, 2008
/s/ Mitchell P. Cybulski  Mitchell P. Cybulski	Director	March 14, 2008
/s/ Richard D. Fulmer  Richard D. Fulmer	Director	March 14, 2008
/s/ Stuart M. Krassner, Sc.D., Psy.D.  Stuart M. Krassner, Sc.D., Psy.D.	Director	March 14, 2008
/s/ Anthony E. Maida, III  Anthony E. Maida, III	Director	March 14, 2008
/s/ Julius A. Vida, Ph.D.	Director	March 14, 2008

Julius A. Vida, Ph.D.

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**  
**Consolidated Financial Statements**  
*As of December 31, 2007 and 2006 and*  
*For Each of the Three Years in the Period Ended December 31, 2007*

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**Consolidated Financial Statements**

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**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of  
Spectrum Pharmaceuticals, Inc.

We have completed the integrated audits of the accompanying consolidated balance sheets of Spectrum Pharmaceuticals, Inc. and Subsidiaries (the Company) as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity and comprehensive income (loss), and cash flows for each of the years in the three-year period ended December 31, 2007. We also have audited Spectrum Pharmaceuticals, Inc. and Subsidiaries' internal control over financial reporting as of December 31, 2007, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Spectrum Pharmaceuticals, Inc. and Subsidiaries' management is responsible for these financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying *Management's annual report on internal control over financial reporting*. Our responsibility is to express an opinion on these consolidated financial statements and an opinion on the Company's internal control over financial reporting based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the consolidated financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide 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 (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) 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 (3) 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.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Spectrum Pharmaceuticals, Inc. and Subsidiaries as of December 31, 2007 and 2006, and the

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consolidated results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2007, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, Spectrum Pharmaceuticals, Inc. and Subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

Kelly & Company

Costa Mesa, California  
March 14, 2008

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Table of Contents**Spectrum Pharmaceuticals, Inc. and Subsidiaries****Consolidated Balance Sheets**

	<b>December 31</b>	
	<b>2007</b>	<b>2006</b>
	<b>(In thousands, except share and per share data)</b>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 1,141	\$ 519
Marketable securities	54,518	50,178
Accounts receivable-trade, net of allowance for doubtful accounts	191	1,150
Prepaid expenses and other current assets	762	440
Total current assets	56,612	52,287
Property and equipment, net	716	625
Other assets	212	205
<b>Total assets</b>	<b>\$ 57,540</b>	<b>\$ 53,117</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable and other accrued liabilities	\$ 1,598	\$ 2,100
Accrued compensation	1,111	1,008
Accrued drug development costs	5,090	3,125
Total current liabilities	7,799	6,233
Deferred revenue and other credits	992	1,035
<b>Total liabilities</b>	<b>8,791</b>	<b>7,268</b>
Commitments and contingencies (Note 7)		
Minority interest		20
Stockholders' equity:		
Preferred stock, par value \$0.001 per share, 5,000,000 shares authorized:		
Series B Junior Participating preferred stock, 1,000,000 shares authorized, no shares issued and outstanding		
Series D 8% Cumulative Convertible Voting preferred stock, 600 shares authorized, stated value \$10,000 per share, issued and outstanding 49 shares at December 31, 2006		233
Series E Convertible Voting preferred stock, 2,000 shares authorized, stated value \$10,000 per share, \$2.0 million aggregate liquidation value, issued and outstanding 170 shares at December 31, 2007 and 2006	1,048	1,048
	31	25
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Common stock, par value \$0.001 per share, 100,000,000 shares authorized; issued and outstanding 31,233,798 and 25,217,793 shares at December 31, 2007 and December 31, 2006, respectively

Additional paid-in capital	288,927	251,880
Accumulated other comprehensive income	493	357
Accumulated deficit	(241,750)	(207,714)
<b>Total stockholders equity</b>	<b>48,749</b>	<b>45,829</b>
<b>Total liabilities and stockholders equity</b>	<b>\$ 57,540</b>	<b>\$ 53,117</b>

The accompanying notes are an integral part of the financial statements.

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Table of Contents**Spectrum Pharmaceuticals, Inc. and Subsidiaries****Consolidated Statements of Operations**

	<b>Years Ended December 31</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(In thousands, except share and per share data)</b>		
Revenues:			
Licensing and milestone revenues	\$ 7,672	\$ 5,000	\$ 56
Other revenue		581	
Product sales		92	521
Total revenues	7,672	5,673	577
Operating expenses:			
Cost of product sold		97	397
Research and development	33,285	23,728	13,483
General and administrative	11,582	7,741	6,619
Total operating expenses	44,867	31,566	20,499
Loss from operations	(37,195)	(25,893)	(19,922)
Other income, net	3,139	2,606	1,279
Net loss before minority interest in consolidated subsidiary	(34,056)	(23,287)	(18,643)
Minority interest in net loss of consolidated subsidiary	20	3	1
<b>Net loss</b>	<b>\$ (34,036)</b>	<b>\$ (23,284)</b>	<b>\$ (18,642)</b>
<b>Basic and diluted net loss per share</b>	<b>\$ (1.17)</b>	<b>\$ (0.96)</b>	<b>\$ (1.06)</b>
<b>Basic and diluted weighted average common shares outstanding</b>	<b>29,013,850</b>	<b>24,311,306</b>	<b>17,659,602</b>

The accompanying notes are an integral part of the financial statements.

Table of Contents**Spectrum Pharmaceuticals, Inc. and Subsidiaries****Consolidated Statements of Stockholders Equity and Comprehensive Income (Loss)**

	Preferred Stock		Common Stock		Additional	Deferred	Accumulated	Accumulated	Total
	Shares	Amount	Shares	Amount	Paid-in	Compensation	Comprehensive	Deficit	
					Capital		Income(Loss)		
	(In thousands, except share data)								
<b>Balance at December 31, 2004</b>	<b>448</b>	<b>\$ 2,542</b>	<b>14,825,558</b>	<b>\$ 15</b>	<b>\$ 201,218</b>	<b>\$ (97)</b>	<b>\$</b>	<b>\$ (165,788)</b>	<b>\$ 37,890</b>
Net loss								(18,642)	(18,642)
Unrealized loss on investments							(26)		(26)
Total comprehensive loss, net							(26)	(18,642)	(18,668)
Issuance of common stock and warrants for cash, net of issuance costs			8,119,617	9	40,087				40,096
Fair value of common stock issued to Altair Nanotechnologies, Inc. for drug license			100,000		594				594
Issuance of common stock upon exercise of warrants			300,963		1,052				1,052
Issuance of common stock upon exercise of employee stock options			16,450		21				21
Repurchase of warrants					(420)				(420)
Issuance of common stock to employees as compensation			115,000		490	(490)			

Fair value of warrants issued to consultants					614	(614)			
Amortization of deferred compensation						418			418
Series D preferred stock dividend paid with common stock			25,569						
<b>Balance at December 31, 2005</b>	<b>448</b>	<b>\$ 2,542</b>	<b>23,503,157</b>	<b>\$ 24</b>	<b>\$ 243,656</b>	<b>\$ (783)</b>	<b>\$ (26)</b>	<b>\$ (184,430)</b>	<b>\$ 60,983</b>
Net loss								(23,284)	(23,284)
Unrealized gain on investments							383		383
Total comprehensive gain (loss), net							383	(23,284)	(22,901)
Conversion of Series D preferred stock into Common Stock	(108)	(514)	460,126		514				
Conversion of Series E preferred stock into Common Stock	(121)	(747)	242,000		747				
Issuance of common stock and warrants to JBCPL for cash			120,000		419				419
Fair value of common stock issued to Targent, Inc. for acquisition of assets			600,000	1	2,741				2,742
Fair value of common stock issued to Altair Nanotechnologies, Inc. for meeting milestones			140,000		574				574
Issuance of common stock upon exercise of warrants			17,750		53				53
Issuance of common stock upon exercise of			1,500		3				3

