SPECTRUM PHARMACEUTICALS INC
Form 10-K
March 31, 2009

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

# Form 10-K

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For the fiscal year ended December 31, 2008**

**Or**

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For the transition period from to**

**Commission File Number: 000-28782**

**Spectrum Pharmaceuticals, Inc.®**
*(Exact Name of Registrant as Specified in its Charter)*

| **Delaware** | **93-0979187** |
|---|---|
| *(State or other jurisdiction of incorporation or organization)* | *(I.R.S. Employer Identification No.)* |
| **157 Technology Drive**<br>**Irvine, California**<br>*(Address of principal executive offices)* | **92618**<br>*(Zip Code)* |

**Registrant s telephone number, including area code:**
**(949) 788-6700**
**Securities registered pursuant to Section 12(b) of the Act:**

| Title of Each Class | Name of Each Exchange on Which Registered |
|---|---|
| Common Stock, $0.001 par value<br>Common Stock Purchase Warrants<br>Rights to Purchase Series B Junior Participating Preferred Stock | The NASDAQ Stock Market, LLC |

**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 o No þ

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 o No þ

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 þ No o

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 o

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 o Accelerated filer o Non-accelerated filer o Smaller reporting company þ
(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 o No þ

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2008 was $42,794,914 based on the closing sale price of such common equity on such date.

As of March 27, 2009 there were 32,530,636 shares of the registrant s common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Proxy Statement for the Registrant s 2009 Annual Meeting of Stockholders, to be filed on or before April 30, 2009, 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 co 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 and other consolidated entities, as a consolidated entity. We primarily conduct all our activities as Spectrum Pharmaceuticals.

Spectrum Pharmaceuticals, Inc.® is a registered trademark of Spectrum Pharmaceuticals, Inc. Fusilev™, Turning Insights Into Hope™ and our logos are trademarks owned by Spectrum Pharmaceuticals, Inc. EOquin® is a registered trademark of Allergan, Inc. Zevalin® is a registered trademark of RIT Oncology, LLC™, and RIT™ and RIT Oncology, LLC™ are registered trademarks of RIT Oncology, LLC, a wholly-owned subsidiary of Spectrum Pharmaceuticals, Inc. RenaZorb® is a registered trademark of Altair Nanomaterials, Inc., and licensed to Spectrum Pharmaceuticals, Inc. All other trademarks and trade names are the property of their respective owners.

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## PART I

### Item 1. *Business*

### Overview

We are a commercial stage biopharmaceutical company committed to developing and commercializing innovative therapies with a focus primarily in the areas of hematology-oncology and urology. We have a fully developed commercial infrastructure that is responsible for the sales and marketing of two drugs in the United States, namely Fusilev and Zevalin. Our lead developmental drug is apaziquone (formerly EOquin), which is presently being studied in two large Phase 3 clinical trials for non-muscle invasive bladder cancer under a strategic collaboration with Allergan Inc. Another drug, ozarelix is in a Phase 2 clinical trial for benign prostatic hypertrophy (BPH).

Our business strategy for 2009 is comprised of the following initiatives:

*Maximizing the growth potential for our marketed drugs, Fusilev and Zevalin.* The company s near-term outlook depends on sales and marketing successes associated with our two marketed drugs. We launched Fusilev in August 2008 and were able to successfully achieve broad utilization in community offices and institutions. Our second drug, Zevalin, is marketed by our subsidiary RIT Oncology LLC (RIT), which was formed in December 2008. A dedicated commercial organization comprised of sales representatives, account managers, medical science liaisons and a complement of other marketing personnel support the sales and marketing of these drugs. Together with multiple initiatives to address historical barriers to uptake of Zevalin, we believe we can capture the substantial growth potential in sales for both Fusilev and Zevalin. Both drugs have additional applications on file with the U.S. Food and Drug Administration (FDA) for new, larger indications in non-Hodgkin s lymphoma and metastatic colorectal cancer, respectively. We plan to fully capitalize on these potential indication approvals in a cash-efficient manner by staging appropriate infrastructure expansions to facilitate broad customer reach and to address other market requirements, as appropriate. These supplemental applications are currently under review by the FDA, with regulatory decisions expected in second half of 2009.

*Maximizing the asset value of apaziquone.* We took a giant step forward with our lead development asset, apaziquone, in late 2008 with the signing of a strategic collaboration with Allergan. We retained exclusive rights to apaziquone in Asia, including Japan and China while Allergan received exclusive rights to apaziquone for the treatment of bladder cancer in the rest of the world, including the United States, Canada and Europe. In the United States, we will co-promote apaziquone with Allergan and share in its profits and expenses. This drug is presently being studied, under a special protocol assessment procedure with the FDA and scientific advice from the European Medicines Agency (EMEA), in two large Phase 3 clinical trials for non-muscle invasive bladder cancer. Our goal is to complete enrollment in these two trials and also begin a study in Bacillus Calmette-Guérin, or BCG, refractory bladder cancer by the end of 2009. These studies have been and will be strategically placed in centers worldwide that have extensive clinical trial experience, so as to ensure proper execution. These studies are designed to clinically differentiate this drug versus standard of care, and to ultimately successfully address the unmet needs in this disease. We hope to continue to partially monetize this asset through seeking additional strategic collaborations in markets where we have sole rights. Specifically, our goal is to secure new partnerships for this agent in Japan and selected markets in Asia.

*Optimizing our development portfolio.* We continue to build on our core expertise in clinical development for the treatment of cancer and urology. We remain reliant on in-licensing strategies to seek drugs for

development. Most recently, the company has undertaken a criteria-based portfolio review, which is expected to result in streamlining our pipeline drugs, allowing for greater focus and integration of our development and commercial goals. The portfolio will be assessed based on factors that include, among others things, probability of clinical success, time and cost of development, market potential, synergies with marketed and other developmental drugs, and competitive landscape. As a result of this portfolio evaluation, a determination will be made whether to: 1) continue with the drug s clinical development; 2) terminate its development; or 3) out-license rights to a third party for development and commercialization.

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*Managing our financial resources effectively.* We remain committed to fiscal discipline, a policy which has allowed us to become exceptionally well capitalized among our peers, despite a very challenging fiscal environment. This policy includes the pursuit of non-dilutive funding options, prudent expense management, and the achievement of critical synergies within our operations in order to maintain a reasonable burn rate. Despite the build-up in operational infrastructure to facilitate the marketing of two drugs, we intend to be fiscally prudent in any expansion we undertake. In terms of revenue generation, we hope to become more reliant on sales from currently marketed drugs and intend to pursue out-licensing of apaziquone and select pipeline drugs in select territories, as discussed above. When appropriate, we may pursue other sources of financing, including non-dilutive financing alternatives. While we are currently focused on advancing our key drug 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, based on clinical success and commercial potential.

*Expanding commercial bandwidth through licensing and business development.* It remains our goal to identify drugs that will create strong synergies with our currently marketed drugs, including drugs in development. To this end, we will continue to explore strategic collaborations as these relate to drugs that are either in advanced clinical trials or are currently on the market. We believe that such opportunistic collaborations will provide synergies with respect to how we deploy our internal resources. In this regard, we intend to identify and secure drugs that have significant growth potential either through enhanced marketing and sales efforts or through pursuit of additional clinical development.

*Further enhancing the organizational structure to meet our corporate objectives.* We have highly experienced staff in pharmaceutical operations, clinical development, regulatory and commercial functions who come from small and mid-size biotech companies to large pharmaceutical companies. We recently strengthened the ranks of our management team, and will continue to pursue talent on an opportunistic basis. Finally, we remain committed to running a lean and efficient organization, while effectively leveraging our critical resources.

**Recent Developments**

In 2008, we continued to execute on our business strategy. Below are some key developments.

On March 7, 2008, we received approval from the FDA for our New Drug Application, or NDA, for Fusilev (levoleucovorin) for injection. We launched Fusilev in August and achieved net sales of approximately $7.7 million for 2008. In October, we filed a supplemental NDA for Fusilev in combination with 5-FU-containing regimens in the treatment of colorectal cancer. In November 2008, we also received a unique J-code for Fusilev from the Centers for Medicare and Medicaid Services (CMS). In December, Fusilev was listed in the National Comprehensive Cancer Network (NCCN) Drugs and Biologic Compendium for use in combination with high-dose methotrexate for the treatment of bone cancer (osteosarcoma and dedifferentiated chrondrosarcoma).

For apaziquone, in October 2008 we signed an exclusive development and commercialization collaboration agreement with Allergan, Inc. Under the terms of the agreement, Allergan paid us $41.5 million at closing and will make additional payments of up to $304 million based on the achievement of certain development, regulatory and commercialization milestones. We retained exclusive rights to apaziquone in Asia, including Japan and China. Allergan received exclusive rights to apaziquone for the treatment of bladder cancer in the rest of the world, including the United States, Canada and Europe. In the United States, we will co-promote apaziquone with Allergan and share equally profits and expenses. Allergan will also pay us royalties on all of its apaziquone sales outside of the United States. If we decide to opt-out of co-promoting the drug in the United States, our share of any future development costs shall be significantly reduced. Part of the aggregate development costs and marketing expenses incurred by us

shall be reimbursed by Allergan in the form of a one-time payment and instead of a sharing of profit and expenses, Allergan will pay us royalties in the United States that are slightly greater than the royalties paid on net sales outside the United States. In addition, Allergan will pay us up to $245 million in additional milestones based upon the achievement of certain sales milestones in the United States. Spectrum will continue to conduct the apaziquone clinical trials pursuant to a joint development plan, with Allergan bearing 65% of these expenses. We

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continue to recruit sites and enroll patients in these two studies and our goal is to complete enrollment for both Phase 3 clinical trials by year-end 2009.

In December 2008, we partnered with Cell Therapeutics, Inc. (CTI) to form a 50-50 owned joint venture, RIT Oncology, LLC (RIT) to commercialize and develop Zevalin ([90Y]-ibritumomab tiuxetan) in the United States. In December 2008, the FDA accepted for filing and review, and granted priority review status for, RIT s supplemental Biologics License Application (sBLA) for the use of Zevalin as first-line therapy for patients with B-cell follicular NHL. In March 2009, CTI sold to us their remaining 50% ownership in RIT, resulting in RIT becoming our wholly-owned subsidiary. A Prescription Drug User Fee Act (PDUFA) target date of July 2, 2009 was established by the FDA for a decision regarding the Zevalin sBLA.

In May 2008, we sold our rights to our share of profits of sumatriptan injection, the generic form of GlaxoSmithKline s Imitrex® injection, to our commercialization partner, Par Pharmaceutical Companies, Inc., which along with the sale of our other generic injectable products to Sagent Pharmaceuticals, netted us approximately $20.7 million.

We continued our efforts to build a global pharmaceutical organization in 2008. We formed two ex-US business entities, one a Canadian affiliate, Spectrum Pharma Canada, Inc. headquartered in the Province of Quebec, Canada, and the other a wholly-owned, Indian subsidiary, OncoRx Pharma Private Ltd., headquartered in Mumbai, India. We established these entities in an effort to facilitate the opening of clinical trials sites in these countries to continue the clinical development of our products at a reduced cost.

**Product Portfolio**

We have a product portfolio consisting of both commercial stage and development stage products. While we are committed to growing the sales of our marketed products, we want to make sure that we have a healthy pipeline of products under development to bring to the market.

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

Some of our drugs may prove to be beneficial in additional disease indications as we continue to study and develop these drugs. In addition, we have intellectual property rights to neurology compounds that we may out-license to third parties for further development.

**Overview of Cancer**

According to the American Cancer Society s publication Cancer Facts & Figures 2008, cancer is the second leading cause of death in the United States, accounting for approximately 25% of all deaths. 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 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, such as smoking.

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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, biological 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 that address cancer or cancer related indications with significant unmet medical need, that:

- are already approved for sale or 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.

**Our drug products**

*Zevalin ([90Y]-ibritumomab tiuxetan):* In December 2008, we acquired rights to commercialize and develop Zevalin in the United States, as the result of a transaction with Cell Therapeutics, Inc., further described below.

Zevalin is a prescribed form of cancer therapy called radioimmunotherapy. Radioimmunotherapy combines a source of radiation, called a radioisotope, with an antibody. As part of the Zevalin therapeutic regimen, the Y-90 radioisotope is combined with a monoclonal antibody (CD20 MAB) that specifically recognizes a particular part of a B-cell (the cells of the immune system that make antibodies to invading pathogens) called the CD20 antigen. The CD20 antigen is found on malignant and normal B-cells. As the patient is infused with Y-90 Zevalin and it enters the bloodstream, the antibody portion recognizes and attaches to the CD20 antigen on tumor cells, allowing the radiation energy emitted from the Y-90 radioisotope (*i.e.*, beta emission) to penetrate and damage the malignant B-cells as well as nearby neighboring cells, many of which are also lymphoma cells.

The current Zevalin therapeutic regimen also requires a bioscan of the prospective patient prior to treatment with Y-90 Zevalin. For the bioscan, the patient is infused with In-111 Zevalin, in which the Y-90 radioisotope is replaced with the In-111 radioisotope and combined with the CD20 MAB. In-111 Zevalin produces a kind of radiation called gamma emission, which is very similar to the kind of radiation used to produce x-rays. Once infused with In-111, the prospective patient goes through a bioscan (also known as an imaging study ). The bioscan allows a physician to follow In-111 Zevalin as it travels within the prospective patient s body. Based upon the distribution of In-111 Zevalin (whether the In-111 Zevalin goes to certain unintended areas of the body), the physician may elect to not infuse the patient with Y-90 Zevalin. Many Zevalin healthcare providers throughout the world do not believe that the In-111 bioscan is a necessary part of the Zevalin therapeutic regimen. Currently, we are working with the FDA to remove this bioscan requirement.

Zevalin is indicated as part of a Zevalin therapeutic regimen for treatment of relapsed or refractory, low-grade or follicular B-cell NHL, including patients with rituximab-refractory follicular NHL. Zevalin is also indicated, under accelerated approval, for the treatment of relapsed or refractory, rituximab-naive, low-grade and follicular NHL based on studies using a surrogate endpoint of overall response rate. Zevalin was approved by the FDA in February of 2002 as the first radioimmunotherapeutic agent for the treatment of NHL. For reference, the term refractory refers to lymphoma that does not respond to a particular therapy. The term relapsed refers to lymphoma that returns after initially responding to therapy. The terms low-grade and follicular refer to types of lymphoma cells as determined by laboratory tests, which have an indolent (slow growing) clinical course. Rituximab is a

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monoclonal antibody that specifically recognizes a particular part of a B-cell also called the CD 20 antigen, and is used as monotherapy or in combination in the treatment of B-cell NHL.

NHL is caused by the abnormal proliferation of white blood cells and normally spreads through the lymphatic system, a system of vessels that drains fluid from the body. There can be many different types of NHL which can be divided into aggressive NHL, a rapidly spreading acute form of the disease, and indolent NHL, which progresses more slowly, and can be classified as either B-cell or T-cell NHL. According to the National Cancer Institute s SEER database there were nearly 400,000 people in the U.S. with NHL in 2004. The American Cancer Society estimated that in the United States 66,120 people were expected to be newly diagnosed with NHL in 2008. Additionally, approximately 19,160 were expected to die from this disease in 2008.

In December 2008, the FDA accepted for filing and review, and granted priority review status for RIT s sBLA for the use of Zevalin as first-line consolidation therapy for patients with B-cell follicular NHL. Under a relapsed or refractory setting, Zevalin is used for treatment if a patient is not responding to first-line therapy with other chemotherapeutic, cytotoxic or anti-cancer drugs or if the lymphoma returns after first-line therapy. Consolidation therapy aims to rapidly improve the quality of the response achieved with initial remission induction treatment. Induction therapy is a treatment designed as a first step toward reducing the number of cancer cells. Currently, a PDUFA target date of July 2, 2009 has been established by the FDA for a decision regarding the Zevalin sBLA.

The sBLA is based upon data from the multinational, randomized Phase 3 First-line Indolent Trial (FIT) which evaluated the benefit and safety of a single infusion of Zevalin in 414 patients with CD20-positive follicular NHL who had achieved a partial response or a complete response after receiving one of the standard first-line chemotherapy regimens. The FIT trial demonstrated that when used as a first-line consolidation therapy for patients with follicular NHL, Zevalin significantly improved the median progression-free survival time from 13 months (control arm) to 37 months (Zevalin arm) ($p<0.0001$).

The primary investigators of the study concluded that Zevalin consolidation of first remission in advanced stage follicular NHL is highly effective, resulting in a total complete response (CR + CRu) rate of 87 percent and prolongation of median progression-free survival by approximately two years, with a toxicity profile comparable to that seen with Zevalin s use in approved indications. Zevalin-treated patients had reversible and manageable Grade 3 or 4 hematologic side effects including neutropenia in 67 percent, thrombocytopenia in 61 percent, and anemia in 3 percent of patients. Non-hematologic toxicities were 24 percent Grade 3, 5 percent Grade 4, and Grade 3 - 4 infection was 8 percent.

The following describes the principal commercial terms relating to Zevalin licensing and development:

On December 15, 2008, we and CTI closed a transaction to enter into a 50/50 owned joint venture called RIT. CTI previously acquired the U.S. rights to develop, market and sell Zevalin from Biogen Idec, Inc. on December 21, 2007.

Upon the closing of the transaction, CTI contributed the Zevalin product assets to RIT in exchange for a 50% membership interest in RIT and the cash payments to CTI noted below. CTI received an initial cash payment of $7.5 million at the closing of the transaction on December 15, 2008, and received an additional $7.5 million cash payment in early January 2009. CTI also had the option to sell its remaining 50% membership interest in RIT to us, subject to adjustment for any amounts owed between RIT and CTI at the time of sale. CTI exercised this Put option in February 2009. On March 15, 2009, we and CTI entered into an agreement to complete such sale for an aggregate amount of $16.5 million subject to certain adjustments for, among other things, payables determined to be owed between CTI and RIT. As a result of the sale, we own 100% of RIT and are its sole member and therefore, we have, through licenses, all of the U.S. rights to Zevalin.

In connection with obtaining the required consent of Biogen to the foregoing transactions, we entered into certain agreements with Biogen. Such agreements included:

an amendment to the original asset purchase agreement between CTI and Biogen (CTI/Biogen Agreement), modifying future milestone payments, to provide that (i) concurrently with the execution of the amendment CTI was required to pay Biogen $0.2 million (which was reimbursed to CTI by RIT from the

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initial capital contributions made by CTI and us), (ii) upon the December 2008 closing of the transaction, CTI was required to pay Biogen an additional $2.0 million (which was paid by RIT as successor to CTI under the amendment), (iii) upon the achievement of the specified FDA approval milestone, RIT (as successor to CTI) will be required to pay Biogen an additional amount of $5.5 million if the milestone event occurs in 2009 (provided that RIT may elect to defer any such payment until January 1, 2010, but upon such election the required payment will increase to $6.0 million), $7.0 million if the milestone event occurs in 2010, $9.0 million if the milestone event occurs in 2011, or $10.0 million if the milestone event occurs in 2012 or later. No other material terms of the CTI/Biogen Agreement were modified. CTI s rights and obligations, including its payment obligations to Biogen, including royalties on net sales of Zevalin and an additional regulatory milestone payment, under both the CTI/Biogen Agreement and the amendment were assigned to and assumed by RIT in connection with the closing of the joint venture transaction.

an amendment to the original supply agreement between Biogen and CTI (CTI/Biogen Supply Agreement), modifying certain of the pricing and manufacturing technology transfer terms contained in the CTI/Biogen Supply Agreement and also providing that the term of the agreement may be shortened in some instances in the event of a mid-term manufacturing technology transfer. CTI s rights and obligations, including its payment obligations to Biogen, under both the CTI/Biogen Supply Agreement and the amendment were assigned to and assumed by RIT in connection with the closing of the joint venture transaction.

a security agreement, by and between RIT and Biogen whereby RIT granted to Biogen a first priority security interest in all of RIT s assets, including the assets contributed to RIT by CTI in connection with the closing of the joint venture transaction, to secure certain payment, indemnification and other obligations of RIT to Biogen.

a guarantee, by Spectrum for the benefit of Biogen whereby we have, among other things, guaranteed the payment and performance all of RIT s obligations to Biogen (including its obligations as assignee of CTI under all contractual arrangements between CTI and Biogen that were assigned to and assumed by RIT in connection with the closing of the joint venture transaction).

pursuant to the transfer of Zevalin assets from CTI to RIT in December 2008, RIT assumed certain license and sublicense agreements with various third parties related to Zevalin intellectual property under which RIT is required to make certain payment obligations including milestone payments and royalties.

*Fusilev (levoleucovorin) for injection:* On March 7, 2008, our NDA for our proprietary drug Fusilev was approved by the FDA. We commercially launched Fusilev in August 2008, with an in-house sales force and commercialization team. Subsequent to the launch, in November 2008, we received a unique J-code for Fusilev from CMS, which went into effect on January 1, 2009. The J-code is a unique, product-specific billing code that assists providers (*e.g.*, physicians that prescribe Fusilev) in obtaining reimbursement for Fusilev.

Fusilev 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 may compete with the active *levo*-isomer for uptake at the cellular level. By removing the inactive *dextro* form, the dosage of Fusilev is one-half that of leucovorin and patients are spared the administration of an inactive substance.

Fusilev rescue 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. Fusilev has been designated as an orphan drug for its approved indications. Methotrexate is a widely used

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

In mid-year 2008, we filed an NDA amendment for Fusilev tablets. Following the tablet submission, in October 2008, we filed a sNDA for Fusilev (levoleucovorin) for injection in combination with 5-FU-containing

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regimens in the treatment of colorectal cancer. A PDUFA target date of October 8, 2009 has been established by the FDA for a decision regarding the sNDA.

Calcium leucovorin is currently a standard combination agent with 5-FU in various colorectal cancer treatment regimens. Calcium leucovorin potentiates the effects of 5-FU and its derivatives by stabilizing the binding of the drug s metabolite to its target enzyme, thus prolonging drug activity. There are peer-reviewed publications wherein Fusilev 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. The National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology[tm] in colon cancer and rectal cancer have been updated to reflect that Fusilev is available in the United States. Additionally, in the fourth quarter of 2008, Fusilev was listed and continues to be listed in the NCCN Drugs and Biologic Compendium for use in combination with high-dose methotrexate for the treatment of bone cancer (osteosarcoma and de-differentiated chrondrosarcoma). The NCCN Drugs and Biologics Compendium is an important reference that has been recognized by United HealthCare as a formal guidance for coverage policy. In addition, CMS announced in June 2008 that it would recognize the NCCN Drugs & Biologics Compendium as a source of information to determine which drugs may be covered under Medicare Part B.

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

In April 2006, we acquired all of the oncology drug product assets of Targent, Inc. Targent is eligible to receive payments, in the form of our common stock and/or cash, upon achievement of certain 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 Fusilev and a non-exclusive license under certain patents and know-how related to Fusilev to develop, make, have made, use, sell and have sold Fusilev 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 Fusilev products outside the field of oncology in North America. Under the terms of the license agreement, we paid Eprova $100,000 for the achievement of FDA approval of Fusilev. Eprova is also eligible to receive a payment upon achievement of another regulatory milestone, in addition to royalties on net sales. 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.

*Apaziquone (formerly known as EOquin):* Apaziquone 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 investigated for the treatment of non-muscle invasive bladder cancer (NMIBC), which is a cancer that is only in the innermost layer of the bladder and has not spread to deeper layers of the bladder.

The American Cancer Society estimated that the 2008 incidence and prevalence of bladder cancer in the United States would be approximately 68,810 and over 500,000, respectively. Based on Globocan data, we estimated that the 2008 incidence and prevalence of bladder cancer in Europe would be 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

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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 treatment of NMIBC. An immediate instillation of apaziquone 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 (also known as chemo-ablation).

Apaziquone is a bio-reductive prodrug that is activated by enzymes that are over expressed by bladder tumors. A pharmacokinetic study verified that apaziquone is not present in detectable levels in the bloodstream when the current proposed dose is given immediately after surgical resection. The proposed dose therefore carries a minimal risk of systemic toxicity which can arise from absorption of a drug through the bladder wall into the bloodstream. Additionally, the current proposed dose is a fraction of the systemic toxic dose. These features of apaziquone are distinct from other intravesical agents in use for the treatment of recurrent bladder cancer.

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

Phase 2 data has confirmed anti-tumor activity in patients with multiple, recurrent NMIBC, as evidenced by 31 of 46 patients (67%) showing a complete response after receiving six weekly treatments with 4 mg of apaziquone instilled into the urinary bladder in this marker lesion study. Apaziquone 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 September 2005, we initiated an open label, multi-center clinical study in Europe in high-risk NMIBC in 53 patients. Patients with high-risk NMIBC 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 has been completed and all patients will be followed for twenty-four months or until recurrence or disease progression is observed.

In 2006, we performed a 20 patient pilot safety study in low-grade NMIBC. In this study, apaziquone 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 apaziquone was not detected in the bloodstream.

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 apaziquone is two randomized, double-blind, placebo-controlled Phase 3 clinical trials, each with 562 patients with $T_aG1$-G2 (low-grade) non-muscle invasive bladder cancer. Patients are being randomized in a one-to-one ratio to apaziquone or placebo. Under the protocol, the patients are given a single 4 mg dose following surgical removal of the tumors. The primary endpoint is a statistically significant difference ($p < 0.05$) in the rate of tumor recurrence at year two between the apaziquone 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. In 2008, we 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 recruit sites and enroll patients in these two studies. Our goal is to complete

enrollment for both Phase 3 clinical trials by year-end 2009.

We plan to begin a study in BCG refractory bladder cancer by the end of 2009.

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

In October 2008, we terminated our 2001 license agreement for apaziquone with INC Research®, formerly NDDO Research Foundation, in the Netherlands as the patents underlying the agreement were all about to expire. Pursuant to the termination, INC assigned to us all rights it had in the know-how or intellectual property licensed under the agreement and all rights in may have had in any know-how or intellectual property created during the term of the agreement. In exchange we paid INC a small amount of cash and issued them a small number of shares of our common stock. In addition, INC is entitled to up to 25,000 additional shares of our common stock and an additional payment of $300,000 upon achievement of certain regulatory milestones.

In October, 2008, we entered into a license, development, supply and distribution agreement with Allergan Sales, LLC, Allergan USA, LLC and Allergan, Inc. pursuant to which we and Allergan agreed to a collaboration for the development and commercialization of a formulation of apaziquone suitable for use in treating cancer or precancerous conditions via instillation. The agreement provides that Allergan has the exclusive right to make, develop and commercialize apaziquone for the treatment of bladder cancer, or pre-bladder cancer conditions worldwide except for Asia (as is defined in the Agreement). We and Allergan also entered into a co-promotion agreement providing for the joint commercialization of apaziquone in the United States whereby we and Allergan will share equally all profits and commercialization expenses. We also have the right, in our sole discretion, to opt-out of the co-promotion agreement before January 1, 2012. If we do so, our share of any future development costs shall be significantly reduced. Part of the aggregate development costs and marketing expenses incurred by us since January 1, 2009 shall be reimbursed by Allergan in the form of a one-time payment. The co-promotion agreement will terminate and instead of a sharing of profit and expenses, Allergan will pay us royalties on a percentage of net sales of the apaziquone in the United States that are slightly greater than the royalties paid on net sales outside the United States. In addition, Allergan will pay us up to $245 million in additional milestones based upon the achievement of certain sales milestones in the United States.

In consideration for the rights granted under the license agreement, Allergan paid us an up-front fee of $41.5 million. In addition, Allergan will pay us up to $304 million based on the achievement of certain development, regulatory and sales milestones. Also, Allergan has agreed to pay us tiered royalties starting in the mid-teens based on a percentage of net sales of the apaziquone outside of the United States.

We will continue to conduct the current Phase 3 clinical trials as well as certain future planned clinical trials pursuant to a joint development plan, of which Allergan will fund 65% of the development costs.

*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, benign prostastic hypertrophy, or 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.

The prostate is a walnut-sized gland that forms part of the male reproductive and urinary 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 an age related 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.

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Testosterone is considered to play a role in BPH development. Unlike LHRH agonists, ozarelix, which is an antagonist of LHRH, has the potential to rapidly reduce testosterone in a dose dependent fashion thus decrease the prostate size and improve urinary 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 prostate around the urethra and the bladder neck without addressing the underlying condition of the enlarged prostate. Drugs in the second category, 5-alpha reductase inhibitors, work by blocking the conversion of testosterone to hormones that stimulate the growth of new prostate cells thereby slowing 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 effects on libido, potency, ejaculation, rhinitis and cardiovascular effects such as dizziness, fainting and lightheadedness. Many patients either do not respond or do not tolerate 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 and prolonged relief of the symptoms of BPH in affected men.

Phase 2 data from a European study with ozarelix in 144 patients with BPH in a double-blinded, randomized, placebo-controlled, multi-center, dose-ranging study were positive. Statistically significant positive 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 used for the next study.

In January 2007, we initiated in the United States a randomized, double-blind, placebo-controlled Phase 2b trial of ozarelix in 76 men with BPH. In the trial, men were dosed by intramuscular injection with 15 mg of ozarelix or placebo on day 1 and day 15 and were followed for nine months. The primary endpoint of the study was the improvement of BPH symptoms at 12 weeks as measured by the International Prostate Symptom Score, which is the instrument used to assess the severity of BPH in all research studies. Additionally, effects on urine flow, residual urine volume and quality of life were measured. While the results of this study were not as robust as seen in the previous study, the data did support clinically meaningful activity in BPH.

Accordingly, based on the results of the previous studies, we have initiated a multi-center, randomized, double-blind, placebo-controlled study to evaluate the efficacy of ozarelix compared to placebo in the treatment of lower urinary tract symptoms (LUTS) secondary to BPH in men as assessed by the IPSS at Week 14.

Patients who meet the entry IPSS inclusion criteria at week 0 will be randomized and enrolled in the double-blind treatment period. Patients will be randomized to one of three treatment arms and will receive two 6-month courses of study drug administered on Days 0 and 14 of each 6-month course. Treatment arms include: ozarelix 30mg + 15mg, ozarelix 15mg + 15mg or placebo + placebo. All injections will be administered subcutaneously. Safety and efficacy assessments will be performed at defined intervals throughout the study. At week 52, all patients on study will be eligible to receive ozarelix for an additional 52 weeks in the open-label treatment period. We estimate that we will enroll approximately 860 patients. Sites in the United States and India will participate in the study.

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, and to determine the best path forward for its development in this indication. Degarelix, another LHRH antagonist, marketed by Ferring Pharmaceuticals, recently received

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marketing approval from the FDA for their one month injectable preparation for the treatment of advanced hormone dependent prostate cancer.

Endometriosis is a condition where tissue similar to the lining of the uterus is also found elsewhere in the body, but primarily in the abdominal cavity. This is a painful condition, typically affects women during their menstruating years and is rarely found after menopause. Currently, there is no cure for endometriosis. However, symptoms associated with endometriosis can be managed through a combination of treatments. We believe intermittent administration of ozarelix may 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 developing the protocol for a Phase 1 study to study ozarelix as a treatment for endometriosis.

The following describes the principal 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 50% financial interest in any income Aeterna Zentaris derives from ozarelix in Japan. We are contingently obligated to pay amounts based upon achievement of milestones and a royalty based on any future net sales.

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 Taxotere®). 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 optimizing the oral formulation for better bioavailiablity, we will consider future studies with the oral formulation.

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

Under the terms of the license agreement with Indena, we are obligated to make 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.

Also, we are obligated to purchase all of our requirements of ortataxel active pharmaceutical ingredient from Indena.

*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. GPC is currently conducting Phase 1 and 2 clinical trials for satraplatin in various solid tumors. Recently, GPC announced that it entered into a merger agreement with Houston-based Agennix Inc.

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

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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.

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. We are entitled to additional revenues upon: achievement of specified milestones by GPC, which are generally based on regulatory and sales milestones; and royalties on worldwide sales, if any, of the product.

*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 NHL. The level of activity seen did not justify further development for this indication as a single agent. However, elsamitrucin appears to have synergy with taxane and platinum derivatives in experimental models. Also, minimal toxicity to bone marrow may allow combinations with other drugs without a need to significantly reduce doses, which may result in improved therapeutic effects. We are currently reviewing all pre-clinical and clinical data of this product to determine the best path forward for its development.

The following describes the principal 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 a small up-front fee and additional future 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.

*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 1 dose-escalation study of lucanthone in patients with recurrent malignant gliomas receiving Temozolomide was initiated and patients are currently being enrolled.

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

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 in May 2005. Under the terms of the license agreement, we made a small up-front payment and are obligated to make additional periodic payments, a payment upon achievement of a certain regulatory milestone and royalties on

potential net sales, if any.

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

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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.

In the first quarter of 2008, we 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. We enrolled the first patient in this study in February 2008, and are continuing to enroll patients in this study.

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

> We acquired an exclusive worldwide license to develop and commercialize SPI-1620 for the prevention and treatment of cancer from Chicago Labs, Inc. in February 2005. We paid Chicago Labs a small up-front fee and 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.

*SPI-205:* SPI-205, a lipid suspension of leteprinim, has demonstrated, in experimental models, benefits in treating chemotherapy induced pheripheral neuropathy. Chemotherapy drugs can damage the nervous system, especially the pheripheral 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 pheripheral nerves is known as neuropathy. Currently, there is no effective treatment for chemotherapy induced neuropathy.

During 2009, we plan to continue preclinical evaluation of SPI-205.

*RenaZorb:* RenaZorb, a second-generation lanthanum-based nanoparticle phosphate binding agent, has the potential to treat 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 United States Renal Data System (USRDS), in 2009 there will be an estimated 600,000 patients with end-stage renal disease in the United States. 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.

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

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

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

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 in January 2005. Under the terms of the license agreement, we made up-front and milestone payments and are obligated to make additional payments upon achievement of certain clinical development and regulatory and sales milestones, in addition to royalties on potential net sales.