employee stock options									
Issuance of common stock to 401(k) plan			39,906			176			176
Fractional share adjustments			(6)						
Share-based compensation expense and common stock issued			77,926			3,023	783		3,806
Series D preferred stock dividend paid with common stock			15,434						
Series D preferred stock dividend paid in cash						(26)			(26)
<b>Balance at December 31, 2006</b>	<b>219</b>	<b>\$ 1,281</b>	<b>25,217,793</b>	<b>\$ 25</b>	<b>\$ 251,880</b>	<b>\$</b>	<b>\$ 357</b>	<b>\$ (207,714)</b>	<b>\$ 45,829</b>
Net loss								(34,036)	(34,036)
Unrealized gain on investments							136		136
Total comprehensive gain (loss), net							136	(34,036)	(33,900)
Conversion of Series D preferred stock into common stock	(49)	(233)	207,957	1	232				
Issuance of common stock and warrants for cash, net of issuance costs			5,134,100	5	30,004				30,009
Fair value of common stock issued to Targent, Inc. for milestones			125,000			520			520
Share-based compensation expense and common stock issued			235,313			5,278			5,278
Issuance of common stock upon exercise of			161,145			519			519



warrants									
Issuance of common stock upon exercise of employee stock options		81,438			120				120
Issuance of common stock to 401(k) plan		44,118			211				211
Fair value of common stock issued to consultant for services		25,000			163				163
Fractional share adjustments		6							
Series D preferred stock dividend paid with common stock		1,928							
<b>Balance at December 31, 2007</b>	<b>170</b>	<b>\$ 1,048</b>	<b>31,233,798</b>	<b>\$ 31</b>	<b>\$ 288,927</b>	<b>\$</b>	<b>\$ 493</b>	<b>\$ (241,750)</b>	<b>\$ 48,749</b>

The accompanying notes are an integral part of the financial statements.

Table of Contents**Spectrum Pharmaceuticals, Inc. and Subsidiaries****Consolidated Statements of Cash Flows**

	<b>Years Ended December 31</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(In thousands, except share and per share data)</b>		
<i>Cash flows from operating activities:</i>			
Net loss	\$ (34,036)	\$ (23,284)	\$ (18,642)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	255	198	264
Share-based compensation	5,652	3,951	418
Fair value of common stock issued in connection with drug license	520	3,316	594
Minority interest in subsidiary	(20)	(3)	(1)
Changes in operating assets and liabilities:			
(Increase) Decrease in Accounts receivable	959	(863)	(88)
(Increase) Decrease in other assets	(268)	(63)	185
Increase in accounts payable and accrued expenses	1,463	2,111	1,141
Increase in accrued compensation and related taxes	103	325	21
Increase (Decrease) in deferred revenue and other credits	(43)	794	63
<b>Net cash used in operating activities</b>	<b>(25,415)</b>	<b>(13,518)</b>	<b>(16,045)</b>
<i>Cash flows from investing activities:</i>			
Sales of marketable securities	\$ 25,735	\$	\$ 60,115
Purchases of marketable securities	(30,000)	(14,901)	(59,171)
Purchases of property and equipment	(346)	(261)	(139)
<b>Net cash provided by (used in) investing activities</b>	<b>(4,611)</b>	<b>(15,162)</b>	<b>805</b>
<i>Cash flows from financing activities:</i>			
Proceeds from issuance of common stock and warrants, net of related offering costs and expenses	\$ 30,009	\$ 419	\$ 40,096
Proceeds from the exercise of warrants	519	53	1,052
Repurchase of warrants			(420)
Proceeds from exercise of stock options	120	3	21
Cash dividends paid on preferred stock		(26)	
<b>Net cash provided by financing activities</b>	<b>30,648</b>	<b>449</b>	<b>40,749</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>622</b>	<b>(28,231)</b>	<b>25,509</b>
<b>Cash and cash equivalents, beginning of period</b>	<b>519</b>	<b>28,750</b>	<b>3,241</b>
<b>Cash and cash equivalents, end of period</b>	<b>\$ 1,141</b>	<b>\$ 519</b>	<b>\$ 28,750</b>

*SUPPLEMENTAL CASH FLOW INFORMATION*

Interest paid	\$		\$	
Income taxes paid	\$	5	\$	5
			\$	4

*SCHEDULE OF NONCASH INVESTING AND FINANCING ACTIVITIES*

Fair value of common stock issued in connection with drug license	\$	520	\$	3,316	\$	594
Fair value of restricted stock granted to employees and directors	\$	1,308	\$	338	\$	490
Fair value of warrants issued to consultants and placement agents	\$		\$	263	\$	614
Preferred stock dividends paid with common stock	\$	12	\$	70	\$	127

The accompanying notes are an integral part of the financial statements.

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

**Notes to the Consolidated Financial Statements**

**1. Nature of Business**

Spectrum Pharmaceuticals, Inc. (the Company) is a biopharmaceutical company engaged in the business of acquiring and advancing a diversified portfolio of drug products, with a focus on oncology, urology and other critical health challenges.

**2. Summary of Significant Accounting Policies and Estimates**

***Principles of Consolidation and Basis of Presentation***

The consolidated financial statements include the accounts of the Company and of our wholly-owned and majority-owned subsidiaries. As of December 31, 2007, we had two subsidiaries: NeoJB LLC (NeoJB), 80% owned, organized in Delaware in April 2002 and Spectrum Pharmaceuticals GmbH, wholly-owned inactive subsidiary, incorporated in Switzerland in April 1997. During 2006, NeoGene Technologies, Inc., an inactive subsidiary, was dissolved. We have eliminated all significant intercompany accounts and transactions.

Investments by outside parties in our majority-owned consolidated subsidiary are recorded as Minority Interest in Consolidated Subsidiary in our accounts, and stated net after allocation of income and losses in the subsidiary.

***Use of Estimates***

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and disclosure of contingent obligations in the financial statements and accompanying notes. Our most significant assumptions are employed in estimates used in determining values of financial instruments and accrued obligations, as well as in estimates used in applying the revenue recognition policy and estimating share-based compensation. 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.

***Reclassification of Accounts***

Certain reclassifications have been made to prior-year comparative financial statements to conform to the current year presentation. These reclassifications had no effect on previously reported results of operations or financial position.

***Cash, Cash Equivalents and Marketable Securities***

Cash, cash equivalents and marketable securities primarily consist of bank checking deposits, short-term treasury securities, 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 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 (FASB) Statement (SFAS) No. 115, Accounting for Certain Investments in Debt and

Equity Securities. Investments that lack immediate liquidity, or which we intend to hold for more than one year are classified as long-term investments, and included in other assets.

***Concentrations of Credit Risk***

All of our cash, cash equivalents and marketable securities are invested at major financial institutions. These institutions are required to invest our cash in accordance with our investment policy with the principal objectives being preservation of capital, fulfillment of liquidity needs and above market returns commensurate with preservation of capital. Our investment policy also requires that investments in marketable securities be in only highly

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

**Notes to the Consolidated Financial Statements (Continued)**

rated instruments, with limitations on investing in securities of any single issuer. To a limited degree these investments are insured by the Federal Deposit Insurance Corporation (FDIC) and by third party insurance. However, these investments are not insured against the possibility of a complete loss of earnings or principal and are inherently subject to the credit risk related to the continued credit worthiness of the underlying issuer and general credit market risks as existed during late 2007 and early 2008.

***Fair Value of Financial Instruments***

The carrying amounts of cash and cash equivalents, marketable securities, accounts receivable, accounts payable and accrued liabilities, as reported in the balance sheets, are considered to approximate fair value given the short term maturity and/or liquidity of these financial instruments.

***Property and Equipment***

We carry property and equipment at historical cost. Equipment is depreciated on a straight-line basis over its estimated useful life (generally 5 to 7 years). Leasehold improvements are amortized over the shorter of the estimated useful life or lease term. Maintenance and repairs are expensed as incurred. Major renewals and improvements that extend the life of the property are capitalized.