**Manufacturing**

We currently do not have internal manufacturing capabilities; therefore, all of our products are manufactured on a contract basis. We expect to continue to contract with third party providers for manufacturing services, including active pharmaceutical ingredient (API), finished-dosage product, as well as packaging operations. We believe that our current agreements with third party manufacturers provide for sufficient operating capacity to support the anticipated commercial demand for our products. However, we have only one approved contract manufacturer for each aspect of the manufacturing process for Zevalin and Fusilev. If we are unable to obtain a sufficient supply of our required products, or if we should encounter delays or difficulties in our relationships with our manufacturers, we may lose potential sales.

We attempt to prevent disruption of supplies through supply agreements, appropriate forecasting, maintaining stock levels and other strategies. Although we are taking these actions to avoid a disruption in supply, we cannot provide assurance that we may not experience a disruption in the future.

**Sales, Marketing and Distribution**

We have built, and continue to build, a sales and marketing infrastructure as part of our commercialization efforts for Fusilev and Zevalin. While we maintain a relatively small sales force, we believe that the size of our sales force is appropriate to effectively reach our target audience for our two commercial products.

We utilize a third-party logistics company to store and distribute our commercial products.

**Customers**

Our largest customers are GPOs and distributors of pharmaceutical products. GPOs accounted for approximately 30% and distributors approximately 70% of the net sales. All sales were to customers in the United States.

**Competition**

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

market share.

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

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specific clinical benefits over competitive drug therapies. Unless our 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 Neurocrine Biosciences, Abraxis Bioscience, Inc., Astra Zeneca LP, Amgen, Inc., Bayer AG, Bioniche Life Sciences Inc., Eli Lilly and Co., Novartis Pharmaceuticals 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., Genzyme Corporation, Shire Pharmaceuticals, Abbott Laboratories, Poniard Pharmaceuticals, Inc., Roche Pharmaceuticals, 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 launched our proprietary product, Fusilev, in August 2008. Fusilev 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 two generic companies currently selling the leucovorin product and therefore we are competing against a low cost alternative. Also, Fusilev will be offered as part of a treatment regimen, and that regimen may change to exclude Fusilev. For these reasons, we may not recognize the full potential value of our investment in the product.

Regarding Zevalin, there are three products which are potential competitors for the indications it is currently approved for.

Treanda® (bendamustine hydrochloride) for Injection, for Intravenous Infusion, marketed by Cephalon, is indicated for the treatment of patients with indolent B-cell NHL that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

Also, the BEXXAR® therapeutic regimen (Tositumomab and Iodine I 131 Tositumomab), a radiopharmaceutical marketed by GlaxoSmithKline, is indicated for the treatment of patients with CD20 antigen-expressing relapsed or refractory, low-grade, follicular, or transformed NHL, including patients with Rituximab-refractory NHL.

Finally, Rituxan® (rituximab), marketed by Genentech and Biogen, is indicated for the treatment of patients with relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL as a single agent; previously untreated follicular, CD20-positive, B-cell NHL in combination with CVP (cyclophosphamide, vincristine and prednisolone combination) chemotherapy; and non-progressing (including stable disease), low-grade, CD20-positive B-cell NHL, as a single agent, after first-line CVP chemotherapy. Rituxan is administered as a part of various chemotherapy regimens and schedules, the vast majority of which, could be used in concert with other therapeutic agents, such as Zevalin, as part of a treatment plan.

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

**Research and Development**

New drug development, which is the process whereby drug product candidates are tested for the purpose of filing a NDA or BLA (or similar filing in other countries) and eventually obtaining marketing approval from the FDA or a

similar 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.

Research and development expenses for such drug development are comprised of the following types of costs incurred in performing research and development activities: personnel expenses, facility costs, contract services,

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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 $26.7 million in 2008, $33.3 million in 2007, and $23.7 million in 2006 broken out by product as follows:

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2008 | 2007 | 2006 |
| | (Amounts in thousands) | | |
| Fusilev | $ 1,791 | $ 1,368 | $ 4,428 |
| Zevalin | 151 | | |
| Apaziquone | 5,477 | 6,348 | 2,617 |
| Ozarelix | 2,435 | 6,217 | 2,881 |
| Ortataxel | 150 | 3,719 | |
| Other drugs | 1,304 | 3,452 | 4,457 |
| Total Direct Costs | 11,308 | 21,104 | 14,383 |
| Indirect Costs | 15,375 | 12,181 | 9,345 |
| Total Research & Development | $ 26,683 | $ 33,285 | $ 23,728 |

**Patents and Proprietary Rights**

***Our Patents and Proprietary Rights***

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 Fusilev, Zevalin, ozarelix, ortataxel, satraplatin, elsamitrucin, lucanthone, RenaZorb and SPI-1620, in each case for the remaining life of the applicable patents. Except for Zevalin, Fusilev and ozarelix, our agreements generally provide us with exclusive worldwide rights to, among other things, develop, sublicense, and commercialize the drug products. Under most of 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. In addition, with regard to apaziquone and SPI-205, we own patent and related intellectual property rights related to these products.

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 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 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.

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 own and in-license from third parties certain patent rights related to our 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, no one patent or license is currently of material importance to our business. For Fusilev, we have one United States formulation patent that covers Fusilev that expires in 2019. For

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Zevalin, we have sublicensed United States patents that cover the processes and tools for making monoclonal anti-bodies (MABs) in general, licensed United States patents that cover the CD-20 MAB in Zevalin as well as the use of Zevalin to treat NHL, and acquired patent applications covering the Zevalin compounding process (*i.e.*, process of linking the CD20 MAB to a radioactive isotope to make the patient-ready dosage form of Zevalin). These patents expire over a wide range of dates beginning in 2009, but the licensed patents covering the CD-20 MAB itself do not begin to expire until 2015. Additionally, we have pending United States patent applications covering the compounding process, and will consider filing more patent applications, if the opportunity arises. For apaziquone, there is a composition patent that will expire in 2009 in the United States, and a United States formulation patent that does not expire until 2022. 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 is one United States patent covering satraplatin, a method of use patent that expires in 2010, and foreign composition patents in Europe that have expired and will expire in various countries between 2008 and 2009. For elsamitrucin, 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. 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 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 Spectrum Pharmaceuticals, Inc.®, Fusilev™, Turning Insights Into Hope™, Zevalin® and RenaZorb®. Additionally, for some other of these and other works related to our business, we have pending United States and ex-United States trademark applications. EOquin® is registered trademark of Allergan. RenaZorb® is a registered trademark of Altair Nanomaterials, Inc., and licensed to Spectrum Pharmaceuticals, Inc.

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 and trade secret protection measures, such as periodic internal and external trade secret audits. It is possible that these agreements will be breached or will not be enforceable in every instance, and that we will not have adequate remedies for any such breach. It is also possible that our trade secrets or know-how will otherwise become known or independently developed by competitors. The protection of know-how is particularly important

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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.

***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 seven 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, for all United States patent applications filed after 1995, 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.

***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 pharmaceutical drugs. Under the Hatch-

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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.

As part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, certain types of settlement agreements entered into between branded and generic pharmaceutical companies related to the manufacture, marketing and sale of generic versions of branded drugs are required to be filed with the Federal Trade Commission and the Department of Justice for review of potential anti-competitive practices. This 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 requirement, and the potential governmental investigations and private-party lawsuits associated with arrangements between brand name and generic drug manufacturers, remains uncertain and could adversely affect our business.

Currently, there is no equivalent ANDA process for biological drugs. However, United States legislation is being contemplated for a similar process for the approval of biosimilar or biogeneric biological drugs.

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

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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.

Fusilev 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.

**Governmental Regulation**

The development, 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 Cosmetic Act, as amended from time to time, and the regulations promulgated thereunder, 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 products that are marketed or in development. 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 the FDA. Domestic manufacturing establishments must comply with the FDA s current good manufacturing practice (cGMP) regulations and are subject to periodic inspections by the FDA. To supply drug ingredients or products for use in the United States, foreign manufacturing establishments must also comply with cGMP and are subject to periodic inspection by the FDA or by other regulatory authorities in certain countries under reciprocal agreements with the FDA.

***General Information about the Drug Approval Process and Post-Marketing Requirements***

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 (IND) Application is submitted to the FDA to request the ability to begin human testing of the drug. An IND becomes effective thirty days after the FDA receives the application (unless the FDA notifies the sponsor of a clinical hold), or upon prior notification by the FDA.

*Phase 1 Clinical Trials:* 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, controlled 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. These clinical trials, and phase 3 trials discussed below, are designed to evaluate the drug s overall benefit-risk profile, and to provide information to inform physician labeling.

*Phase 3 Clinical Trials:* This phase usually involves larger number of patients with the targeted disease. Investigators (typically physicians) monitor the patients to determine the drug candidate s efficacy and to observe

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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 (NDA) is filed with the FDA requesting FDA approval to market the new drug as a treatment for the target disease.

*Fast Track and Priority Review:* The FDA has established procedures for accelerating the approval of drugs to be marketed for serious or life threatening diseases for which the manufacturer can demonstrate the potential to address unmet medical needs.

*Abbreviated New Drug Application (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 drug development and approval process generally takes less time than the NDA drug development and approval process since the ANDA process usually does not require new clinical trials establishing the safety and efficacy of the drug product.

*NDA and ANDA Approval:* The FDA approves drugs that are subject to NDA review based on data in the application demonstrating the drug is safe and effective in its proposed use(s) and that the drug s benefits outweigh its risks. FDA will also review the NDA applicant s manufacturing process and controls to ensure they are adequate to preserve the drug s identity, strength, quality, and purity, and FDA will review and approve the drug s proposed labeling. As for the ANDA approval process, these abbreviated applications are generally not required to include preclinical or clinical data to establish safety and effectiveness. Rather, an ANDA must demonstrate both chemical equivalence and bio-equivalence (the rate and extent of absorption in the body) to the innovator drug unless a bio-equivalence waiver is granted by the FDA.

*Phase 4 Clinical Trials:* After a drug has been approved by the FDA, phase 4 studies may be 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.

*Post-Approval Studies Requirements under FDAAA:* The Food and Drug Administration Amendments Act of 2007 (the FDAAA ), which President Bush signed into law in September 2007, significantly added to the FDA s authority to require post-approval studies. Under the FDAAA, if the FDA becomes aware of new safety information after approval of a product, they may require us to conduct further clinical trials to assess a known serious risk, signals of serious risk or to identify an unexpected serious risk. If required to conduct a post-approval study, periodic status reports must be submitted to the FDA. Failure to conduct such post-approval studies in a timely manner may result in administrative action being taken by FDA, including substantial civil fines.

*Risk Evaluation and Mitigation Strategy Authority under FDAAA:* The FDAAA also gave the FDA new authority to require the implementation of a Risk Evaluation and Mitigation Strategy ( REMS ) for a product when necessary to minimize known and preventable safety risks associated with the product. The FDA may require the submission of a REMS before a product is approved, or after approval based on new safety information, including new analyses of existing safety information. A REMS may include a medication guide, patient package insert, a plan for

communication with healthcare providers, or other elements as the FDA deems are necessary to assure safe use of the product, which could include imposing certain restrictions on distribution or use of a product. A REMS must include a timetable for submission of assessments of the strategy at specified time intervals. Failure to comply with a REMS including the submission of a required assessment may result in substantial civil or criminal penalties.

*Other Issues Related to Product Safety:* Adverse events that are reported after marketing approval also can result in additional limitations being placed on a product s use and, potentially, withdrawal of the product from the

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market. In addition, under the FDAAA, the FDA has authority to mandate labeling changes to products at any point in a product s lifecycle based on new safety information derived from clinical trials, post-approval studies, peer-reviewed medical literature, or post-market risk identification and analysis systems data.

***FDA Enforcement***

The development of drug products, as well as the marketing of approved drugs, 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 the 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.

With respect specifically to information submitted to FDA in support of marketing applications, the FDA, under its Fraud, Untrue Statements of Material Facts, Bribery and Illegal Gratuities Policy, can significantly delay the approval of a marketing application or seek to withdraw an approved application where it identifies fraud or discrepancies in regulatory submissions. Such actions by 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. In addition, 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.

***Healthcare Reform***

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 may vary, sometimes significantly, 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.

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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 is 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.

More generally, in the coming years, the United States Government could enact significant changes to governmental healthcare programs, and the United States healthcare system as a whole, that may result in significantly increased rebates, decreased pricing flexibility, diminished negotiating flexibility, coverage and reimbursement limitations based upon comparative and cost-effectiveness reviews, and other measures that could significantly impact the success 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, 2008, we had 84 employees, of which 5 held a M.D. degree and 11 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.

**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, Proxy Statements for our annual stockholder s meetings, 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.

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**Risks Related to Our Business**

***Like other early-stage biotech companies, we have a history of operating losses and our losses may continue to increase as we expand our commercialization and development efforts, and our efforts may never result in profitability.***

Our cumulative losses since our inception in 1987 through December 31, 2008 were in excess of $250 million. Our net losses in 2008 and 2007 were approximately $15 million and $34 million, respectively. We expect to continue to incur additional losses as we implement our growth strategy of commercializing our approved drug products and developing our pipeline products for at least the next few years. 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 sufficient cash to finance our ongoing operations and therefore, we will likely need to continue to raise additional capital.***

Our current commercial operations do not generate sufficient operating cash to finance the clinical development of all our drug products, to commercialize our approved drug products and to capitalize on growth opportunities. While we have been successful recently in generating funds through the licensing and sale of our assets, 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. Although we began selling products in 2008, we believe that in the near-term we will likely need to continue to raise funds in order to continue drug product commercialization, development and acquisition.

We may not be able to raise additional capital on favorable terms, if at all, particularly with the current volatile financial 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 and commercialization 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 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 may not be able to successfully complete 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.

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

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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 effectively maintain and expand our sales and marketing capabilities, we may be unable to successfully commercialize our approved products.***

Historically, we have had limited internal experience in selling, marketing or distributing pharmaceutical products. However, we have recently established a small direct sales force to market our approved products. We also are expanding our direct sales force in connection with the re-launch of Zevalin. If we are not able to effectively hire and train qualified individuals as part of our sales force, our product sales and resulting revenues will be negatively impacted.

***If we are unable to expand approved usage of Zevalin, or to maintain or obtain improved reimbursement rates for it, the product s operating results may be harmed, which could adversely affect our financial and operating results.***

We intend to seek expansion of the approved uses of Zevalin in the United States. If we are unable to expand the approved uses of Zevalin, or if we are otherwise unable to fulfill our marketing, sales and distribution plans for Zevalin, we may not recognize the full anticipated value of our investment in the product and our financial and operating results could be adversely affected.

In 2007, CMS implemented new outpatient reimbursement rates for radiopharmaceuticals, including Zevalin. The new reimbursement rates are significantly below the institution or provider s current acquisition cost for Zevalin. Congress has passed legislation to delay the implementation of those new rates and stabilize reimbursement rates through January 1, 2010, with the intention of giving drug manufacturers and CMS time to reach an agreement that more adequately reflects costs associated affected pharmaceuticals. However, CMS may not agree to a rate or methodology that provides an acceptable reimbursement on radiopharmaceuticals such as Zevalin. In the event that CMS does not agree to a reimbursement rate that is adequate to cover an institution or provider s acquisition cost for Zevalin, we could face significant difficulty in getting care providers to use Zevalin, which would have an adverse impact on the product s expected operating results, and in turn adversely impact our investment in the product and our financial and operating results.

***We may face difficulties in achieving broader market acceptance of Zevalin if we do not invest significantly in our sales and marketing infrastructure.***

United States sales of Zevalin have declined over the several years prior to our acquisition of the Zevalin assets. We believe that an enhanced sales and marketing strategy for Zevalin, in conjunction with efforts to obtain approval by the FDA for expanded uses of Zevalin, has significant potential to increase sales of and revenue from Zevalin over the next few years. However, implementation of the sales and marketing strategy for Zevalin, and the efforts to expand approved usage of Zevalin, will require a significant investment of financial and other resources by us for the foreseeable future and may not ultimately increase Zevalin sales or allow us to realize the anticipated benefits from our investment in the product. Additionally, our efforts to establish an effective direct sales force for Zevalin will require significant commitments of both financial and management resources by us, and may not ultimately be successful due a variety of factors, including industry competition for effective sales and marketing personnel or the inability of us to dedicate the necessary resources to those efforts.

***The intellectual property and assets owned by our subsidiary, RIT, are subject to a security agreement with Biogen that secures the entity s payment and other obligations to Biogen, and we have guaranteed all of those obligations.***

In connection with the formation of RIT, RIT entered into a security agreement with Biogen pursuant to which RIT granted to Biogen a first priority security interest in all of its assets, which consist of the Zevalin-related intellectual property and other assets RIT. The security agreement secures certain payment, indemnification and

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other obligations of RIT to Biogen related to Zevalin. If RIT were to default on certain of its obligations to Biogen, or in certain other circumstances generally related to a bankruptcy or insolvency of RIT, Biogen could seek to foreclose on the collateral under the security agreement to obtain satisfaction of RIT s obligations to it. If RIT were to default on its obligations to Biogen, and Biogen were to foreclose on the collateral under the security agreement, RIT s business could be materially and adversely impacted, which could in turn materially and adversely impact our investment in RIT and our financial condition and results of operations.

Furthermore, in connection with the formation of RIT we guaranteed all of RIT s obligations to Biogen. If RIT were to default on its obligations to Biogen, Biogen could require us alone to satisfy all of those obligations under our guarantee.

The financial and other obligations that we would incur could have a material and adverse effect on our financial condition and results of operations.

***If we are unable to expand the approved usage of Fusilev, the product s operating results may be harmed, which could adversely affect our financial and operating results.***

We have filed a supplemental new drug application for Fusilev for use in combination with 5-FU-containing regimens in the treatment of colorectal cancer. The greatest potential use of this product is in this indication. If we are not able to obtain approval for this indication, we may not recognize the full anticipated value of our investment in the product and our financial and operating results could be adversely affected.

***Our drug product Fusilev 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.***

Fusilev 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 generic companies currently selling the product and therefore, Fusilev competes against a low-cost alternative. Also, Fusilev will be offered as part of a treatment regimen, and that regimen may change to exclude Fusilev. Accordingly, it may not gain acceptance by the medical field or become commercially successful.

***The marketing and sale of Fusilev and Zevalin may be adversely affected by the marketing and sales efforts of third parties who sell these products outside the United States.***

We have only licensed the rights to develop, market and sell Fusilev in North America, and have licensed the rights to develop, market and sell Zevalin in the United States. Other companies market and sell the same products 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 these products, may be adversely impacted.

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

In 2008, we entered into a co-development and license agreement with Allergan, Inc., or Allergan, for the worldwide development and commercialization of our drug product, apaziquone. Allergan has agreed to partially fund development and commercialization expenses for apaziquone. We do not fully control the drug development process under the license agreement. In addition, if we do not achieve certain milestones under the license agreement and it has been determined that failure to achieve these milestones was a result of our actions or inactions, Allergan is entitled to assume additional control over the development process. As a result, success of this product could depend,

in part, upon the efforts of Allergan. Allergan may not be successful in the clinical development of the drug, obtaining approval of the product by regulatory authorities, or the eventual commercialization of apaziquone.

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***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, or its partners, may conduct their own clinical trials on ozarelix for regulatory approval in all other parts of the world. We will not have control over such development activities and our ability to attain regulatory approvals for ozarelix may be adversely impacted if its 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 AG, or GPC, 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 any of its sublicensees. GPC 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.

***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. Dr. Shrotriya has been President since 2000 and Chief Executive Officer since 2002, and has spearheaded our business strategy since that time. The loss of the services of Dr. Shrotriya or any other key personnel could delay or preclude us from achieving our business objectives.

We also require 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.***

We only recently began commercial sales of our products and have had to increase our personnel accordingly, including establishing a direct sales force. In addition, 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.

***If we acquire additional businesses, we may not successfully integrate their operations.***

We may acquire additional businesses that complement or augment our existing business. 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.

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***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 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, which could negatively impact our research and development activities.

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

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

***We 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

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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;
- attempts by either party to terminate the collaboration;
- our ability to to maintain or defend our intellectual property rights may be compromised by our partner s acts or omissions;
- a partner may utilize our intellectual property rights in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability;
- a partner may change the focus of their development and commercialization efforts. As previously noted, pharmaceutical and biotechnology companies historically have re-evaluated their priorities following mergers and consolidations, which have been common in recent years in these industries. The ability of our products to reach their potential could be limited if future partners decrease or fail to increase spending relating to such products;
- unwillingness of a partner to fully fund or commit sufficient resources to the testing, marketing, distribution or development of our products; and/or
- unwillingness or ability of a partner to fulfill their obligations to us. A partner may develop alternative products either on their own or in collaboration with others, or encounter conflicts of interest or changes in business strategy or other business issues.

Given these risks, it is possible that any collaborative arrangements which we have or may enter into may not be successful.

***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 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.

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***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 that we sell or that 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 Neurocrine Biosciences, Abraxis Bioscience, Inc., Astra Zeneca LP, Amgen, Inc., Bayer AG, Bioniche Life Sciences Inc., Eli Lilly and Co., Novartis Pharmaceuticals 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., Genzyme Corporation, Shire Pharmaceuticals, Abbott Laboratories, Poniard Pharmaceuticals, Inc., Roche Pharmaceuticals, 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.

***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 supplies to timely meet our requirements 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.

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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 the FDA s current Good Manufacturing Practice, or 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.

We rely on contract suppliers to supply our existing products, and will likely do the same for other products that we may develop, commercialize or acquire in the future. Contract suppliers may not be able to meet our needs with respect to timing, cost, quantity or quality. All of our suppliers are sole-source suppliers, including for Zevalin and Fusilev, and no currently qualified alternative suppliers exist.

If we are unable to obtain a sufficient supply of our required products and services on acceptable terms, or if we should encounter delays or difficulties in our relationships with our manufacturers, or if any required approvals by the FDA and other regulatory authorities do not occur on a timely basis, we will lose sales. Moreover, contract suppliers that we may use must continually adhere to current good manufacturing practices enforced by the FDA. If the facilities of these suppliers cannot pass an inspection, we may lose FDA approval of our products. Failure to obtain products for sale for any reason may result in an inability to meet product demand and a loss of potential revenues.

***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 development 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 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

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

***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.

***If actual future payments for allowances, discounts, returns, rebates and chargebacks exceed the estimates we made at the time of the sale of our products, our financial position, results of operations and cash flows may be materially and negatively impacted.***

We recognize product revenue net of estimated allowances for discounts, returns, rebates and chargebacks. Such estimates require our most subjective and complex judgment due to the need to make estimates about matters that are inherently uncertain. Based on industry practice, pharmaceutical companies, including us, have liberal return policies. Generally, we are obligated to accept from customers the return of pharmaceuticals that have reached their expiration date up to 12 months after their expiration. We authorize returns for damaged products and exchanges for expired products in accordance with our return goods policy and procedures. In addition, like our competitors, we also give credits for chargebacks to wholesale customers that have contracts with us for their sales to hospitals, group purchasing organizations, pharmacies or other retail customers. A chargeback is the difference between the price the wholesale customer (in our case, the GPOs) pays (wholesale acquisition cost) and the price that the GPO s end-customer pays for a product (contracted customer). Since we have only recently begun commercial distribution of our products, we do not have historical data on returns and allowances. Although we have estimated the allowances very conservatively, actual results may differ significantly from our estimated allowances for discounts, returns, rebates and chargebacks. Changes in estimates and assumptions based upon actual results may have a material impact on our results of operations and/or financial condition. Such changes to estimates will be made to the financial statements in the year in which the estimate is charged. In addition, our financial position, results of operations and cash flows may be materially and negatively impacted if actual future payments for allowances, discounts, returns, rebates and chargebacks exceed the estimates we made at the time of the sale of our products.

**Risks Related to Our Industry**

***If third-party payors do not adequately reimburse providers for any of our products, 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 payors 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.

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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.

***The consolidation of drug wholesalers and other wholesaler actions could increase competitive and pricing pressures on pharmaceutical manufacturers, including us.***

We sell our pharmaceutical products primarily through wholesalers. These wholesale customers comprise a significant part of the distribution network for pharmaceutical products in the United States. This distribution network is continuing to undergo significant consolidation. As a result, a smaller number of large wholesale distributors control a significant share of the market. We expect that consolidation of drug wholesalers will increase competitive and pricing pressures on pharmaceutical manufacturers, including us. In addition, wholesalers may apply pricing pressure through fee-for-service arrangements, and their purchases may exceed customer demand, resulting in reduced wholesaler purchases in later quarters. We cannot assure you that we can manage these pressures or that wholesaler purchases will not decrease as a result of this potential excess buying.

***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 patient population, the nature of the trial protocol, the proximity of patients to clinical sites and the eligibility criteria for the study. The delay or inability to meet planned patient enrollment may result in

increased costs and delays or termination of the trial, which could have a harmful effect on our ability to develop products.

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***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.

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.

***Guidelines and recommendations published by various organizations can reduce the use of our products.***

Government agencies promulgate regulations and guidelines directly applicable to us and to our products. However, professional societies, practice management groups, insurance carriers, physicians, private health/science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to healthcare providers, administrators and payers, and patient communities. Recommendations of government agencies or these other groups/organizations may relate to such matters as usage, dosage, route of administration and use of related therapies and reimbursement of our products by government and private payers. Organizations like these have in the past made recommendations about our products. Recommendations or guidelines that are followed by patients

and healthcare providers could result in decreased use and/or dosage of our products.

Any recommendations or guidelines that result in decreased use, dosage or reimbursement of our products could adversely affect our product sales and operating results materially. In addition, the perception by the investment community or stockholders that such recommendations or guidelines will result in decreased use and dosage of our products could adversely affect the market price for our common stock.

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***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 CROs, our CMOs 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 or change the labeling of our products or take other potentially limiting or costly actions if we or others identify side effects after our products are on the market.***

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.

On September 27, 2007, President Bush signed into law the FDAAA, significantly adding to the FDA s authority including allowing the FDA to (i) require sponsors of marketed products to conduct post-approval clinical studies to assess a known serious risk, signals of serious risk or to identify an unexpected serious risk; (ii) mandate labeling changes to products, at any point in a product s lifecycle, based on new safety information and (iii) require sponsors to implement a Risk Evaluation and Mitigation Strategy REMS for a product which could include a medication guide, patient package insert, a communication plan to healthcare providers, or other elements as the FDA deems are necessary to assure safe use of the drug (either prior to approval or post-approval as necessary), which could include imposing certain restrictions on distribution or use of a product. Failure to comply with the new requirements, if imposed on a sponsor by the FDA under the FDAAA, could result in significant civil monetary

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penalties or other administrative actions by FDA. Further, regulatory agencies could change existing, or promulgate new, regulations at any time which may affect our ability to obtain or maintain approval of our existing or future products or require significant additional costs to obtain or maintain such approvals.

***Our failure to comply with FDA (and related) regulations applicable to our business may subject us to sanctions, which could damage our reputation and adversely affect our business condition.***

In the U.S., the FDA, and comparable state regulatory agencies and enforcement authorities, impose requirements on us as a manufacturer and marketer of prescription drug products. Drug manufacturers are required to register with FDA, and are required to comply with various regulatory requirements regarding drug research, manufacturing, distribution, reporting and recordkeeping. Most drug products must be approved by the FDA prior to marketing, and companies are required to comply with numerous post-marketing requirements. Companies are also subject to periodic inspection by the FDA for compliance with cGMP and other applicable regulations.

Further, drug manufacturers are required to comply with FDA requirements for labeling and advertising, as well as other Federal and state requirements for advertising. This includes a prohibition on promotion for unapproved or off-label uses, *e.g.*, promotion of products for uses that are not described in the product s FDA-approved labeling. While a physician may prescribe a medication for off-label uses where appropriate, companies may not generally promote drug products for off-label uses.

If FDA or other Federal and state agencies believe that a company is not in compliance with applicable regulations, they have various enforcement authorities to address violations. FDA can issue a warning letter and seek voluntary compliance from a company in the form of remedial or corrective action. FDA may also impose civil money penalties by administrative action, and through judicial enforcement seek actions including injunctions, seizures, and criminal penalties. FDA or other Federal and state authorities may also seek operating restrictions on a company in order to achieve compliance, including termination or suspension of company activities. Such agencies and enforcement authorities may also disseminate information to the public about their enforcement actions.

If we were to become subject to any FDA or similar enforcement action related to any of our drug products, our business condition could be adversely affected, and the public release of such information could be damaging to our reputation.

***Legislative or regulatory reform of the healthcare system and pharmaceutical industry related to pricing or reimbursement 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 U.S. and foreign governments continue to propose and pass new legislation and regulations designed to contain or reduce the cost of health care. Such legislation and regulations may result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce the prices charged for prescription drugs. This could harm our ability to market our products and generate revenues.

It is possible that proposals will be adopted, or existing regulations that affect the coverage or pricing of pharmaceutical and other medical products may 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.

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

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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.

***If we market products in a manner that violates health care anti-kickback or other fraud and abuse laws, we may be subject to civil or criminal penalties, including exclusions from participation in Federal health care programs.***

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 applies to arrangements between pharmaceutical manufacturers and prescribers, purchasers and formulary managers. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities, the exemptions and safe harbors are drawn narrowly, and practices that involve 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 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.

The Health Insurance Portability and Accountability Act of 1996 also created prohibitions against 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 PhRMA Code on Interactions with Healthcare Professionals, as amended. 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 may not 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

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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 pharmaceutical and 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.

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

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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. Likewise, although we conduct periodic trade secret audits of certain partners, vendors and contract manufacturers, these trade secret audits may not protect our trade secrets or other confidential and proprietary information. It is possible that despite having certain trade secret audited security measures in place, trade secrets or other confidential and proprietary information may still be leaked or disclosed to a third party. 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 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 or Europe that claim technology we also claim, we may have to participate in interference proceedings required by the USPTO to determine priority of invention or opposition proceedings in Europe, both of which could result in substantial costs, even if we ultimately prevail. Results of interference and opposition 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.

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***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 held liable if any product we or our partners develop causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing or sale. Regardless of merit or eventual outcome, product liability claims could result in decreased demand for our product candidates, injury to our reputation, withdrawal of patients from our clinical trials, substantial monetary awards to trial participants and the inability to commercialize any products that we may develop. These claims might be made directly by consumers, health care providers, pharmaceutical companies or others selling or testing 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. However, our insurance may not reimburse us or may not be sufficient to reimburse us for expenses or losses we may suffer. Moreover, if insurance coverage becomes more expensive, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. 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.

On occasion, juries have awarded large judgments in class action lawsuits for claims based on drugs that had unanticipated side effects. In addition, the pharmaceutical and biotechnology industries, in general, have been subject to significant medical malpractice litigation. A successful product liability claim or series of claims brought against us could harm our reputation and business and would decrease our cash reserves.

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

Our research and development efforts have involved and currently involve the use of hazardous materials. We are subject to federal, state and local laws and regulations governing the storage, use and disposal of these materials and some waste products. We believe that our safety procedures for the storage, use and disposal of these materials comply with the standards prescribed by federal, state and local regulations. However, we cannot completely eliminate the risk of accidental contamination or injury from these materials. If there were to be an accident, we could be held liable for any damages that result, which could exceed our financial resources. We currently maintain insurance coverage for injuries resulting from the hazardous materials we use; 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 Common 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 27, 2009, there were approximately 32.5 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 12.7 million additional shares of common stock. However, we would receive over $89 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 have a shelf registration statement to sell up to $150 million of our securities, some or all of which may be shares of our common stock or securities convertible into or exercisable for shares of our common stock, and all of which would be available for 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 primarily financed our operations, and we anticipate that we will have to finance a large portion of our operating cash requirements, 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 or other

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dilutive issuances would also cause our net income, if any, per share to decrease in future periods. As a result, the market price of our common stock could drop.

***The market price and trading 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 trading volume fluctuations that are unrelated to the operating performance of particular companies. These broad market fluctuations may cause the market price and trading volume of our common stock to decrease. In addition, the market price and trading volume of our common stock is often 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;
- concerns about our products being reimbursed;
- any lawsuit involving us or our drug products;
- developments with respect to our patents and proprietary rights;
- 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. Since January 1, 2008 through March 27, 2009, the price of our common stock ranged between $0.46 and $3.35, and the daily trading volume was as high as 4,369,800 shares and as low as 20,200 shares. In addition, due in large part to the current global economic crisis many institutional investors that historically had invested in specialty pharmaceutical companies have ceased operations or further investment in these companies, which has had negatively impacted trading volume for our stock.

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

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

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

- the ability of our board of directors to amend our bylaws without stockholder approval;
- the inability of stockholders to call special meetings;
- the ability of members of the board of directors to fill vacancies on the board of directors;
- the inability of stockholders to act by written consent, unless such consent is unanimous; and
- the establishment of advance notice requirements for nomination for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

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

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.

***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, or the SEC, 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 foreseeable 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 expires on June 30, 2009. While

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we have a 5-year renewal option, we are evaluating whether to renew the lease for an additional 5 years or consider securing an alternate facility. We believe that the market for office properties is currently favorable for us, and expect our lease costs to compare favorably with our current leasing costs, including utilities, taxes, insurance and common area maintenance. In the event we decide to secure an alternate facility, we do not expect the relocation to adversely affect our operations. We also lease small administrative offices in Zurich, Switzerland, Montreal, Canada, and Mumbai, India on an expense-sharing basis. The financial and other terms of these lease arrangements are not material to our business.

**Item 3.** ***Legal Proceedings***

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.