We review long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. If impairment is indicated, we reduce the carrying value of the asset to fair value.

***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.

***Industry Segment and Geographic Information***

We operate in one business segment, that of acquiring, developing and commercializing prescription drug products. Accordingly, the accompanying financial statements are reported in the aggregate, including all our activities in one segment. We had no foreign operations for any of the years presented herein.

***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,

Table of Contents**Spectrum Pharmaceuticals, Inc. and Subsidiaries****Notes to the Consolidated Financial Statements (Continued)**

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. The Company reviews and accrues drug development 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 recorded in the period in which the facts that give rise to the revision become known.

***Basic and Diluted Net Loss Per Share***

In accordance with FASB Statement No. 128, Earnings Per Share, we calculate basic and diluted net loss per share using the weighted average number of common shares outstanding during the periods presented, and adjust the amount of net loss, used in this calculation, for preferred stock dividends declared during the period.

We incurred net losses in each of the periods presented, and as such, did not include the effect of potentially dilutive common stock equivalents in the diluted net loss per share calculation, as their effect would be anti-dilutive for all periods. Potentially dilutive common stock equivalents would include the common stock issuable upon conversion of preferred stock and the exercise of warrants and stock options that have conversion or exercise prices below the market value of our common stock at the measurement date.

The following data show the amounts used in computing basic loss per share for each of the three years in the period ended December 31, 2007.

	<b>For the Years Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(In thousands, except share and per share data)</b>		
Net loss	\$ (34,036)	\$ (23,284)	\$ (18,642)
Less: Preferred dividends paid in cash or stock	(12)	(96)	(127)
Loss attributable to common stockholders used in computing basic earnings per share	\$ (34,048)	\$ (23,380)	\$ (18,769)
Weighted average shares	29,013,850	24,311,306	17,659,602
Basic and diluted net loss per share	\$ (1.17)	\$ (0.96)	\$ (1.06)



***Accounting for Share-Based Compensation***

In December 2004, the 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 (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 equity 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

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**Table of Contents****Spectrum Pharmaceuticals, Inc. and Subsidiaries****Notes to the Consolidated Financial Statements (Continued)**

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 share-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 options based 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 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.

We recorded share-based compensation during each of the three years in the period ended December 31, 2007 as follows:

	2007	2006	2005
	(In thousands)		
Research and development	\$ 3,555	\$ 2,540	\$ 289
General and administrative	2,097	1,411	129
<b>Total Share-based compensation</b>	<b>\$ 5,652</b>	<b>\$ 3,951</b>	<b>\$ 418</b>

The following table illustrates the effect on net loss and loss per share if we had applied the fair value recognition provisions of SFAS No. 123, Accounting for Stock-Based Compensation, to stock-based employee compensation, using the straight-line method, for periods prior to January 1, 2006.

	Year Ended December 31, 2005 (Amounts in thousands except share and per share data)
Net loss, as reported	\$ (18,642) (4,387)

Less: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effect

Pro forma net loss	\$	(23,029)
Loss per share:		
Basic and diluted as reported	\$	(1.06)
Basic and diluted pro forma	\$	(1.31)

***Income Taxes***

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on the deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. The Company has determined that the deferred tax asset does not meet the more likely than not criteria under

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

**Notes to the Consolidated Financial Statements (Continued)**

SFAS No. 109, *Accounting for Income Taxes*, and, accordingly, a valuation allowance has been recorded to reduce the net deferred tax asset to zero.

***Comprehensive Income***

Comprehensive income is calculated in accordance with SFAS No. 130, *Reporting Comprehensive Income*. SFAS No. 130 requires the disclosure of all components of comprehensive income, including net income and changes in equity during a period from transactions and other events and circumstances generated from non-owner sources. The Company's accumulated other comprehensive income at December 31, 2007 and 2006 consisted primarily of unrealized gains and losses on investments in marketable securities as of those dates and the change during the years then ended is reported in the statements of stockholders' equity and comprehensive income (loss).

***New Accounting Pronouncements***

In September 2006, FASB Statement No. 157 *Fair Value Measurements*, or SFAS 157, was issued. This Statement defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, or GAAP, and expands disclosures about fair value measurements. The Statement is effective January 1, 2008. We are currently evaluating the impact, if any, this standard will have on our financial statements.

In February 2007, FASB Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, including an amendment of FASB Statement No. 115, or SFAS 159, was issued. This Statement permits us to choose to measure many financial instruments and certain other items at fair value. It also establishes presentation and disclosure requirements. This Statement is effective January 1, 2008. We are currently evaluating the impact, if any, this standard will have on our financial statements.

In June 2007, EITF 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*, or EITF 07-3, was issued. EITF 07-3 provides that nonrefundable advance payments made for goods or services to be used in future research and development activities should be deferred and capitalized until the related goods or services are delivered or are performed, when the amounts would be recognized as an expense. This standard is effective for new contracts entered into after January 1, 2008. We are currently evaluating the impact, if any, this standard will have on our financial statements.

In December 2007, the EITF of the FASB reached a consensus on Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). The EITF concluded on the definition of a collaborative arrangement and that revenues and costs incurred with third parties in connection with collaborative arrangements would be presented gross or net based on the criteria in EITF 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*, and other accounting literature. Based on the nature of the arrangement, payments to or from collaborators would be evaluated and its terms, the nature of the entity's business, and whether those payments are within the scope of other accounting literature would be presented. Companies are also required to disclose the nature and purpose of collaborative arrangements along with the accounting policies and the classification and amounts of significant financial-statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other accounting literature; however required disclosure under EITF 07-1 applies to the entire collaborative agreement. This Issue is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, and is to be applied retrospectively to all periods

presented for all collaborative arrangements existing as of the effective date. We do not expect this will have a significant impact on our financial statements.

In December 2007, the FASB issued SFAS No. 141(R), Business Combinations (SFAS No. 141(R)), which replaces SFAS No. 141, Business Combinations, requires an acquirer to recognize the assets acquired, the liabilities assumed, and any non-controlling interest in the acquiree at the acquisition date, measured at their fair values as of that date, with limited exceptions. This Statement also requires the acquirer in a business combination achieved in stages to recognize the identifiable assets and liabilities, as well as the non-controlling interest in the acquiree, at the

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

**Notes to the Consolidated Financial Statements (Continued)**

full amounts of their fair values. SFAS No. 141(R) makes various other amendments to authoritative literature intended to provide additional guidance or to confirm the guidance in that literature to that provided in this Statement. This Statement applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. We do not expect this will have a significant impact on our financial statements.

In December 2007, the FASB issued SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements (SFAS No. 160), which amends Accounting Research Bulletin No. 51, Consolidated Financial Statements, to improve the relevance, comparability, and transparency of the financial information that a reporting entity provides in its consolidated financial statements. SFAS No. 160 establishes accounting and reporting standards that require the ownership interests in subsidiaries not held by the parent to be clearly identified, labeled and presented in the consolidated statement of financial position within equity, but separate from the parent's equity. This statement also requires the amount of consolidated net income attributable to the parent and to the non-controlling interest to be clearly identified and presented on the face of the consolidated statement of income. Changes in a parent's ownership interest while the parent retains its controlling financial interest must be accounted for consistently, and when a subsidiary is deconsolidated, any retained non-controlling equity investment in the former subsidiary must be initially measured at fair value. The gain or loss on the deconsolidation of the subsidiary is measured using the fair value of any non-controlling equity investment. The Statement also requires entities to provide sufficient disclosures that clearly identify and distinguish between the interests of the parent and the interests of the non-controlling owners. This Statement applies prospectively to all entities that prepare consolidated financial statements and applies prospectively for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. We do not expect this will have a significant impact on our financial statements.

**3. Products Under Development**

We are developing our proprietary drugs for the treatment of a variety of cancers and other unmet medical needs. On March 7, 2008, we received approval of our NDA for LEVOleucovorin and we anticipate launching LEVOleucovorin in mid-2008. Also, during the 4th quarter of 2008, we will launch sumatriptan injection, through our commercialization partner, Par Pharmaceutical Companies, Inc., or Par.

The following is a brief description of the key products under development as of December 31, 2007 that represent nearer term Revenue or Development expense potential and related business alliances:

***Levoleucovorin for Injection:*** On March 7, 2008, our NDA for our proprietary drug LEVOleucovorin was approved by the FDA. LEVOleucovorin is indicated after high-dose methotrexate therapy in patients with osteosarcoma, and to diminish the toxicity and counteract the effects of impaired methotrexate elimination or inadvertent overdose of folic acid antagonists.

In April 2006, we acquired all of the oncology drug assets of Targent, Inc. The principal asset in the transaction was a license agreement to market LEVOleucovorin in the field of oncology in North America. We paid an up-front fee in common stock, with a fair market value of approximately \$2.7 million, and are contingently obligated to pay additional amounts based upon achievement of milestones. At our option, cash payments for milestones specified in the agreement may be paid in shares of the Company's common stock having a value determined as provided in the asset purchase agreement, equal to the cash payment amount. In 2007, we recorded a stock-based research and

development charge of \$520,000, which represents the fair market value of 125,000 shares of our common stock issued in October 2007 as a milestone payment to Targent, LLC.

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**Table of Contents****Spectrum Pharmaceuticals, Inc. and Subsidiaries****Notes to the Consolidated Financial Statements (Continued)**

*Sumatriptan Injection:* In connection with the 2004 filing of an ANDA with paragraph IV certification for sumatriptan injection, which is marketed by GlaxoSmithKline, or GSK, under the brand name Imitrex®, during 2005 and 2006 we were in litigation with GSK. In December 2006, this patent litigation was 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 distribute authorized generic versions of sumatriptan injection products in the United States with an expected launch in the fourth quarter of 2008 during GSK's sumatriptan pediatric exclusivity period. We will launch sumatriptan injection through our partner for the sale and distribution of the drug, Par Pharmaceutical Companies, Inc., or Par, with whom we entered into a strategic alliance in February 2006. Pursuant to the agreement with Par, as amended, we received a \$5 million payment from Par related to sumatriptan injection. Pursuant to our revenue recognition policy, this amount was recorded as revenue in 2006 based on a determination that we had no significant remaining obligations in connection with the milestone.

*EOquin®:* EOquin, a synthetic drug which is activated by certain enzymes present in higher amounts in cancer cells than in normal tissues, is currently being developed for non-invasive bladder cancer. In March 2007, we received concurrence from the FDA for the design of a Phase 3 study protocol for the treatment of non-invasive bladder cancer under a special protocol assessment procedure. The development plan for EOquin calls for two randomized, double-blind, placebo-controlled Phase 3 clinical trials, each with 562 patients with T<sub>a</sub> G1-G2 (low grade) non-invasive bladder cancer. The first study began during the second quarter of 2007, and the second study began during the third quarter of 2007. We recently received scientific advice from the European Medicines Agency, or EMEA, whereby the EMEA agreed that the two Phase 3 studies being conducted at this time, mostly in the United States, should be sufficient for a regulatory decision regarding European registration. We continue to enroll patients in these two studies and plan to add study sites in Canada to accelerate enrollment since we recently received authorization from the Canadian Health Authorities allowing us to initiate the trial in Canada.

In 2001, we in-licensed exclusive worldwide rights to EOquin from the New Drug Development Office in the Netherlands. We paid an up-front fee, and are contingently obligated to pay additional amounts based upon achievement of specified milestones and royalties based on any future net sales.

*Ozarelix:* Ozarelix, a fourth generation LHRH (Luteinizing Hormone Releasing Hormone, also known as GnRH or Gonadotropin Releasing Hormone) antagonist has initially exhibited potential in hormone-dependent prostate cancer and benign prostatic hypertrophy (BPH). 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 76 men suffering from BPH. We completed patient enrollment and expect that complete data will be available by mid-April 2008. While we wait for the data, we are concurrently working on the design of the protocol for the next study, which is expected to initiate soon thereafter.

In 2004, we entered into a license agreement with a subsidiary of Aeterna Zentaris Inc., Aeterna 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 Phase 2 trials, we paid to Aeterna Zentaris a milestone payment of 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 up-front 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

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

**Notes to the Consolidated Financial Statements (Continued)**

our license agreement with Aeterna Zentaris, we are entitled to receive fifty percent of the up-front and milestone payments and royalties received from Nippon Kayaku Co. Ltd. by Aeterna Zentaris. Our share of the up-front payments, \$891,000 received in January 2007, was recorded as deferred income at December 31, 2006, and will be recorded as revenue in accordance with our revenue recognition policy, namely when we have no significant future performance obligations.

*Ortataxel:* Ortataxel belongs to a new generation of taxanes with the potential to be active against tumors resistant to paclitaxel (Bristol-Myers Squibb's Taxol®) and docetaxel (Sanofi-Aventis' Taxotere®). Phase 1 and 2 studies in over 350 patients in solid tumors have indicated a substantial level of activity. While we are optimizing the oral formulation for better bioavailability, we are considering some studies with the parenteral formulation.

In July 2007, we entered into a worldwide license agreement and acquired certain rights from Indena S.p.A., the Italian company that discovered ortataxel, and agreed to make an upfront payment, subject to certain conditions, plus regulatory and sales milestones, and royalties on future net sales. In October 2007, we paid Indena approximately \$2.8 million in upfront license fees.

*Satraplatin:* Satraplatin is an orally administered chemotherapeutic agent whose development is being funded by our development partner, GPC Biotech AG, or GPC. In 2007 we recorded \$7.2 million in milestone revenues from GPC in connection with the filing with and acceptance of an NDA by the FDA, and the filing and acceptance of a Marketing Authorization Application that was filed by a sub-licensee of GPC with the EMEA. Also, in 2007, we paid Johnson Matthey, our licensor for the drug, an aggregate of \$1 million in milestone payments, \$500,000 on the filing of the NDA and \$500,000 upon the acceptance of the NDA. On October 30, 2007, GPC announced that the Phase 3 Satraplatin and Prednisone Against Refractory Cancer trial evaluating satraplatin for the treatment of hormone-refractory prostate cancer did not meet its primary efficacy endpoint. GPC has stated that it has revised its development plans for Satraplatin and has decided to continue certain trials, stop other studies and selectively initiate new trials.

In 2001, we in-licensed satraplatin from Johnson Matthey PLC. In 2002, in exchange for an up-front license fee and future milestones and royalties, we entered into a co-development and license agreement with GPC for further development and commercialization of satraplatin. Under the terms of this agreement, GPC agreed to fully fund the development expenses for satraplatin. Licensing fees in 2007 and 2005 amounted to approximately \$472,000 and \$56,000, respectively, and represented product commissions.

**Table of Contents****Spectrum Pharmaceuticals, Inc. and Subsidiaries****Notes to the Consolidated Financial Statements (Continued)****4. Marketable Securities**

Cash, cash equivalents, and investments in marketable securities totaled \$55.8 million and \$50.8 million as of December 31, 2007 and 2006, respectively. The following is a summary of such investments (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash	Marketable Security Current	Security Long Term
December 31, 2007							
Cash, Cash Equivalents	\$ 1,141			\$ 1,141	\$ 1,141		
U.S. Government securities	491			491		\$ 491	
Corporate debt securities	51,676		\$ 117	51,559		51,559	
Other securities	2,020	\$ 610		2,630		2,468	\$ 162
Total investments	\$ 55,328	\$ 610	\$ 117	\$ 55,821	\$ 1,141	\$ 54,518	\$ 162
December 31, 2006							
Cash, Cash Equivalents	\$ 519			\$ 519	\$ 519		
U.S. Government securities	13,508			13,508		13,508	
Corporate debt securities	33,957			33,957		33,957	
Other securities	2,457	357		2,814		2,713	\$ 101
Total investments	\$ 50,441	\$ 357	\$	\$ 50,798	\$ 519	\$ 50,178	\$ 101

*Available-for-sale* marketable securities are carried at fair value, with any unrealized gains and losses included as a component of accumulated other comprehensive income (loss) in stockholders' equity. Realized gains and losses and declines in value judged to be other-than-temporary, as well as interest income and dividends on investments, are included in other income and expense. Net realized gains and losses were not significant for any of the three years in the period ended December 31, 2007. In order to preserve the liquidity of our investments, subsequent to December 31, 2007, we converted substantially all of our investments, including all of our market auction debt securities, into highly liquid investments.