**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, 2008.

## PART II

**Item 5.** ***Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

**Common Stock**

As of March 27, 2009 there were 32,530,636 shares of common stock outstanding and 355 shareholders of record. On March 27, 2009, the closing sale price of our common stock was $1.88 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 2008 and 2007 were as follows:

| | High | Low |
|---|---|---|
| **Year 2008** | | |
| Quarter Ended | | |
| March 31 | $ 3.35 | $ 2.25 |
| June 30 | $ 2.98 | $ 0.46 |
| September 30 | $ 1.90 | $ 1.30 |
| December 31 | $ 2.25 | $ 0.55 |
| **Year 2007** | | |
| 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 |

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

**Dividends**

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

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**Unregistered Sales of Equity Securities**

In the fourth quarter 2008, we issued 50,000 shares of our common stock to INC Research®, formerly NDDO Research Foundation, and its designees, pursuant to the termination of a license agreement with INC Research.

On March 19, 2009, as required by an asset purchase agreement with Targent, Inc., we became obligated to issue 125,000 shares of our common stock to Targent, or its designees, due to the acceptance by the FDA of our sNDA for Fusilev. We agreed to register for resale one-third of the shares; the rest are unregistered. We received no cash proceeds in connection with this issuance.

Each of the securities issued described above have been issued without registration under the Securities Act of 1933 in reliance upon the exemptions from registration provided under Section 4(2) of the Securities Act and Regulation D promulgated thereunder. The foregoing transactions did not involve any public offering; we made no solicitation in connection with the issuances; we obtained representations from the parties regarding their investment intent, experience and sophistication; the parties either received or had access to adequate information about us in order to make an informed investment decision; and we reasonably believed that the parties were sophisticated within the meaning of Section 4(2) of the Securities Act. No underwriting discounts or commissions were paid in conjunction with the issuances.

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**Item 6.** ***Selected Financial Data***

The following table presents our selected financial data. Financial data for the years ended December 31, 2008, 2007, and 2006 and as of December 31, 2008 and 2007 has been derived from our audited financial statements included elsewhere in this Annual Report on 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, 2005 and 2004 and as of December 31, 2006, 2005 and 2004 has been derived from our audited financial statements not included herein.

**CONSOLIDATED FINANCIAL INFORMATION**

| | 2008 | 2007 | 2006 | 2005 | 2004 |
|---|---|---|---|---|---|
| | (In thousands, except Share data) | | | | |
| **Statement of Operations Data for the Years Ended December 31:** | | | | | |
| Revenues | $ 28,725 | $ 7,672 | $ 5,673 | $ 577 | $ 258 |
| Operating expenses: | | | | | |
| Cost of product sold | 1,193 | | 97 | 397 | 123 |
| Research and development | 26,683 | 33,285 | 23,728 | 13,483 | 7,588 |
| Acquired in-process research and development | 4,700 | | | | |
| Amortization of purchased intangibles | 158 | | | | |
| Selling, general and administrative | 15,161 | 11,582 | 7,741 | 6,619 | 5,347 |
| Loss from operations | (19,170) | (37,195) | (25,893) | (19,922) | (12,800) |
| Other income (expense) | 1,165 | 3,139 | 2,606 | 1,279 | 518 |
| Net loss before minority interest in consolidated entities | $ (18,005) | $ (34,056) | $ (23,287) | $ (18,643) | $ (12,282) |
| Minority interest in net loss of consolidated entities | 2,538 | 20 | 3 | 1 | (4) |
| Net loss | $ (15,467) | $ (34,036) | $ (23,284) | $ (18,642) | $ (12,286) |
| Basic and diluted net loss per share | $ (0.49) | $ (1.17) | $ (0.96) | $ (1.06) | $ (0.98) |
| Cash Dividends on common stock | $ | $ | $ | $ | $ |
| **Balance Sheet Data at December 31:** | | | | | |
| Cash, cash equivalents and marketable securities | $ 78,086 | $ 55,659 | $ 50,697 | $ 63,667 | $ 39,206 |
| Other current assets | 7,536 | 953 | 1,590 | 718 | 795 |
| Property and equipment, net | 1,782 | 716 | 625 | 562 | 687 |
| Intangible Assets, net | 37,042 | | | | |
| Other Assets | 289 | 212 | 205 | 128 | 70 |

| | | | | | |
|---|---|---|---|---|---|
| Total assets | $ 124,735 | $ 57,540 | $ 53,117 | $ 65,075 | $ 40,758 |
| Current liabilities | $ 28,032 | $ 7,799 | $ 6,233 | $ 3,828 | $ 2,666 |
| Other non-current-liabilities | 42,822 | 992 | 1,035 | 241 | 178 |
| Minority interest in consolidated subsidiaries | 14,262 | | 20 | 23 | 24 |
| Total stockholders equity | 39,619 | 48,749 | 45,829 | 60,983 | 37,890 |
| Total liabilities and stockholders equity | $ 124,735 | $ 57,540 | $ 53,117 | $ 65,075 | $ 40,758 |

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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**

We are a commercial stage biopharmaceutical company committed to developing and commercializing innovative therapies with a focus primarily in the areas of hematology-oncology and urology. We have a fully developed commercial infrastructure that is responsible for the sales and marketing of two drugs in the United States, namely Fusilev and Zevalin. Our lead developmental drug is apaziquone, which is presently being studied in two large Phase 3 clinical trials for bladder cancer under a strategic collaboration with Allergan Inc. Another drug, ozarelix is in a Phase 2 clinical trial for BPH.

Our business strategy for 2009 is comprised of the following initiatives:

*Maximizing the growth potential for our marketed drugs, Fusilev and Zevalin.* The company s near-term outlook depends on sales and marketing successes associated with our two marketed drugs. We launched Fusilev in August 2008 and were able to successfully achieve broad utilization in community offices and institutions. Our second drug, Zevalin, is marketed by our subsidiary RIT Oncology LLC (RIT), which was formed in December 2008. A dedicated commercial organization comprised of sales representatives, account managers, medical science liaisons and a complement of other marketing personnel support the marketing and sales of these drugs. Together with multiple initiatives to address historical barriers to uptake of Zevalin, we believe we can capture the substantial growth potential in sales for both Zevalin and Fusilev. Both drugs have additional applications on file with the FDA for new, larger indications in non-Hodgkin s lymphoma and metastatic colorectal cancer, respectively. We plan to fully capitalize on these potential indication approvals in a cash-efficient manner by staging appropriate infrastructure expansions to facilitate broad customer reach and to address other market requirements, as appropriate. These supplemental applications are currently under review by the FDA, with regulatory decisions expected in second half of 2009.

*Maximizing the asset value of apaziquone.* We took a giant step forward with our lead development asset, apaziquone, in late 2008 with the signing of a strategic collaboration with Allergan. We retained exclusive rights to apaziquone in Asia, including Japan and China while Allergan received exclusive rights to apaziquone for the treatment of bladder cancer in the rest of the world, including the United States, Canada and Europe. In the United States, we will co-promote apaziquone with Allergan and share in its profits and expenses. This drug is presently being studied, under a special protocol assessment procedure with the FDA and scientific advice from the EMEA, in two large Phase 3 clinical trials for non-muscle invasive bladder cancer. Our goal is to complete enrollment in these two trials and also begin a second study in BCG refractory bladder cancer by the end of 2009. These studies have been and will be strategically placed in centers worldwide that have extensive clinical trial experience, so as to ensure proper execution. These studies are designed to clinically differentiate this drug versus standard of care, and to ultimately successfully address the unmet needs in this disease. We hope to continue to partially monetize this asset through seeking additional strategic collaborations

in markets where we have sole rights. Specifically, our goal is to secure new partnerships for this agent in Japan and selected markets in Asia.

*Optimizing our development portfolio.* We continue to build on our core expertise in clinical development for the treatment of cancer and urology. We remain reliant on in-licensing strategies to seek drugs for

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development. Most recently, the company has undertaken a criteria-based portfolio review, which is expected to result in streamlining of our pipeline drugs that will allow for greater focus and integration of our development and commercial goals. The portfolio will be assessed based on factors that include, among others, probability of clinical success, time to and cost of development, market potential, synergies with marketed and other developmental drugs and competitive landscape. As a result of this portfolio evaluation a determination will be made of whether to: 1) continue with the drug s clinical development; 2) terminate its development; or 3) out-license rights to a third party for development and commercialization.

*Managing our financial resources effectively.* We remain committed to fiscal discipline, a policy which has allowed us to become exceptionally well capitalized among our peers, despite a very challenging fiscal environment. This policy includes the pursuit of non-dilutive funding options, prudent expense management, and the achievement of critical synergies within our operations in order to maintain a reasonable burn rate. Despite the build-up in operational structure to facilitate the marketing of two drugs, we intend to be fiscally prudent in any expansion we undertake. In terms of revenue generation, we hope to become more reliant on sales from currently marketed drugs and intend to pursue out-licensing of apaziquone in select territories and select pipeline drugs, as discussed above. If and when appropriate, we may pursue other sources of financing, including non-dilutive financing alternatives. While we are currently focused on advancing our key drug 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 drug candidate, as well as an ongoing assessment as to the drug candidate s commercial potential.

*Expanding commercial bandwidth through licensing and business development.* It remains our goal to identify drugs that will create strong synergies with our currently marketed drugs, including drugs in development. To this end, we will continue to explore strategic collaborations as these relate to drugs that are either in advanced clinical trials or are currently on the market. We believe that such opportunistic collaborations will provide synergies not only with respect to how we deploy our internal resources, but also in terms of how customers and investors view our drug offerings. In this regard, we intend to identify and secure drugs that have significant growth potential either through enhanced marketing and sales efforts or through pursuit of additional clinical development.

*Further enhancing the organizational structure to meet our corporate objectives.* We have highly experienced staff in pharmaceutical operations, clinical development, regulatory and commercial functions. All key functional areas are comprised of individuals with extensive experience in the health care industry derived from small and mid-size biotech companies to large pharmaceutical companies. We also recently strengthened the ranks of our management team, and will continue to pursue talent on an opportunistic basis. Finally, we remain committed to running a lean and efficient organization, while effectively leveraging our critical resources

**Financial Condition**

***Liquidity and Capital Resources***

Our current commercial operations do not generate sufficient operating cash to finance the clinical development of our drug product candidates, to commercialize our approved drug products and to capitalize on growth opportunities. Our cumulative losses, since inception in 1987 through December 31, 2008, have exceeded $250 million. We expect to continue to incur additional losses for at least the next few years, as we implement our growth strategy of commercializing Fusilev and Zevalin, while continuing to develop our portfolio of late-stage drug products, unless they are offset, if at all, by the out-license of any of our drugs.

We believe that the approximately $78 million in cash, cash equivalents and marketable securities that we had as of December 31, 2008 will allow us to fund our current planned operations for at least the next twelve months. We also believe the financial institutions through which we have invested our funds are strong, well capitalized and our instruments are held in accounts segregated from the assets of the institutions. However, due to the extremely

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volatile financial and credit markets and liquidity crisis currently faced by most banking institutions, the financial viability of these institutions, and the safety and liquidity of our funds is being constantly monitored.

We may seek to obtain additional capital through the sale of debt or equity securities, if necessary, especially in conjunction with opportunistic acquisitions or license of drugs. In this regard, in April 2008, we filed a shelf registration statement with the SEC to give us the ability, from time to time, to offer any combination of our securities described in the registration statement in one or more offerings for up to $150 million. There can be no assurance that we will be able to obtain such additional capital when needed, or, if available, that it will be on terms favorable to us or to our stockholders. If additional funds are raised by issuing equity securities, the percentage ownership of our stockholders will be reduced, stockholders may experience additional dilution or such equity securities may provide for rights, preferences or privileges senior to those of the holders of our common stock. If additional funds are raised through the issuance of debt securities, the terms of such securities may place restrictions on our ability to operate our business. If and when appropriate, just as we have done in the past, we may pursue non-dilutive financing alternatives as well. However, from a revenue generation perspective, we eventually hope to completely finance our operations from sales of our currently marketed products.

We are not able to provide any revenue guidance at this time. For Fusilev, our goal is to be able to maintain current usage patterns, even though it appears that the leucovorin shortage may be over. In addition, successful and continual growth of Fusilev sales will largely depend upon obtaining FDA approval for use of Fusilev in combination with 5-FU containing regimens for the treatment of colorectal cancer. For Zevalin, sales growth is largely dependent on obtaining FDA approval of our sBLA for use in first-line consolidation treatment for NHL, establishing reimbursement standards in concert with CMS and obtaining FDA approval to remove the In-111 bio-scan requirement. We are unable to reasonably estimate when, if ever, we will realize sustainable net profit from sales of these two products or any of our other products, if they are approved by the FDA.

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. 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 up-front 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. To the extent that costs, including personnel costs, are not tracked to a specific product development program, they are included in the Indirect Costs category in the table below. We charge all research and development expenses to operations as incurred.

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2008 | 2007 | 2006 |
| | (Amounts in thousands) | | |
| Fusilev | $ 1,791 | $ 1,368 | $ 4,428 |
| Zevalin | 151 | | |
| Apaziquone | 5,477 | 6,348 | 2,617 |
| Ozarelix | 2,435 | 6,217 | 2,881 |

| | | | |
|---|---|---|---|
| Ortataxel | 150 | 3,719 | |
| Other drugs | 1,304 | 3,452 | 4,457 |
| Total Direct Costs | 11,308 | 21,104 | 14,383 |
| Indirect Costs (including non-cash share-based compensation of $3,925, $3,555, and $2,540, respectively) | 15,375 | 12,181 | 9,345 |
| Total Research & Development | $ 26,683 | $ 33,285 | $ 23,728 |

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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 on-going 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.

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 2009. Upon successful achievement of these milestones, we will likely become obligated to pay up to approximately $14 million during 2009. Of this amount $4 million may be paid in cash or stock, at our option. The FDA s acceptance of our sNDA for Fusilev for CRC in March 2009, triggered the issuance of an aggregate of 125,000 shares of our common stock to Targent, or its stockholders, with a fair market value of approximately $185,000.

Our anticipated net use of cash for operations in the fiscal year ending December 31, 2009, excluding the cost of in-licensing or acquisitions of additional drugs, if any, is expected to range between approximately $25 and $30 million. The programs that will represent a significant part of our expenditures are the on-going clinical study of apaziquone and the commercialization of Fusilev, and the re-launch of Zevalin. The level of funding of our other development projects is subject to:

- the continued success of the commercialization of Fusilev;
- the success of the re-launch of Zevalin;
- continued patient enrollment in our apaziquone 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 entered into a collaboration agreement with Allergan whereby, commencing January 1, 2009, Allergan will bear 65% of the future development costs of apaziquone.

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.

*Net Cash used in Operating Activities*

During the years ended December 31, 2008 and 2007, net cash used in operations was approximately $8.0 million and $25.4 million, respectively. The decrease of approximately $17.4 million in cash required for operations is primarily due to an increase of approximately $21 million in revenues, partially offset by increases in accounts receivable, inventory and accounts payable.

*Net Cash used for Investing Activities*

Net cash used for investing activities was approximately $24.8 million and $4.6 million during the years ended December 31, 2008 and 2007, respectively. The amounts were primarily as follows: $13.1 million and $4.3 million, respectively, was invested in marketable securities and $1.5 million and $0.3 million, respectively, for capital to support operations. In addition, during 2008 we invested approximately $10.2 million for the acquisition (including

acquisition costs) of a 50% joint venture interest in Zevalin with a balance of $7.5 million payable in January 2009.

*Net Cash provided by Financing Activities*

Net cash provided by financing activities totaled approximately $41.5 million and $30.6 million for the years ended December 31, 2008 and 2007, respectively. The amounts were primarily as follows: in 2007, approximately $30 million derived from the sale of 5,134,100 shares of common stock; and in 2008, the $41.5 million up-front payment received from Allergan was recorded as deferred revenue to be amortized over future periods in accordance with our revenue recognition policy.

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**Results of Operations**

***Results of Operations for Fiscal 2008 Compared to Fiscal 2007***

In 2008, we incurred a net loss of approximately $15.5 million compared to a net loss of approximately $34 million in 2007. The principal components of the year-to-year changes in line items are discussed below.

We recognized revenue of approximately $28.7 million in 2008 as compared to approximately $7.7 million in 2007. During 2008, we recorded approximately $7.7 million of revenue from the August 2008 commercial launch of our proprietary oncology drug Fusilev, which was approved by the FDA in March 2008. While shipments of Fusilev for the period ended December 31, 2008 were approximately $10.8 million (net of estimates for promotional, price and other adjustments), based on our revenue recognition policy, we have deferred the recognition of approximately $3.1 million of such revenue until we have more experience with the amount of product returns. We also recognized approximately $0.3 million net sales of Zevalin from the consolidation of RIT Oncology effective December 15, 2008. We do expect to continue to generate revenue from the sales of these two products in 2009, however, we are not able to provide any revenue guidance at this time. In addition, during 2008, we recognized revenue from: (i) an agreement with Par Pharmaceutical, our former marketing partner for sumatriptan injection, pursuant to which we received a non-refundable $20 million cash payment from Par for the transfer of our share of the profits from the commercialization of sumatriptan injection; and (ii) the transfer of rights to certain of our ANDAs to Sagent Pharmaceuticals for $660,000. No similar revenues were generated during 2007. During 2007, we recognized approximately $7.7 million in licensing milestone and related revenues, pursuant to our agreement with GPC Biotech for satraplatin. The milestones were related to the filing and acceptance of a Marketing Authorization Application by Pharmion with the EMEA.

Research and development expenses decreased by approximately $6.6 million, from approximately $33.3 million in 2007 to approximately $26.7 million in 2008. During 2008, in line with the strategy outlined at the start of the year, and in response to the global financial crisis we focused on executing a successful launch of Fusilev and prioritized our R&D efforts to the rapid enrollment in the apaziquone clinical study. Principal components of the decrease in 2008 were as follows. Approximately:

$3.8 million and $3.6 million, respectively, due to reductions in direct development costs related to Ozarelix and Ortataxel; partially offset by,

$2.0 million increase in employee compensation expense associated substantially with the hiring of personnel to advance the apaziquone clinical study.

We anticipate research and development expense in 2009 to be lower than that during as 2008 primarily due to our joint development agreement with Allergan, under which Allergan has agreed to fund 65% of the development costs and we have agreed to fund the remaining development costs.

Selling, general and administrative expenses increased by approximately $3.6 million, from approximately $11.6 million in 2007 to approximately $15.2 million in 2008, primarily due to approximately:

$5.9 million increase attributable to sales and marketing expenses, including payroll costs, incurred with the launch of Fusilev.

$2.4 million decrease in legal expenses, largely attributable to the non-recurrence of arbitration costs against GPC Biotech incurred during 2007, partially offset by legal expenses in connection with business development activities, including the collaboration agreement with Allergan.

$1.2 million increase in employee compensation attributed to the expanded scope of operations.

We expect an increase in selling, general and administrative expenses for 2009 primarily related to sales and marketing of Fusilev and Zevalin.

Other income consisted of net interest income of approximately $1.2 and $3.1 million for the years ended December 31, 2008 and 2007 and in 2008 included approximately $200,000 realized investment gains. The decrease in interest income was primarily due to lower investment yields in 2008 due to the shift in our investment strategy to more conservative US Treasury investments. We expect similar yields going forward until such time the credit markets improve.

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***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.

We recognized revenue of approximately $7.7 million in 2007 as compared to approximately $5.7 million in 2006. 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 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.

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 apaziquone, which initiated during 2007, a Phase 2b and toxicological study of ozarelix, and the acquisition of ortataxel, milestone payments related to satraplatin and employee compensation. The increases were offset by a decrease in the development costs of other drugs, primarily Fusilev.

Selling, 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.

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.

**Off-Balance Sheet Arrangements**

We do not have any off balance sheet arrangements.

**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, 2008, approximately:

| | Total | Less than 1 Year | 2-3 Years | 4-5 Years | After 5 Years |
|---|---|---|---|---|---|
| **Contractual Obligations(1)** | | | | | |
| Capital Lease Obligations(2) | $ 201 | $ 50 | $ 101 | 50 | |
| Operating Lease Obligations(3) | 241 | 239 | 2 | | |
| Purchase Obligations(4) | 13,675 | 8,537 | 4,669 | 469 | |
| Contingent Milestone Obligations(5) | 86,600 | 14,110 | 4,679 | 7,536 | 60,275 |

| | | | | | |
|---|---|---|---|---|---|
| Total | $ 100,717 | $ 22,936 | $ 9,451 | $ 8,055 | $ 60,275 |

(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) The capital lease obligations are related to leased office equipment.

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(3) The operating lease obligations are primarily related to the facility lease for our corporate office, which expires in 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, 2008. Approximately 90% of the purchase obligations consist of expenses associated with clinical trials and related costs for apaziquone 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, 2008, given the unpredictability of the drug development process, and the impossibility of predicting the success of current and future clinical trials, the timelines estimated above do not represent a forecast of when payment milestones will actually be reached, if at all. Rather, they assume that all development and regulatory milestones under all of our license agreements are successfully met, and represent our best estimates of the timelines. In the event that the milestones are met, we believe it is likely that the increase in the potential value of the related drug product will significantly exceed the amount of the milestone obligation.

***Licensing Agreements***

Almost all of our 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 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.

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.

***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.

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, 2008, we were committed under such contracts for up to approximately $13.7 million, for future goods and services, including approximately $8.5 million due within one year. 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 contracts 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 Agreement***

We have entered into an employment agreement with Dr. Shrotriya, our President and Chief Executive Officer, which expires January 2, 2011. The employment agreement automatically renews for a one-year calendar term

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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 agreement requires Dr. Shrotriya to devote his full working time and effort to the business and affairs of the Company during the term of the agreement. The employment agreement provides 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.

Dr. Shrotriya s employment may be terminated due to non-renewal of his employment agreement by us, mutual agreement, death or disability, or by us for cause (as that term is defined in the employment agreement) or without cause, or by Dr. Shrotriya for no reason, good reason (as defined in the agreement) or non-renewal. The employment agreement provides for various guaranteed severance payments and benefits if: (i) the agreement is not renewed by us, (ii) Dr. Shrotriya s employment is terminated without cause, (iii) Dr. Shrotriya resigns for good reason, (iv) the agreement is terminated due to death or disability of Dr. Shrotriya, (v) if Dr. Shrotriya voluntarily resigns his employment for no reason or (vi) if Dr. Shrotriya s employment is terminated (other than by Dr. Shrotriya) without cause within twelve months after a change in control, or Dr. Shrotriya is adversely affected in connection with a change in control and resigns within twelve months. If the agreement is terminated due to mutual agreement, Dr. Shrotriya s non-renewal of the agreement, or by us for cause, Dr. Shrotriya shall not be entitled to any severance.

If any payment or distribution by us to or for the benefit of Dr. Shrotriya is subject to the excise tax imposed by Section 4999 of the Internal Revenue Code (IRC) or any interest or penalties are incurred by Dr. Shrotriya with respect to such excise tax, then Dr. Shrotriya shall be entitled to receive an additional payment in an amount such that after payment by Dr. Shrotriya of all taxes (including any interest and penalties imposed with respect thereto) and excise tax imposed upon such payment, Dr. Shrotriya retains an amount of the payment equal to the excise tax imposed upon the payment.

If we determine that any payments to Dr. Shrotriya under the agreement fail to satisfy the distribution requirement of Section 409A(a)(2)(A) of the IRC, the payment schedule of that benefit shall be revised to the extent necessary so that the benefit is not subject to the provisions of Section 409A(a)(1) of the IRC. We may attach conditions to or adjust the amounts so paid to preserve, as closely as possible, the economic consequences that would have applied in the absence of this adjustment; provided, however, that no such condition or adjustment shall result in the payments being subject to Section 409A(a)(1) of the IRC.

**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

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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 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. If revenue from sales is not reasonably determinable due to provisions for estimates, promotional adjustments, price adjustments, returns or any other potential adjustments, we defer the revenue and recognize revenue when the estimates are reasonably determinable, even if the monies for the gross sales have been received.

***Purchase Price Allocation***

Based on the provisions of SFAS No. 141, *Business Combinations*, for transactions that occurred prior to December 31, 2008, the purchase price for our acquisitions was allocated to the tangible and identifiable intangible assets acquired and liabilities assumed based on their estimated fair values at the acquisition date. For each acquisition, we engaged an independent third-party valuation firm to assist in determining the fair value of in-process research and development and identifiable intangible assets. Such a valuation requires significant estimates and assumptions including but not limited to: determining the timing and expected costs to complete the in-process projects, projecting regulatory approvals, estimating future cash flows from product sales resulting from in-process projects, and developing appropriate discount rates and probability rates by project. We believe the fair values assigned to the assets acquired and liabilities assumed are based on reasonable assumptions. However, these assumptions may be inaccurate, and unanticipated events and circumstances may occur.

***Research and Development***

Research and development expenses include related salaries and benefits, clinical trial and related manufacturing costs, contract and other outside service fees, and facilities and overhead costs related to our research and

development efforts. Research and development expenses also consist of costs incurred for proprietary and collaboration research and development and include activities such as product registries and investigator-sponsored trials. In accordance with Statement of Financial Accounting Standards, or SFAS, No. 2, *Accounting for Research and Development Costs,* research and development costs are expensed as incurred. In instances where we enter into agreements with third parties for research and development activities we may prepay fees for services at the initiation of the contract. We record the prepayment as a prepaid asset and charge research and development

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expense over the period of time the contracted research and development services are performed in accordance with EITF 07-3, *Accounting for Nonrefundable Advance Payment for Goods or Services to be Used in Future Research and Development Activities.* Other types of arrangements with third parties may be fixed fee or fee for service, and may include monthly payments or payments upon the completion of milestones or receipt of deliverables.

We review and accrue 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.

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

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.

***New Accounting Pronouncements***

See Note 2: *Recent Accounting Pronouncements* of our accompanying consolidated financial statements for a description of recent accounting pronouncements that have a potentially significant impact on our financial reporting and our expectations of their impact on our results of operations and financial condition.

**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, (3) general credit market risks as have existed since late 2007 and became more prominent during 2008 and (4) the financial viability of the institutions which hold our capital and through which we have invested our funds. We manage such risks on our investment portfolio by matching scheduled investment maturities with our cash requirements and investing in highly rated instruments.

In response to the dislocation in the credit markets since the latter part of 2007, in early 2008 we converted substantially all of our investments, including all of our market auction debt securities, into highly liquid and safe instruments. Our investments, as of December 31, 2008, were primarily in money market accounts, short-term corporate bonds, U.S. Treasury bills and U.S. Treasury-backed securities. We believe the financial institutions through which we have invested our funds are strong, well capitalized and our instruments are held in accounts segregated from the assets of the institutions. However, due to the current extremely volatile financial and credit markets and liquidity crunch faced by most banking institutions, the financial viability of these institutions, and the safety and liquidity of our funds is being constantly monitored.

Because of our ability to generally redeem these investments at par at 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, 2008, 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.

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, some of our obligations are incurred in Euros. We mitigate such risk by maintaining a limited portion of our cash in Euros and other currencies.

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**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 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 of Finance, of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2008, the end of the period covered by this report (Evaluation Date). Based on the foregoing, our Chief Executive Officer and Vice President of Finance concluded that our disclosure controls and procedures were effective.

**(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. Due to the timing of our acquisition of our membership interest in RIT Oncology, LLC (RIT) in a purchase business combination, we excluded RIT from the scope of our assessment of internal controls over financial reporting for the period ended December 31, 2008.

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

During the quarter ended December 31, 2008, 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, 2008, 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.

## 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 2009 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A, on or before April 30, 2009 (the 2009 Proxy Statement ).

**Item 11.** ***Executive Compensation***

The information required under this item is incorporated by reference from our 2009 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 2009 Proxy Statement.

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

The information required under this item is incorporated by reference from our 2009 Proxy Statement.

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

The information required under this item is incorporated by reference from our 2009 Proxy Statement.

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## PART IV

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

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


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| Report of Independent Registered Public Accounting Firm | F-2 |
| Consolidated Balance Sheets as of December 31, 2008 and 2007 | F-3 |
| Consolidated Statements of Operations for the years ended December 31, 2008, 2007 and 2006 | F-4 |
| Consolidated Statements of Stockholders Equity for the years ended December 31, 2008, 2007 and 2006 | F-5 |
| Consolidated Statements of Cash Flow for the years ended December 31, 2008, 2007 and 2006 | F-6 |
| Notes to Consolidated Financial Statements | 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 No. | Description |
|---|---|
| 2.1# | Asset Purchase Agreement by and between the Registrant, Targent Inc. and Certain Stockholders of Targent, Inc., dated March 17, 2006. (Filed as Exhibit 2.1 to Form 10-K/A, Amendment No. 1, as filed with the Securities and Exchange Commission on May 1, 2006, and incorporated herein by reference.) |
| 2.2 | Asset Purchase Agreement by and between the Registrant and Par Pharmaceutical, Inc., dated as of May 6, 2008. (Filed as Exhibit 2.1 to Form 10-Q, as filed with the Securities and Exchange Commission on August 11, 2008, and incorporated herein by reference.) |
| 2.3# | Purchase and Formation Agreement, dated as of November 26, 2008, by and among the Registrant, Cell Therapeutics, Inc. and RIT Oncology, LLC. (Filed as Exhibit 2.1 to Form 8-K, as filed with the Securities and Exchange Commission on December 19, 2008, and incorporated herein by reference.) |
| 3.1 | Amended Certificate of Incorporation, as filed. (Filed as Exhibit 3.1 to Form 10-Q, as filed with the Securities and Exchange Commission on August 8, 2006, and incorporated herein by reference.) |
| 3.2 | Form of Amended and Restated Bylaws of the Registrant. (Filed as Exhibit 3.1 to Form 10-Q, as filed with the Securities and Exchange Commission on August 16, 2004, and incorporated herein by reference.) |
| 4.1 | Rights Agreement, dated as of December 13, 2000, between the Registrant and ComputerShare Trust Company, N.A. (formerly 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 | Amendment No. 1 to the Rights Agreement dated as of December 13, 2000 by and between the Registrant and ComputerShare Trust Company, N.A. (formerly 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.)

4.3 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.)

4.4 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.)

4.5 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.)

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| Exhibit No. | Description |
|---|---|
| 4.6 | Amendment No. 2 to the Rights Agreement dated as of December 13, 2000 by and between the Registrant and ComputerShare Trust Company, N.A. (formerly 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.) |
| 4.7 | Amendment No. 3 to the Rights Agreement dated as of December 13, 2000 by and between the Registrant and ComputerShare Trust Company, N.A. (formerly 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.) |
| 4.8 | 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.) |
| 4.9 | 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.) |
| 4.10 | 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.) |
| 4.11 | 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.) |
| 4.12 | 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.) |
| 4.13 | 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.) |
| 4.14 | 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.) |
| 4.15 | 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.) |
| 4.16 | Amendment No. 5 to the Rights Agreement dated as of December 13, 2000 by and between the Registrant and ComputerShare Trust Company, N.A. (formerly 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.) |
| 4.17 | 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.) |
| 4.18 | Warrant issued by the Company to a Consultant, dated as of April 28, 2008. (Filed as Exhibit 4.1 to Form 10-Q, as filed with the Securities and Exchange Commission on August 11, 2008, 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.) |

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|---|---|
| 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 | License Agreement dated as of August 28, 2001, by and between the Registrant and Johnson Matthey PLC. (Filed as Exhibit 10.5 to Form 10-Q, as filed with the Securities and Exchange Commission on November 14, 2001, and incorporated herein by reference.) |

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| Exhibit No. | Description |
|---|---|
| 10.5 | 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.) |
| 10.6 | 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.) |
| 10.7 | 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.) |
| 10.8 | 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.) |
| 10.9# | 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.) |
| 10.10# | 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.) |
| 10.11 | 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.) |
| 10.12* | 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.) |
| 10.13# | 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.) |
| 10.14# | 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.) |
| 10.15* | 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.) |
| 10.16# | 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.) |
| 10.17 | 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.) |
| 10.18* | 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.) |
| 10.19# | 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.)

10.20* 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.)

10.21# 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.)

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| Exhibit No. | Description |
|---|---|
| 10.22 | 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.) |
| 10.25 | 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.) |
| 10.26* | 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.) |
| 10.27* | 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.) |
| 10.28# | 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.) |
| 10.29# | License Agreement by and between the Registrant and Indena, S.p.A. dated July 17, 2007. (Filed as Exhibit 10.4 to Form 10-Q, as filed with the Securities and Exchange Commission on November 9, 2007.) |
| 10.30* | Executive Employment Agreement by and between the Registrant and Rajesh C. Shrotriya, M.D., entered into June 20, 2008 and effective as of January 2, 2008. (Filed as Exhibit 10.1 to Form 8-K, as filed with the Securities and Exchange Commission on June 26, 2008, and incorporated herein by reference.) |
| 10.31 | Consulting Agreement by and between the Registrant and Luigi Lenaz, M.D., effective as of July 1, 2008. (Filed as Exhibit 10.2 to Form 10-Q, as filed with the Securities and Exchange Commission on August 11, 2008, and incorporated herein by reference.) |
| 10.32*+ | Form of Indemnity Agreement of the Registrant. |
| 10.33#+ | License, Development, Supply and Distribution Agreement dated October 28, 2008 by and among the Registrant and Allergan Sales, LLC, Allergan USA, Inc. and Allergan, Inc. |
| 21+ | Subsidiaries of Registrant. |
| 23.1+ | Consent of Kelly & Company. |
| 31.1+ | Certification of Chief Executive Officer, pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934. |
| 31.2+ | Certification of Vice President Finance, pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934. |
| 32.1+ | Certification of Chief Executive Officer, pursuant to Rule 13a-14(b)/15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350. |
| 32.2+ | Certification of Vice President Finance, pursuant to Rule 13a-14(b)/15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350. |

* 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 31, 2009

## POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints each of Rajesh C. Shrotriya and Shyam K. Kumaria as his attorney-in-fact, with full power of substitution, for him in any and all capacities, to sign any amendments to this Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each attorney-in-fact, or his substitute, may do or cause to be done by virtue hereof.