*Available-for-sale* securities that lack immediate liquidity, or which we intend to hold for more than one year are classified as long-term investments and are included in other assets.

**5. Property and Equipment**

As of December 31, 2007 and 2006, property and equipment consisted of:

	<b>2007</b>	<b>2006</b>
	<b>(Amounts in thousands)</b>	
Equipment	\$ 1,435	\$ 1,161
Leasehold improvements	588	556
Total property and equipment	2,023	1,717
Less: accumulated depreciation and amortization	(1,307)	(1,092)
<b>Property and equipment, net</b>	<b>\$ 716</b>	<b>\$ 625</b>

For the years ended December 31, 2007, 2006 and 2005, the Company recorded depreciation expense of approximately \$255,000, \$198,000 and \$264,000, respectively.

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**Table of Contents****Spectrum Pharmaceuticals, Inc. and Subsidiaries****Notes to the Consolidated Financial Statements (Continued)****6. Income Taxes**

In July 2006, the FASB issued FIN 48, Accounting for Uncertainty in Income Taxes. Under FIN 48, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, FIN 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company adopted the provisions of FIN 48 on January 1, 2007. There were no unrecognized tax benefits as of the date of adoption. As a result of the implementation of FIN 48, the Company did not recognize an increase in the liability for unrecognized tax benefits. There are no unrecognized tax benefits included in the balance sheet that would, if recognized, affect the effective tax rate.

Significant components of the income tax expense for each of the three years in the period ended December 31, 2007 are as follows:

	<b>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(Amounts in thousands)</b>		
Current:			
Federal			
State	\$ 5	\$ 5	\$ 4
Foreign			
	5	5	4
Deferred:			
Federal			
State			
Foreign			
	<b>\$ 5</b>	<b>\$ 5</b>	<b>\$ 4</b>

The following is a reconciliation from the statutory federal income tax rate to our effective tax rate for income taxes:

	<b>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(Amounts in thousands)</b>		
Computed at statutory tax rate	\$ (14,890)	\$ (9,904)	\$ (7,675)
Non-utilization of net operating losses	14,890	9,904	7,675
<b>Tax expense using effective tax rate</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>



Table of Contents**Spectrum Pharmaceuticals, Inc. and Subsidiaries****Notes to the Consolidated Financial Statements (Continued)**

Significant components of our deferred tax assets and liabilities as of December 31, 2007 and 2006 are shown below. A valuation allowance has been recognized to fully offset the net deferred tax assets as of December 31, 2007, 2006 and 2005 as realization of such assets is uncertain.

	<b>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(Amounts in thousands)</b>		
Deferred tax assets:			
Net operating loss and business credit carryforwards	\$ 76,869	\$ 66,426	\$ 58,453
Stock-based compensation	2,459	1,596	
Depreciation and amortization differences	340	318	240
<b>Net deferred tax assets</b>	<b>79,668</b>	<b>68,340</b>	<b>58,693</b>
Valuation allowance for deferred tax assets	(79,668)	(68,340)	(58,693)
<b>Total deferred tax assets</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>

At December 31, 2007 and 2006, we had Federal and California income tax loss carryforwards of approximately \$160 million and \$90 million, respectively. The Federal and California tax loss carryforwards will begin to expire in 2009 and 2008, respectively. Both Federal and California law limit the use of net operating loss carryforwards and other tax attributes in the case of an ownership change of a corporation as that term is defined by section 382 of the Internal Revenue Code. We have not yet completed an analysis to determine whether or not we have undergone any ownership changes, but we believe that one or more ownership changes may have occurred due to our issuances of equity securities over the past several years. Any ownership changes, as defined by the tax code, may severely restrict utilization of our carryforwards to the point that they may never be utilized. In addition, at December 31, 2007 we had research and development credit carryforwards of approximately \$8 million which will begin to expire in 2008 and also had foreign loss carryforwards of approximately \$41 million.

**7. Commitments and Contingencies*****Facility and Equipment Leases***

As of December 31, 2007 we were obligated under a facility lease and operating equipment leases. During 2004 we renewed our facility lease for five years through June 2009, at which time we will have the option to renew for one additional five-year term.

Minimum lease requirements for each of the next five years and thereafter, under the property and equipment operating leases, are as follows:

**Lease  
Commitments**

(Amounts in thousands)

Year ending December 31:		
2008	\$	494
2009		253
2010		5
2011		
2012		
Thereafter		
	\$	<b>752</b>

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

**Notes to the Consolidated Financial Statements (Continued)**

Rent expense for the years ended December 31, 2007, 2006 and 2005 amounted to approximately \$579,000, \$343,000 and \$328,000, respectively, and was net of sub-lease rent income of \$225,000 and \$216,000 during the years ended December 31, 2006 and 2005, respectively.

***Licensing Agreements***

Almost all of our drug candidates are being developed pursuant to license agreements that provide us with rights to certain territories to, among other things, develop, sublicense, and sell the drugs. We have out-licensed development and commercialization rights to satraplatin, one of our drug product candidates, to GPC Biotech AG in exchange for upfront and milestone payments and royalties on sales of product. 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. Par Pharmaceutical Companies, Inc. is responsible for marketing our generic sumatriptan injection product and we will 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, if at all. Accordingly, the milestone payments represent contingent obligations that will be recorded as expense when the milestone is achieved. While it is difficult to predict when milestones will be achieved, we may achieve certain milestones over the next twelve months, thereby obligating us to issue up to 250,000 shares of our common stock and to pay up to approximately \$880,000 in cash. We further estimate that if all of our contingent milestones were successfully achieved within our anticipated timelines, our potential contingent cash development and regulatory milestone obligations, aggregating approximately \$70.8 million as of December 31, 2007, would be due approximately as follows: \$0.9 million in 2008; \$6.8 million in 2 to 3 years; \$14.2 million in 4 to 5 years; and \$48.9 million after 5 years. In the event these milestones are achieved, 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.

***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. At each period end, we accrue for all costs of goods and services received, with such accruals based on factors such as estimates of work performed, patient enrollment, completion of patient studies and other events.

As of December 31, 2007, we were committed under such contracts for up to approximately \$15.6 million, for goods and services estimated to be received in future periods as follows: \$9.0 million in 2008, \$4.8 million in 2 to 3 years,

and \$1.8 million in 4 to 5 years. 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. We are in a position to accelerate, slow-down or discontinue any or all of the projects that we are working on at any given point in time. Should we decide to discontinue and/or slow-down the work on any project, the associated costs for those projects would get limited to the extent of the work completed. Generally, we are able to

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

**Notes to the Consolidated Financial Statements (Continued)**

terminate these agreements due to the discontinuance of the related project(s) and thus avoid paying for the services that have not yet been rendered and our future purchase obligations would reduce accordingly.

***Employment Agreements***

We have entered into employment agreements with two of our named executive officers, Dr. Shrotriya, President and Chief Executive Officer, and Dr. Lenaz, Chief Scientific Officer, expiring December 31, 2008 and July 1, 2008, respectively. The employment agreements automatically renew for a one-year term unless either party gives written notice of such party's intent not to renew the agreement at least 90 days prior to the commencement of the next year. The employment agreements require each officer to devote his full working time and effort to the business and affairs of the Company during the term of the agreement. The employment agreements provide for a minimum annual base salary with annual increases, periodic bonuses and option grants as determined by the Compensation Committee of the Board of Directors.