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

| Signature | Title | Date |
|---|---|---|
| /s/ Rajesh C. Shrotriya, M.D.<br>Rajesh C. Shrotriya, M.D. | Chairman of the Board,<br>Chief Executive Officer, and President<br>(Principal Executive Officer) | March 31, 2009 |
| /s/ Shyam K. Kumaria<br>Shyam K. Kumaria | Vice President Finance<br>(Principal Financial and Accounting Officer) | March 31, 2009 |
| /s/ Mitchell P. Cybulski<br>Mitchell P. Cybulski | Director | March 31, 2009 |
| /s/ Richard D. Fulmer<br>Richard D. Fulmer | Director | March 31, 2009 |
| /s/ Stuart M. Krassner, Sc.D., Psy.D.<br>Stuart M. Krassner, Sc.D., Psy.D. | Director | March 31, 2009 |

| | | |
|---|---|---|
| /s/ Anthony E. Maida, III<br>Anthony E. Maida, III | Director | March 31, 2009 |
| /s/ Julius A. Vida, Ph.D.<br>Julius A. Vida, Ph.D. | Director | March 31, 2009 |

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

**Consolidated Financial Statements**

*As of December 31, 2008 and 2007 and*

*For Each of the Three Years in the Period Ended December 31, 2008*

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

**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, 2008 and 2007, 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, 2008. We also have audited Spectrum Pharmaceuticals, Inc. and Subsidiaries internal control over financial reporting as of December 31, 2008, 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.

As described in Management s Report on Internal Control over Financial Reporting the Company s, management has excluded RIT Oncology, LLC (RIT) from its assessment of internal control over financial reporting as of December 31, 2008 because it was acquired by the Company in a purchase business combination during 2008. We have also excluded RIT from our audit of internal control over financial reporting.

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, 2008 and 2007, and the consolidated results of its operations and its cash flows for each of the years in the three-year period ended

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December 31, 2008, 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, 2008, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO)

Kelly & Company,
Certified Public Accountants

Costa Mesa, California
March 31, 2009

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

**Consolidated Balance Sheets**

| | December 31, 2008 | December 31, 2007 |
|---|---|---|
| | (In thousands, except share and per share data) | |
| **ASSETS** | | |
| Current Assets: | | |
| Cash and cash equivalents | $ 9,860 | $ 1,141 |
| Marketable securities | 68,226 | 54,518 |
| Accounts receivable-trade, net | 5,002 | 191 |
| Inventory | 1,841 | |
| Prepaid expenses and other current assets | 693 | 762 |
| Total current assets | 85,622 | 56,612 |
| Property and equipment, net | 1,782 | 716 |
| Zevalin related intangible assets, net | 37,042 | |
| Other assets | 289 | 212 |
| **Total assets** | **$ 124,735** | **$ 57,540** |
| **LIABILITIES AND STOCKHOLDERS EQUITY** | | |
| Current Liabilities: | | |
| Accounts payable and accrued obligations | $ 5,627 | $ 1,598 |
| Accrued compensation | 2,956 | 1,111 |
| Note payable to Cell Therapeutics in connection with Zevalin joint venture | 7,500 | |
| Current portion of deferred revenue and other credits | 8,500 | |
| Accrued drug development costs | 3,449 | 5,090 |
| Total current liabilities | 28,032 | 7,799 |
| Capital lease obligations, net of current portion | 95 | |
| Zevalin related contingent obligations | 8,798 | |
| Deferred revenue and other credits, net of current portion | 33,929 | 992 |
| **Total liabilities** | **70,854** | **8,791** |
| Commitments and contingencies (Note 10) | | |
| Minority interest in consolidated entity | 14,262 | |
| 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 | 419 | 1,048 |

| | | |
|---|---|---|
| Series E Convertible Voting Preferred Stock, 2,000 shares authorized, stated value $10,000 per share, $0.8 million aggregate liquidation value, issued and outstanding, 68 and 170 shares at December 31, 2008 and 2007, respectively | | |
| Common stock, par value $0.001 per share, 100,000,000 shares authorized; Issued and outstanding, 32,166,316 and 31,233,798 shares at December 31, 2008 and 2007, respectively | 32 | 31 |
| Additional paid-in capital | 296,531 | 288,927 |
| Accumulated other comprehensive income <loss> | (146) | 493 |
| Accumulated deficit | (257,217) | (241,750) |
| **Total stockholders equity** | **39,619** | **48,749** |
| **Total liabilities and stockholders equity** | **$ 124,735** | **$ 57,540** |

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

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

**Consolidated Statements of Operations**

| | Years Ended December 31, | | |
|---|---|---|---|
| | **2008** | **2007** | **2006** |
| Revenues | | | |
| License and contract revenue | $ 20,676 | $ 7,672 | $ 5,000 |
| Product sales | 8,049 | | 92 |
| Other revenue | | | 581 |
| Total revenues | $ 28,725 | $ 7,672 | $ 5,673 |
| Operating expenses: | | | |
| Cost of product sold | 1,193 | | 97 |
| Research and development | 26,683 | 33,285 | 23,728 |
| Acquired in-process research and development | 4,700 | | |
| Amortization of purchased intangibles | 158 | | |
| Selling, general and administrative | 15,161 | 11,582 | 7,741 |
| Total operating expenses | 47,895 | 44,867 | 31,566 |
| Loss from operations | (19,170) | (37,195) | (25,893) |
| Other income, net | 1,165 | 3,139 | 2,606 |
| Loss before minority interest in consolidated entities | (18,005) | (34,056) | (23,287) |
| Minority interest in net loss of consolidated entities | 2,538 | 20 | 3 |
| **Net loss** | **$ (15,467)** | **$ (34,036)** | **$ (23,284)** |
| **Basic and diluted net loss per share** | **$ (0.49)** | **$ (1.17)** | **$ (0.96)** |
| **Basic and diluted weighted average common shares outstanding** | **31,551,152** | **29,013,850** | **24,311,306** |

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

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

**Consolidated Statements of Stockholders Equity and Comprehensive Income (Loss)**

| | Preferred Stock | | Common Stock | | Additional Paid-In | Accumulated Other Comprehensive Income | Accumulated | |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Capital | (Loss) | Deficit | Total |
| **Balance at December 31, 2005** | **448** | **$ 2,542** | **23,503,157** | **$ 24** | **$ 242,873** | **$ (26)** | **$ (184,430)** | **$ 60,983** |
| 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 milestones | | | 140,000 | | 574 | | | 574 |
| Issuance of common stock upon exercise of warrants | | | 17,750 | | 53 | | | 53 |
| Issuance of common stock | | | 1,500 | | 3 | | | 3 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| upon exercise of 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 | | 3,806 | | | 3,806 |
| Series D Preferred Stock dividend paid with common stock | | | 15,434 | | | | | |
| Series D Preferred Stock dividend paid in cash | | | | | (26) | | | (26) |
| **Balance at December 31, 2006** | **219** | **$ 1,281** | **25,217,793** | **$ 25** | **$ 251,880** | **$ 357** | **$ (207,714)** | **$ 45,829** |
| 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 | | | 161,145 | | 519 | | | 519 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| upon exercise of 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 | | | | | |
| **Balance at December 31, 2007** | **170** | **$ 1,048** | **31,233,798** | **$ 31** | **$ 288,927** | **$ 493** | **$ (241,750)** | **$ 48,749** |
| Net Loss | | | | | | | (15,467) | (15,467) |
| Realized gains on investments | | | | | | (493) | | (493) |
| Unrealized loss on investments | | | | | | (146) | | (146) |
| Total comprehensive loss, net | | | | | | (639) | (15,467) | (16,106) |
| Conversion of Series E Preferred Stock into Common Stock | (102) | (629) | 204,000 | | 629 | | | |
| Fair value of common stock issued to Targent, Inc. for NDA Approval | | | 125,000 | | 305 | | | 305 |
| Fair value of common stock issued to NDDO, University of Bradford | | | 75,000 | | 74 | | | 74 |
| Share-based compensation expense and | | | 362,088 | 1 | 6,322 | | | 6,323 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| common stock issued | | | | | | | | |
| Issuance of common stock to 401(k) plan | | | 166,430 | | 274 | | | 274 |
| Fractional share adjustments | | | | | | | | |
| **Balance at December 31, 2008** | **68** | **$ 419** | **32,166,316** | **$ 32** | **$ 296,531** | **$ (146)** | **$ (257,217)** | **$ 39,619** |

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

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

**Consolidated Statements of Cash Flows**

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2008 | 2007 | 2006 |
| | (In thousands, except share and per share data) | | |
| *Cash Flows From Operating Activities*: | | | |
| Net loss | $ (15,467) | $ (34,036) | $ (23,284) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation and amortization | 610 | 255 | 198 |
| Acquired in-process research and development | 4,700 | | |
| Share-based compensation expense | 6,537 | 5,652 | 3,951 |
| Fair value of common stock issued in connection with drug license | 379 | 520 | 3,316 |
| Minority interest in consolidated entities | (2,538) | (20) | (3) |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | (4,811) | 959 | (863) |
| Inventory | (1,841) | | |
| Prepaid expenses and other assets | 101 | (268) | (63) |
| Accounts payable and accrued obligations | 2,387 | 1,463 | 2,111 |
| Accrued compensation and related taxes | 1,845 | 103 | 325 |
| Deferred revenue and other credits | 93 | (43) | 794 |
| **Net cash used in operating activities** | **(8,005)** | **(25,415)** | **(13,518)** |
| *Cash Flows From Investing Activities*: | | | |
| Net purchases of marketable securities | $ (13,056) | (4,265) | (14,901) |
| Investment in Zevalin joint venture | (10,202) | | |
| Purchases of property and equipment | (1,518) | (346) | (261) |
| **Net cash used in investing activities** | **(24,776)** | **(4,611)** | **(15,162)** |
| *Cash Flows From Financing Activities*: | | | |
| Proceeds from issuance of common stock and warrants, net of related offering costs and expenses | | 30,009 | 419 |
| Proceeds from exercise of warrants | | 519 | 53 |
| Proceeds from exercise of stock options | | 120 | 3 |
| Proceeds from Allergan collaboration | 41,500 | | |
| Cash dividends paid on preferred stock | | | (26) |
| **Net cash provided by financing activities** | **41,500** | **30,648** | **449** |
| **Net increase <decrease> in cash and cash equivalents** | **8,719** | **622** | **(28,231)** |
| **Cash and cash equivalents, beginning of period** | **1,141** | **519** | **28,750** |
| **Cash and cash equivalents, end of period** | **$ 9,860** | **$ 1,141** | **$ 519** |

| | | | |
|---|---|---|---|
| *SUPPLEMENTAL CASH FLOW INFORMATION*: | | | |
| Interest paid | $ 36 | $ | $ |
| Income taxes paid | $ | $ | $ 5 |
| *SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES*: | | | |
| Fair value of common stock issued in connection with drug license | $ 379 | $ 520 | $ 3,316 |
| Fair value of restricted stock granted employees and directors | $ 606 | $ 1,308 | $ 338 |
| Fair value of stock issued to match employee 401k contributions | $ 274 | $ 179 | $ 176 |
| Preferred stock dividends paid with common stock | $ | $ 12 | $ 70 |
| Fair value of equity awarded to consultants and placement agents | $ 70 | $ 70 | $ 263 |

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

We are a commercial stage biopharmaceutical company committed to developing and commercializing innovative therapies with a focus primarily in the areas of hematology-oncology and urology. We have a fully developed commercial infrastructure that is responsible for the sales and marketing of two drugs in the United States, namely Fusilev and Zevalin. Our lead developmental drug is apaziquone (formerly, EOquin), which is presently being studied in two large Phase 3 clinical trials for bladder cancer under a strategic collaboration with Allergan Inc. Another drug, ozarelix is in a Phase 2 clinical trial for benign prostatic hypertrophy (BPH).

## 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, our wholly-owned subsidiaries, and joint ventures the Company controls, or of which it is the primary beneficiary. We evaluate the need to consolidate joint ventures based on standards set forth in Financial Accounting Standards Board ( FASB ) Financial Interpretation ( FIN ) No. 46R, *Consolidation of Variable Interest Entities* ( FIN 46R ). Investments by outside parties in our consolidated entities are recorded as Minority Interest in Consolidated entities in our accounts, and stated net after allocation of income and losses in the entity.

As of December 31, 2008, we had two consolidated subsidiaries: OncoRx Pharma Private Limited ( OncoRx ), 100% owned, organized in Mumbai, India in 2008 and Spectrum Pharmaceuticals GmbH, wholly-owned inactive subsidiary, incorporated in Switzerland in April 1997; and two consolidated joint ventures: RIT Oncology, LLC ( RIT ), organized in Delaware in October 2008; and Spectrum Pharma Canada, organized in Quebec, Canada in January 2008. During 2008, we dissolved NeoJB LLC ( NeoJB ), which was 80% owned by us and organized in Delaware in April 2002.

We have eliminated all significant intercompany accounts and transactions.

### *Use of Estimates*

The preparation of financial statements in conformity with generally accepted accounting principles ( GAAP ) 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.

### *Fair Value of Financial Instruments*

Effective January 1, 2008, we adopted Statement of Financial Accounting Standards No. 157, *Fair Value Measurements*, or FAS 157. In February 2008, FASB issued its Staff Position No. FAS 157-2, Effective Date of FASB Statement No. 157, which provides a one year deferral of the effective date of FAS 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually. Therefore, we adopted the provisions of FAS 157 with respect to our financial assets and liabilities

only. FAS 157 defines fair value, establishes a framework for measuring fair value under GAAP and enhances disclosures about fair value measurements. Fair value is defined under FAS 157 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value under FAS 157 must maximize the use of observable inputs and minimize the use of unobservable inputs.

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

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

We utilize the market approach to measure fair value for our financial assets and liabilities. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets or liabilities. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

*Level 1:* Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

*Level 2:* Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

*Level 3:* Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, we utilize valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible, as well as consider counterparty credit risk in assessment of fair value.

The adoption of this statement did not have a material impact on our consolidated results of operations and financial condition. The carrying values of our cash, cash equivalents and marketable securities, carried at fair value as of December 31, 2008, are classified in the table below in one of the three categories described above:

| | Fair Value Measurements at December 31, 2008 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Cash & Equivalents | $ 9,860 | | | $ 9,860 |
| FDIC insured Bank Certificates of Deposit | $ 10,509 | | | 10,509 |
| Money Market Currency Funds | $ 128 | | | 128 |
| U.S. Treasury Backed Securities | $ 43,650 | | | 43,650 |
| U.S. Treasury T-Bills | $ 12,217 | | | 12,217 |
| Corporate Debt Securities | $ 1,912 | | | 1,912 |
| Other Securities | $ 47 | | | 47 |
| | $ 78,323 | | | $ 78,323 |

***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, 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 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.

As of December 31, 2008, substantially all of our marketable securities were held in short-term US treasury bills or US treasury backed mutual funds or FDIC insured bank certificates of deposits and held 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 rated instruments, which are primarily US treasury bills or US treasury backed

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

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

securities, with limitations on investing in securities of any single issuer. To a limited degree these investments are insured by the Federal Deposit Insurance Corporation 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 have existed since late 2007. We manage such risks on our portfolio by matching scheduled investment maturities with our cash requirements and investing in highly rated instruments.

***Certain Risks and Concentrations***

We are subject to concentration of credit risk primarily from our cash investments. Under our investment guidelines, credit risk is managed by diversification of the investment portfolio and by the purchase of investment-grade securities. We do not require collateral or other security to support credit sales, but provide an allowance for bad debts when warranted.

Our product sales are concentrated in a limited number of customers. Our largest customers are Group Purchasing Organizations (GPOs) of oncology products who accounted for approximately 30% of our net revenues and approximately 70% of the net revenues were generated by distributors. GPOs accounted for approximately 30% of the net accounts receivables and distributors accounted for approximately 70% of net receivables.

Currently we have single source suppliers for raw materials, and the manufacturing of finished product of Fusilev and Zevalin. A disruption in supply could materially affect our sales.

Similarly, we have single source suppliers for raw materials, and manufactured finished product for our development drug products. If we are unable to obtain sufficient quantities of such product, our research and development activities may be adversely affected.

***Inventory***

Inventory is stated at the lower of cost (first-in, first-out method) or market. The lower of cost or market is determined based on net estimated realizable value after appropriate consideration is given to obsolescence, excessive levels, deterioration, and other factors.

***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.

***Purchase price allocation***

Based on the provisions of SFAS No. 141, Business Combinations, the purchase price for the acquisition of Zevalin rights was allocated to identifiable intangible assets acquired and liabilities assumed based on their estimated fair values at the acquisition date, as determined by an independent third-party valuation firm. Such a valuation requires significant estimates and assumptions including but not limited to: determining the timing and

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

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

expected costs to complete the in-process projects, projecting regulatory approvals, estimating future cash flows from product sales resulting from in-process projects, and developing appropriate discount rates and probability rates by project. We believe the fair values assigned to the assets acquired and liabilities assumed are based on reasonable assumptions. However, these assumptions may be inaccurate, and unanticipated events and circumstances may occur.

***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. Our foreign operations were not significant 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, 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 also state the related accounts receivable at net realizable value, with any allowance for doubtful accounts charged to general operating expenses. If revenue from sales is not reasonably determinable due to provisions for estimates, promotional adjustments, price adjustments, returns or any other potential adjustments, we defer the revenue and recognize revenue when the estimates are reasonably determinable, even if the monies for the gross sales have been received.