Each officer's employment may be terminated due to expiration of the term of his employment agreement, mutual agreement, death or disability, or by us for cause (as that term is defined in the respective employment agreements) or without cause, or by the officer at any time upon ninety days' notice. The employment agreements provide for certain guaranteed severance payments and benefits if the officer's employment is terminated by us at the expiration of the term of the agreement, the officer is terminated without cause, if the officer's employment is terminated (other than by the officer) due to a change in control, or the officer is adversely affected (as described below) in connection with a change in control and the officer resigns. However, if the officer terminates his employment at any time upon ninety days' notice, or death or disability, he shall not be entitled to any severance.

***Litigation***

At December 31, 2007, we are involved with various legal matters arising from the ordinary course of business. Although the ultimate resolution of these various matters cannot be determined at this time, we do not believe that such matters, individually or in the aggregate, will have a material adverse effect on our future consolidated results of operations, cash flows or financial condition.

**8. Stockholders' Equity**

***Authorized Stock***

On July 6, 2006, our stockholders approved an amendment to our Certificate of Incorporation to increase the authorized number of shares of our common stock from 50 million shares to 100 million shares. The amendment was filed with the Delaware Secretary of State on July 7, 2006. Further, on July 7, 2006, we amended the Certificate of Designation of Rights, Preferences and Privileges of Series B Junior Participating Preferred Stock filed with the Delaware Secretary of State on December 18, 2000 to increase the authorized number of Series B Junior Participating Preferred Stock from 200,000 shares to 1,000,000 shares.

***Preferred Stock***

In December 2000, we adopted a stockholder rights plan pursuant to which we distributed rights to purchase units of our Series B Junior Participating Preferred Stock ( Series B Preferred Stock ). Under this plan, as amended through December 31, 2007, 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. Five days after the rights become exercisable, each right, other than rights held by the person or group of affiliated persons whose acquisition of more than 15% of our outstanding

**Table of Contents****Spectrum Pharmaceuticals, Inc. and Subsidiaries****Notes to the Consolidated Financial Statements (Continued)**

common stock caused the rights to become exercisable, will entitle its holder to buy, in lieu of shares of Series B Preferred Stock, a number of shares of our common stock having a market value of twice the exercise price of the rights. After the rights become exercisable, if we are a party to certain merger or business combination transactions or transfers 50% or more of our assets or earnings power (as defined), each right will entitle its holder to buy a number of shares of common stock of the acquiring or surviving entity having a market value of twice the exercise price of the right. The rights expire on December 13, 2010 and may be redeemed by us at one-tenth of one cent per right at any time up to ten days after a person has announced that they have acquired 15% or more of our outstanding common stock.

In May 2003, we received gross cash proceeds of \$6,000,000 in exchange for the issuance of 600 shares of our Series D 8% Cumulative Convertible Voting Preferred Stock (Series D Preferred Stock), convertible into 2,553,191 shares of common stock, and Series D Warrants, exercisable for five years, to purchase up to a total of 1,276,595 shares of our common stock at an exercise price of \$3.00 per share and up to a total of 1,276,595 shares of our common stock at an exercise price of \$3.50 per share. As of December 31, 2007, all Series D Preferred Stock had been converted to common stock. Dividends on the Series D Preferred Stock were payable quarterly at an annual rate of 8 percent either in cash or shares of our common stock at our discretion.

In September 2003, we received gross cash proceeds of \$20,000,000 in exchange for the issuance of 2,000 shares of our Series E Convertible Voting Preferred Stock (Series E Preferred Stock), convertible into 4,000,000 shares of common stock, and Series E Warrants, exercisable for five years, to purchase up to a total of 2,800,000 shares of our common stock at an exercise price of \$6.50 per share. No dividends are payable on the Series E Preferred Stock. Pursuant to certain provisions of the Certificate of Designation, Rights and Preferences of the Series E Preferred Stock, we have the option to redeem all of the unconverted Series E Preferred Stock outstanding at the end of a 20-day trading period if, among other things, in that period the common stock of the Company trades above \$12.00 per share.

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation, before any distribution of assets of the Corporation shall be made to the common stockholders, the holders of the Series D and Series E Preferred Stock shall be entitled to receive a liquidation preference in an amount equal to 120% of the stated value per share plus any declared and unpaid dividends thereon.

***Common Stock Issuances for Cash***

During each of the three years in the period ended December 31, 2007, we issued common stock and warrants for cash as follows:

	<b>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(In thousands, except share and per share data)</b>		
Shares of common stock	5,134,100	120,000	8,119,617
Weighted average price per share	\$ 6.25	\$ 3.49	\$ 5.27
Amount of financing	32,088	419	42,750

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Less: Offering Costs		2,079		2,654
Proceeds from common stock and warrants issued for cash	\$	30,009	\$ 419	\$ 40,096
Range of issuance prices on common stock sold	\$	6.25	\$ 3.49	\$ 5.25 to \$6.27
Warrants issued			50,000	4,000,000
Average exercise price per share on warrants	\$		\$ 5.25	\$ 6.62

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

**Notes to the Consolidated Financial Statements (Continued)**

In February 2005, in connection with the FDA approval of our ciprofloxacin tablets ANDA, an entity affiliated with J.B. Chemical & Pharmaceuticals Ltd., our joint venture partner for ciprofloxacin, invested \$750,000 in our common stock. We issued 119,617 restricted shares of common stock to that entity, based on the closing price of our common stock, \$6.27, on the day prior to the FDA approval.

In September 2005, we sold 8,000,000 shares of our common stock at a purchase price of \$5.25 per share and six-year warrants to purchase up to a total of 4,000,000 shares of our common stock at an exercise price of \$6.62 per share, for net cash proceeds of approximately \$39.3 million after offering costs of approximately \$2.7 million.

In July 2006, we agreed to terminate the supply agreement dated April 16, 2002, by and between J.B. Chemicals & Pharmaceuticals Ltd., or JBCPL, and NeoJB LLC, or NeoJB, an 80% owned subsidiary, whereby in addition to certain named products we also had the right of first refusal on products sold by JBCPL in the United States; and agreed to enter into a new supply agreement limited to four specified products, including ciprofloxacin and fluconazole tablets, to be supplied by JBCPL. JBCPL also agreed to purchase 120,000 shares of our common stock. We received an aggregate payment of \$1 million in consideration for the aforementioned modification of the supply agreement and issuance of shares. \$419,000 of the proceeds, representing the fair value of the common stock on the effective date of the agreement was recorded as sale of common stock. Pursuant to our revenue recognition policy, the remainder of the proceeds, \$581,000 was recorded as other revenue for 2006.

In May 2007, we sold 5,134,100 shares of our common stock at a purchase price of \$6.25 per share for net cash proceeds of approximately \$30 million, after placement agent fees and other offering costs of approximately \$2 million. No warrants were issued in connection with this offering.

***Other Equity Transactions***

In January 2005, in connection with the license agreement with Altair Nanotechnologies, Inc, we issued 100,000 shares of the Company's common stock to Altair. The fair value of the stock, \$594,000, was recorded as a stock-based research and development charge for the year ended December 31, 2005.

In connection with the acquisition in April 2006 of all of the oncology assets of Targent, Inc., we issued to Targent and its stockholders an aggregate amount of 600,000 shares of the Company's common stock, with a fair value of \$2,742,000 as of the transaction closing date, all of which amount representing purchased research and development, has been charged to expense at the closing of the transaction as a stock-based charge. Targent is eligible to receive additional payments of shares of the Company's common stock and/or cash upon achievement of certain regulatory and sales milestones, if any. At our option, cash payments specified in the agreement may be paid in shares of the Company's common stock having a value determined as provided in the asset purchase agreement, equal to the cash payment amount.

In June 2006, we issued to Altair Nanotechnologies, Inc., or Altair, 140,000 shares of the Company's common stock, representing payment of a milestone pursuant to the license agreement for RenaZorb, as well as additional amounts for transfer of technology related to formulation improvements to RenaZorb developed by Altair. The fair value of the stock, \$574,000, was recorded as a stock-based research and development charge for the year ended December 31, 2006.

In October 2007, we issued to Targent, Inc. 125,000 shares of the Company's common stock, for payment of a milestone pursuant to the license agreement for LEVOleucovorin. The fair value of the stock, \$520,000, was recorded as a stock-based research and development charge for the year ended December 31, 2007.



**Table of Contents****Spectrum Pharmaceuticals, Inc. and Subsidiaries****Notes to the Consolidated Financial Statements (Continued)*****Common Stock Reserved for Future Issuance***

As of December 31, 2007, approximately 16 million shares of common stock were issuable upon conversion or exercise of rights granted under prior financing arrangements and stock options and warrants, as follows:

Conversion of Series E preferred shares	340,000
Exercise of stock options	6,482,260
Exercise of warrants	9,652,051
<b>Total shares of common stock reserved for future issuances</b>	<b>16,474,311</b>

***Warrants Activity***

We typically issue warrants to purchase shares of our common stock to investors as part of a financing transaction or in connection with services rendered by placement agents and consultants. Our outstanding warrants expire on varying dates through September 2013. Below is a summary of warrant activity during each of the three years in the period ended December 31, 2007. A summary of warrant activity follows:

	<b>2007</b>		<b>2006</b>		<b>2005</b>	
	<b>Common Stock Warrants</b>	<b>Weighted Average Exercise Price</b>	<b>Common Stock Warrants</b>	<b>Weighted Average Exercise Price</b>	<b>Common Stock Warrants</b>	<b>Weighted Average Exercise Price</b>
Outstanding at beginning of year	9,917,077	\$ 6.71	9,920,703	\$ 7.20	6,561,789	\$ 9.71
Granted			50,000	5.25	4,120,000	6.58
Repurchased					(420,000)	6.50
Exercised	(161,145)	3.22	(17,750)	3.00	(300,963)	3.50
Expired	(103,881)	30.54	(35,876)	(143.44)	(40,123)	388.06
<b>Outstanding, at end of year</b>	<b>9,652,051</b>	<b>\$ 6.51</b>	<b>9,917,077</b>	<b>\$ 6.71</b>	<b>9,920,703</b>	<b>\$ 7.20</b>
<b>Exercisable at the end of year</b>	<b>9,572,051</b>	<b>\$ 6.52</b>	<b>9,782,077</b>	<b>\$ 6.73</b>	<b>9,800,703</b>	<b>\$ 7.23</b>

During 2007, no warrants were issued. During the years ended December 31, 2006 and 2005, we granted warrants to consultants at exercise prices equal to or greater than the quoted price of our common stock on the grant dates. The fair value of warrants granted to consultants in the years ended December 31, 2006 and 2005 were valued at \$177,000

and \$593,000, respectively using the Black-Scholes option pricing model, with the following assumptions: dividend yield of 0%; expected volatility of 80% (2006) and 90% (2005); risk free interest rate of 5.21% (2006) and 4.0% (2005); and an expected life of 5 years; and is being amortized to expense, net of forfeitures, as a component of stock-based charges, over the vesting period of the related grants. The following table summarizes information about warrants outstanding at December 31, 2007:

<b>Range of Exercise Price</b>	<b>Warrants Outstanding 12/31/2007</b>	<b>Weighted Average Remaining Life</b>	<b>Weighted Average Exercise Price</b>	<b>Warrants Exercisable at 12/31/2007</b>	<b>Weighted Average Exercise Price</b>
\$3.00 to \$5.00	1,645,846	0.99	\$ 3.72	1,645,846	\$ 3.72
\$5.01 to \$10.00	7,981,205	2.83	7.07	7,901,205	7.09
\$10.01 to \$87.50	25,000	1.81	11.50	25,000	11.50
	9,652,051			9,572,051	

Table of Contents**Spectrum Pharmaceuticals, Inc. and Subsidiaries****Notes to the Consolidated Financial Statements (Continued)****9. Share-Based Compensation***Stock Options*

We have two stock incentive plans: the 1997 Stock Incentive Plan (1997 Plan) and the 2003 Amended and Restated Incentive Award Plan (2003 Plan), (collectively, the Plans). Subsequent to the adoption of the 2003 Plan, no new options have been granted pursuant the 1997 Plan. The 2003 Plan authorizes the grant, in conjunction with all of our other plans, of incentive awards, including stock options, for the purchase of up to a total of 30% of our issued and outstanding stock at the time of grant. As of December 31, 2007, approximately 2 million incentive awards were available for grant under the 2003 Plan.

During each of the three years in the period ended December 31, 2007, we granted stock options at exercise prices equal to or greater than the quoted price of our common stock on the grant dates. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions used for grants in 2007, 2006 and 2005, respectively: risk-free interest rates of 4.57% (2007), 4.58% (2006) and 3.87% (2005); zero expected dividend yields; expected lives of 5 years; expected volatility of 68.3% (2007), 75.2% (2006) and 90.0% (2005). The risk-free interest rate assumption is based upon observed interest rates appropriate for the expected term of the Company's employee stock options. The expected volatility is based on the historical volatility of the Company's stock. The Company has not paid any dividends on common stock since its inception and does not anticipate paying dividends on its common stock in the foreseeable future. The weighted average fair value of stock options, using the Black-Scholes option pricing model, that were granted in 2007, 2006 and 2005, was \$3.54, \$3.26 and \$4.27, respectively.

A summary of stock option activity for each of the three years in the period ended December 31, 2007, is as follows:

	2007		2006		2005	
	Common Stock Options	Weighted Average Exercise Price	Common Stock Options	Weighted Average Exercise Price	Common Stock Options	Weighted Average Exercise Price
Outstanding at beginning of year	4,640,252	\$ 5.86	3,661,682	\$ 6.98	2,370,026	\$ 7.97
Granted	1,974,700	5.85	1,277,000	5.10	1,415,202	5.95
Exercised	(81,438)	1.48	(1,500)	2.12	(16,450)	1.32
Forfeited	(39,425)	5.04	(66,002)	3.70	(49,392)	6.25
Expired	(11,829)	8.80	(230,928)	20.11	(57,704)	24.62
<b>Outstanding, at end of year</b>	<b>6,482,260</b>	<b>\$ 5.91</b>	<b>4,640,252</b>	<b>\$ 5.86</b>	<b>3,661,682</b>	<b>\$ 6.98</b>
<b>Exercisable at the end of year</b>	<b>4,185,273</b>	<b>\$ 5.89</b>	<b>3,045,015</b>	<b>\$ 5.88</b>	<b>2,003,257</b>	<b>\$ 7.58</b>

The following table summarizes information about stock options outstanding under all plans at December 31, 2007:

<b>Range of Exercise Price</b>	<b>Options Outstanding 12/31/2007</b>	<b>Weighted Average Remaining Life</b>	<b>Weighted Average Exercise Price</b>	<b>Options Exercisable at 12/31/2007</b>	<b>Weighted Average Exercise Price</b>
\$1.00 to \$2.50	493,250	5.39	\$ 1.71	493,250	\$ 1.71
\$2.51 to \$5.00	1,424,950	7.85	4.17	870,075	4.40
\$5.01 to \$10.00	4,533,632	8.04	6.22	2,795,520	6.17
\$10.01 to \$325.00	30,428	2.99	110.18	26,428	103.92
	6,482,260			4,185,273	

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Table of Contents**Spectrum Pharmaceuticals, Inc. and Subsidiaries****Notes to the Consolidated Financial Statements (Continued)**

Presented below is the aggregate intrinsic value of the stock options outstanding, vested and expected to vest, and exercisable as of December 31, 2007. The intrinsic value represents the total difference between the Company's closing common stock price on December 31, 2007 and the exercise price, multiplied by the number of all in-the-money options, that would have been received by the option holders had all option holders exercised their options on December 31, 2007. This amount changes based on the fair market value of the Company's common stock.

	<b>Common Stock Options</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Term  (In Years)</b>	<b>Aggregate Intrinsic Value (In thousands)</b>
Stock options as of December 31, 2007:				
Outstanding	6,482,260	\$ 5.91	7.51	\$ 499
Vested and expected to vest	6,252,561	\$ 5.91	7.47	\$ 499
Exercisable	4,185,273	\$ 5.89	6.87	\$ 499

During the years ended December 31, 2007 and 2006, the share-based charge in connection with the expensing of stock options was \$4.6 million and \$3.5 million, respectively. As of December 31, 2007, there was \$7.9 million of unrecognized share-based compensation cost related to stock options, which is expected to be recognized over a weighted average period of 2.3 years.

***Restricted Stock***

A summary of the status of the Company's restricted stock awards as of December 31, 2007 and of changes in unvested shares outstanding is as follows:

	<b>2007</b>		<b>2006</b>	
	<b>Restricted Stock Awards</b>	<b>Average Grant date Fair Value</b>	<b>Restricted Stock Awards</b>	<b>Average Grant date Fair Value</b>
Nonvested at beginning of period	146,250	\$ 4.25	115,000	\$ 4.26
Granted	265,000	\$ 5.56	80,000	\$ 4.23
Vested	(133,750)	\$ 5.22	(48,750)	\$ 4.25
Nonvested at the end of period	277,500	\$ 5.03	146,250	\$ 4.25

The fair value of restricted stock awards is the quoted market price of our stock on the grant date, and is charged to expense over the period of vesting. These awards are subject to forfeiture to the extent that the recipient's service is terminated prior to the shares becoming vested.

During the years ended December 31, 2007 and 2006, the stock-based charge in connection with the expensing of restricted stock awards was approximately \$842,000 and \$296,000, respectively. As of December 31, 2007, there was approximately \$1 million of unrecognized stock-based compensation cost related to nonvested restricted stock awards, which is expected to be recognized over a weighted average period of 2.0 years.

***401(k) Plan Matching Contribution***

During 2007 and 2006, we issued 44,118 and 39,906 shares of common stock as the Company's match of approximately \$211,000 and \$176,000 on the 401(k) contributions of its employees during those periods.

Table of Contents**Spectrum Pharmaceuticals, Inc. and Subsidiaries****Notes to the Consolidated Financial Statements (Continued)****10. Quarterly Financial Information (Unaudited)**

The following is a summary of the unaudited quarterly results of operations for each of the calendar quarters ended in the two-year period ended December 31, 2007 (in thousands, except per share data):

	<b>March 31</b>	<b>June 30</b>	<b>September 30</b>	<b>December 31</b>
	<b>(Amounts in thousands except share and per share data)</b>			
<b>Fiscal 2007</b>				
Revenues	\$ 343	\$ 4,032	\$ 3,250	\$ 47
Total operating expenses	\$ 8,817	\$ 11,060	\$ 11,559	\$ 13,431
Net loss	\$ (7,892)	\$ (6,258)	\$ (7,382)	\$ (12,346)
Basic and diluted loss per share	\$ (0.31)	\$ (0.22)	\$ (0.24)	\$ (0.04)
Shares used in calculation	25,290,717	28,442,904	31,034,241	31,207,861
<b>Fiscal 2006</b>				
Revenues	\$	\$	\$ 92	\$ 5,581
Total operating expenses	\$ 6,506	\$ 9,676	\$ 8,154	\$ 7,230
Net loss	\$ (5,873)	\$ (9,018)	\$ (7,402)	\$ (991)
Basic and diluted loss per share	\$ (0.25)	\$ (0.37)	\$ (0.30)	\$ (0.04)
Shares used in calculation	23,626,960	24,231,045	24,485,369	24,886,100

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**Table of Contents****EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
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 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.)
4.3	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.)
4.4	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.)
4.5	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.)
4.5*	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.)
4.6*	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.)
4.7	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.)
4.8	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.)
4.9	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.)
4.10	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.)
4.11	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.)
4.12	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.)
4.13	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.)



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- 4.14 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.)
  - 4.15 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.)
  - 4.16 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.)
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<b>Exhibit No.</b>	<b>Description</b>
4.17	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.)
4.18	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.)
4.19	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.)
4.20	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.)
4.21	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.)
4.22	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.)
4.23	Amendment No. 2 dated as of March 26, 2007, to Warrant issued by the Registrant to a consultant, dated as of September 17, 2003. (Filed as Exhibit 4.1 to Form 10-K/A, as filed with the Securities and Exchange Commission on April 30, 2007, 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.)
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	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.)
10.9	

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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.)

- 10.10\* 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.)
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<b>Exhibit No.</b>	<b>Description</b>
10.11	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.)
10.12*	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.)
10.13	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.)
10.14*	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.)
10.15	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.)
10.16#	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.)
10.17#	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.)
10.18	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.)
10.19*	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.)
10.20#	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.)
10.21#	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.)
10.22*	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.)
10.23#	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.)
10.24	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.)
10.25*	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.)

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- 10.26# 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.)
  - 10.27 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.)
  - 10.28# 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.)
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<b>Exhibit No.</b>	<b>Description</b>
10.29#	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.)
10.30#	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.)
10.31*	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.)
10.32#	Agreement by and between Registrant and Glaxo Group Limited (d/b/a GlaxoSmithKline) dated November 10, 2006. (Filed as Exhibit 10.38 to Form 10-K, as filed with the Securities and Exchange Commission on March 14, 2007, and incorporated herein by reference.)
10.33#	First Amendment to the Development and Marketing Agreement by and between Registrant and Par Pharmaceutical Companies, Inc. dated November 10, 2006. (Filed as Exhibit 10.39 to Form 10-K, as filed with the Securities and Exchange Commission on March 14, 2007, and incorporated herein by reference.)
10.34#	Supply and Distribution Agreement among Glaxo Group Limited, Glaxo Wellcome Manufacturing PTE Limited and Par Pharmaceutical, Inc. dated November 10, 2006. (Filed as Exhibit 10.40 to Form 10-K, as filed with the Securities and Exchange Commission on March 14, 2007, and incorporated herein by reference.)
10.35	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.)
10.36	Placement Agreement dated as of May 4, 2007, between the Registrant, Oppenheimer & Co. Inc., and Capital Markets LLC, Rodman & Renshaw, LLC, and Think Equity Partners, LLC. (Filed as Exhibit 1.1 to Form 8-K, as filed with the Securities and Exchange Commission on May 4, 2007, and incorporated herein by reference.)
10.37	Form of Subscription Agreement. (Filed as Exhibit 10.1 to Form 8-K, as filed with the Securities and Exchange Commission on May 4, 2007, and incorporated herein by reference.)
10.38*	2003 Amended and Restated Incentive Award Plan. (Filed as Exhibit 10.3 to Form 10-Q, as filed with the Securities and Exchange Commission on August 9, 2007, and incorporated herein by reference.)
10.39*	Summary of Director Compensation. (Filed as Exhibit 10.4 to Form 10-Q, as filed with the Securities and Exchange Commission on August 9, 2007, and incorporated herein by reference.)
10.40#	First Amendment to License Agreement Dated August 28, 2001 between Johnson Matthey PLC and Registrant dated September 30, 2002. (Filed as Exhibit 10.3 to Form 10-Q, as filed with the Securities and Exchange Commission on November 9, 2007.)
10.41#	License Agreement by and between the Registrant and Indena, S.p.A. dated as of July 17, 2007. (Filed as Exhibit 10.4 to Form 10-Q, as filed with the Securities and Exchange Commission on November 9, 2007.)
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.

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- 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.

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

# 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.

+ Filed herewith.