***Research and Development***

Research and development expenses include related salaries and benefits, clinical trial and related manufacturing costs, contract and other outside service fees, and facilities and overhead costs related to our research and development efforts. Research and development expenses also consist of costs incurred for proprietary and collaboration research and development and include activities such as product registries and investigator-sponsored trials. In accordance with Statement of Financial Accounting Standards, or SFAS, No. 2, *Accounting for Research and*

*Development Costs,* research and development costs are expensed as incurred. In instances where we enter into agreements with third parties for research and development activities we may prepay fees for services at the initiation of the contract. We record the prepayment as a prepaid asset and charge research and development expense over the period of time the contracted research and development services are performed in accordance with EITF 07-3, *Accounting for Nonrefundable Advance Payment for Goods or Services to be Used in Future Research and Development Activities.* Other types of arrangements with third parties may be fixed fee or fee for service, and may include monthly payments or payments upon the completion of milestones or receipt of deliverables.

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We review and accrue 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.

***Acquired In-Process Research and Development.***

In accordance with SFAS No. 141, Business Combinations, we immediately charge the costs associated with purchased in-process research and development ( IPR&D ), to the statement of operations upon acquisition. These amounts represent an estimate of the fair value of purchased IPR&D for projects that, as of the acquisition date, had not yet reached technological feasibility, had no alternative future use, and had uncertainty in generating future economic benefits. We determine the future economic benefits from the purchased IPR&D to be uncertain until such technology is incorporated into products approved for marketing by the FDA or when other significant risk factors are abated.

***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, 2008.

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2008 | 2007 | 2006 |
| | (Amounts in thousands except share and per share data) | | |
| Net loss | $ (15,467) | $ (34,036) | $ (23,284) |
| Less: Preferred dividends paid in cash or stock | | (12) | (96) |
| Loss attributable to common stockholders used in computing basic loss per share | $ (15,467) | $ (34,048) | $ (23,380) |
| Weighted average shares outstanding | 31,551,152 | 29,013,850 | 24,311,306 |

| | | | |
|---|---|---|---|
| Basic and diluted net loss per share | $ (0.49) | $ (1.17) | $ (0.96) |

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

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.

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

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.

We recorded share-based compensation during each of the three years in the period ended December 31, 2008 as follows:

| | 2008 | 2007 | 2006 |
|---|---|---|---|
| | (Amounts in thousands) | | |
| Research and development | $ 3,925 | $ 3,555 | $ 2,540 |
| Selling, general and administrative | 2,612 | 2,097 | 1,411 |
| **Total Share-based compensation** | **$ 6,537** | **$ 5,652** | **$ 3,951** |

***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 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, 2008 and 2007 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).

***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.

***New Accounting Pronouncements***

Effective January 2008, we adopted the provisions of EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, or Issue 07-3, which addresses the accounting for nonrefundable advance payments. The EITF concluded that nonrefundable advance payments for goods or services to be received in the future for use in research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services are performed. If an entity s expectations change such that it does not expect it will need the goods to be delivered or the services to be rendered, capitalized nonrefundable advance payments should be charged to expense. The adoption of Issue No. 07-3 did not have a material impact on our results of operations or financial position.

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In December 2007, FASB ratified the final consensuses in Emerging Issues Task Force, or EITF, Issue No. 07-1, *Accounting for Collaborative Arrangements,* or Issue 07-1, which requires certain income statement presentation of transactions with third parties and of payments between parties to the collaborative arrangement, along with disclosure about the nature and purpose of the arrangement. Issue 07-1 is effective for us beginning January 1, 2009. We do not expect the adoption of this accounting pronouncement to have a significant impact on our financial statements.

In December 2007, FASB issued SFAS No. 141(R), *Business Combinations* (SFAS No. 141(R)), which replaces SFAS No. 141, *Business Combinations* . SFAS No. 141(R), 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 the adoption of this accounting pronouncement to 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 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 the adoption of this accounting pronouncement to have a significant impact on our financial statements.

In March 2008, FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133* ( SFAS No. 161 ). SFAS No. 161 amends and expands the disclosure requirements of SFAS No. 133 with the intent to provide users of financial statements with an enhanced understanding of: (i) How and why an entity uses derivative instruments; (ii) How derivative instruments and related hedged items are accounted for under SFAS No. 133 and its related interpretations and (iii) How derivative instruments and related hedged items affect an entity s financial position, financial performance and cash flows. This Statement is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. We do not expect the adoption of this accounting pronouncement to have a significant impact on our financial statements.

In May 2008, FASB issued SFAS No. 162 *The Hierarchy of Generally Accepted Accounting Principles* ( SFAS 162 ), which is effective 90 days following the SEC s approval of the Public Company Oversight Board amendments to AU Section 411, The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles. SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in

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conformity with GAAP in the United States (the GAAP hierarchy). We do not expect the adoption of this accounting pronouncement to have a significant impact on our financial statements.

In June 2008, FASB issued FSP EITF 03-6-1, *Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities* ( FSP EITF 03-6-1 ). FSP EITF 03-6-1 addresses whether instruments granted in share-based payment transactions are participating securities prior to vesting and, therefore, need to be included in computing earnings per share under the two-class method described in SFAS No. 128, *Earnings Per Share*. FSP EITF 03-6-1 requires companies to treat unvested share-based payment awards that have non-forfeitable rights to dividend or dividend equivalents as a separate class of securities in calculating earnings per share. FSP EITF 03-6-1 will be effective for the Company s fiscal year beginning March 1, 2009, with early adoption prohibited. We are evaluating the effect the implementation of FSP EITF 03-6-1 will have, if any, on basic net earnings per share.

## 3. Commercial and Development Drug Products

We currently market two products in the United States, Zevalin and Fusilev. In addition, we have multiple products in clinical development, including apaziquone (formerly Eoquin) which is in two Phase 3 clinical trials for bladder cancer and ozarelix which is in a Phase 2 clinical trial for benign prostatic hypertrophy (BPH). The following is a brief description of our key products as of December 31, 2008.

*Zevalin:* In December 2008, we partnered with Cell Therapeutics, Inc. (CTI) to form a 50/50 owned joint venture, RIT Oncology, LLC (RIT), to commercialize and develop Zevalin ([90Y]-ibritumomab tiuxetan) in the U.S. In March 2009, CTI sold to us their remaining 50% ownership in RIT, resulting in RIT becoming a wholly-owned subsidiary. (See Note 14 for discussion of subsequent event, and proforma effect on 2008 financial results).

Zevalin is a prescribed form of cancer therapy called radioimmunotherapy. Radioimmunotherapy combines a source of radiation, called a radioisotope, with an antibody. As part of the Zevalin therapeutic regimen, the Y-90 radioisotope is combined with a monoclonal antibody (CD20 MAB) that specifically recognizes a particular part of a B-cell (the cells of the immune system that make antibodies to invading pathogens) called the CD20 antigen. The CD20 antigen is found on malignant and normal B-cells. As the patient is infused with Y-90 Zevalin and it enters the bloodstream, the antibody portion recognizes and attaches to the CD20 antigen on tumor cells, allowing the radiation energy emitted from the Y-90 radioisotope (*i.e.*, beta emission) to penetrate and damage the malignant B-cells as well as nearby neighboring cells, many of which are also lymphoma cells. In December 2008, the FDA accepted for filing and review, and granted priority review status for, RIT s supplemental Biologics License Application ( sBLA ) for the use of Zevalin as first-line consolidation therapy for patients with B-cell follicular NHL. Under a relapsed or refractory setting, Zevalin is used for treatment if a patient is not responding to first-line therapy with other chemotherapeutic, cytotoxic or anti-cancer drugs or if the lymphoma returns after first-line therapy. Consolidation therapy aims to rapidly improve the quality of the response achieved with initial remission induction treatment. Induction therapy is a treatment designed as a first step toward reducing the number of cancer cells. Currently, a PDUFA target date of July 2, 2009 has been established by the FDA for a decision regarding the Zevalin sBLA.

Upon the closing of the transaction mentioned above, CTI contributed the Zevalin product assets to RIT in exchange for a 50% membership interest in RIT and the cash payments to CTI noted below. CTI received an initial cash payment of $7.5 million at the closing of the transaction on December 15, 2008, and received an additional $7.5 million cash payment in early January 2009.

The assets contributed by CTI to RIT were all of its interests in the Zevalin business, which included the following: (i) assets acquired in the December 2007 agreement with Biogen, which included the U.S. development, sales and marketing rights to Zevalin. The assets acquired included the Zevalin FDA registration, FDA dossier, U.S. trademark, trade name and trade dress, customer list, certain patents and the assignment of numerous contracts. There was no continuity of physical facilities or personnel from the December 2007 transaction; (ii) assets acquired

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in the June 2008 Access Agreement with Bayer Schering Pharma AG, which holds the rights to Zevalin outside of the United States. Under the agreement, Bayer gave CTI access to data from Bayer s phase 3 first-line indolent trial (FIT Trial), of Zevalin; and (iii) CTI s September 30, 2008 submission of the Zevalin sBLA for use in first-line consolidation therapy for patients with B-cell follicular NHL. The FDA has granted priority review status for this sBLA and a decision is targeted for July 2009. The joint venture also assumed obligations of $2.2 million in current liabilities and certain contingent obligations.

The allocation of the initial capitalization of the joint venture, detailed below, was based on the relative fair values of the intangible assets acquired, as determined by an independent valuation consultant, and the obligations assumed by the joint venture.

| | | |
|---|---|---|
| Developed technology | | $ 23,100 |
| Core technology | | 14,100 |
| Acquired in-process research and development | | 4,700 |
| Assumed Obligation to pay Biogen | | (2,200) |
| Acquisition transaction costs | | (902) |
| Fair Value of Assumed Contingent Obligations | $ 12,500 | |
| Less: Limitation based on excess of values of Intangibles acquired over Initial capitalization | (1,898) | |
| Contingent Obligations, as recorded | | (8.798) |
| Total initial capitalization of Joint Venture | | $ 30,000 |

The total fair value of intangible assets equals $41.9 million which includes developed technology, core technology and acquired in-process research and development. The developed technology asset relates to intellectual property and rights thereon related to Zevalin as approved by the FDA for relapsed or refractory, low-grade or follicular B-cell NHL. The core technology asset represents the value of the intellectual property and rights therein expected to be leveraged in the development of label expansions for Zevalin. Developed and core technologies will be amortized over the term of the patents related to such technologies. We estimate aggregate amortization expense related to these acquired intangible assets to be $3.7 million annually. IPR&D for RIT was evaluated utilizing the present value of the estimated after-tax cash flows expected to be generated by purchased undeveloped technology related to the Zevalin business or label expansions for indications that have not been approved by the FDA. Since, at the effective time of the transaction establishing RIT, the IPR&D had not reached technological feasibility, such amount has been charged to retained earnings as of the formation date of RIT.

In accordance with SFAS 141 *Business Combinations,* because the RIT transaction involves contingent consideration, we recognized $8.8 million as a Zevalin related contingent obligation on the balance sheet, which is equal to the excess of the fair value of the intangible assets over the initial capitalization, and is less than the approximately $12.5 million fair value of the contingent consideration, as determined by the independent valuation consultant. When the contingencies are resolved and the contingent consideration becomes payable, any excess of the fair value of the contingent consideration over the amount initially recognized as a liability shall be recognized as an additional cost of

the acquired entity. If the amount initially recognized as a liability exceeds the fair value of the contingent consideration, that excess will be allocated as a pro rata reduction of the amounts assigned to the assets acquired.

The following describes certain additional terms relating to Zevalin licensing and development:

In connection with obtaining the required consent of Biogen to the foregoing transactions, we entered into certain agreements with Biogen. Such agreements included:

an amendment to the original asset purchase agreement between CTI and Biogen (CTI/Biogen Agreement), modifying future milestone payments, to provide that (i) concurrently with the execution of the

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

amendment CTI was required to pay Biogen $0.2 million (which was reimbursed to CTI by RIT from the initial capital contributions made by CTI and us), (ii) upon the December 2008 closing of the transaction, CTI was required to pay Biogen an additional $2.0 million (which was paid by RIT as successor to CTI under the amendment), (iii) upon the achievement of the specified FDA approval milestone, RIT (as successor to CTI) will be required to pay Biogen an additional amount of $5.5 million if the milestone event occurs in 2009 (provided that RIT may elect to defer any such payment until January 1, 2010, but upon such election the required payment will increase to $6.0 million), $7.0 million if the milestone event occurs in 2010, $9.0 million if the milestone event occurs in 2011, or $10.0 million if the milestone event occurs in 2012 or later. No other material terms of the CTI/Biogen Agreement were modified. CTI s rights and obligations, including its payment obligations to Biogen, including royalties on net sales of Zevalin and an additional regulatory milestone payment, under both the CTI/Biogen Agreement and the amendment were assigned to and assumed by RIT in connection with the closing of the joint venture transaction.

an amendment to the original supply agreement between Biogen and CTI (CTI/Biogen Supply Agreement), modifying certain of the pricing and manufacturing technology transfer terms contained in the CTI/Biogen Supply Agreement and also providing that the term of the agreement may be shortened in some instances in the event of a mid-term manufacturing technology transfer. CTI s rights and obligations, including its payment obligations to Biogen, under both the CTI/Biogen Supply Agreement and the amendment were assigned to and assumed by RIT in connection with the closing of the joint venture transaction.

a security agreement, by and between RIT and Biogen whereby RIT granted to Biogen a first priority security interest in all of RIT s assets, including the assets contributed to RIT by CTI in connection with the closing of the joint venture transaction, to secure certain payment, indemnification and other obligations of RIT to Biogen.

a guarantee, by Spectrum for the benefit of Biogen whereby we have, among other things, guaranteed the payment and performance all of RIT s obligations to Biogen (including its obligations as assignee of CTI under all contractual arrangements between CTI and Biogen that were assigned to and assumed by RIT in connection with the closing of the joint venture transaction).

*Fusilev for Injection:* On August 15, 2008, we commercially launched our proprietary oncology drug Fusilev, which New Drug Application ( NDA ) was approved by the U.S. Food and Drug Administration ( FDA ) in March 2008.

Fusilev rescue is indicated after high-dose methotrexate therapy in patients with osteosarcoma, the most common form of bone cancer, and is also indicated to diminish the toxicity and counteract the effects of impaired methotrexate elimination or inadvertent overdose of folic acid antagonists. We filed a supplemental NDA for its use in colorectal cancer in 5-fluorouracil containing regimens with the FDA at the end of October 2008. Also, in June 2008, we filed an NDA amendment for a tablet formulation.

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 Fusilev 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 and 2008, we recorded stock-based research and

development charges of $520,000 and $305,000, respectively, which represents the fair market value of 125,000 shares of our common stock issued at each of October 2007 and March 2008 as milestone payments to Targent, LLC.

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*Apaziquone (formerly EOquin):* Apaziquone, 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-muscle invasive bladder cancer.

In October 2008, we signed an exclusive development and commercialization collaboration agreement with Allergan for apaziquone. Under the terms of the agreement, Allergan paid us an upfront non-refundable $41.5 million at closing and will make additional payments of up to $304 million based on the achievement of certain development, regulatory and commercialization milestones. We retained exclusive rights to apaziquone in Asia, including Japan and China. Allergan received exclusive rights to apaziquone for the treatment of bladder cancer in the rest of the world, including the United States, Canada and Europe.

In the United States, Allergan and we will co-promote apaziquone and share equally in its profits and expenses. Allergan will also pay us royalties on all of its apaziquone sales outside of the United States. Under the terms of the agreement, we will continue to conduct the development program, including the manufacture of clinical supplies and the conduct of the current and future phase 3 clinical trials, and will be jointly responsible for obtaining regulatory approval for the product. Both parties will share development expenses with Allergan bearing 65% of the cost. Pursuant to our revenue recognition policy, we expect that we will recognize the up front payment of $41.5 million over the period of the development work, estimated at 4 to 5 years. As of December 31, 2008, we have classified $8.5 million of such amount on the balance sheet as current portion of deferred revenue.

We also have the right, in our sole discretion, to opt-out of the co-promotion agreement before January 1, 2012. If we do so, our share of any future development costs shall be significantly reduced. Part of the aggregate development costs and marketing expenses incurred by us since January 1, 2009 shall be reimbursed by Allergan in the form of a one-time payment. The co-promotion agreement will terminate and instead of a sharing of profit and expenses, Allergan will pay us royalties on a percentage of net sales of the apaziquone in the United States that are slightly greater than the royalties paid on net sales outside the United States. In addition, Allergan will pay us up to $245 million in additional milestones based upon the achievement of certain sales milestones in the United States.

In October 2008, we terminated our 2001 license agreement for apaziquone with INC Research®, formerly NDDO Research Foundation, in the Netherlands as the patents underlying the agreement were all about to expire. Pursuant to the termination, INC assigned to us all rights it had in the know-how or intellectual property licensed under the agreement and all rights in may have had in any know-how or intellectual property created during the term of the agreement. In exchange we paid INC a small amount of cash and issued them a small number of shares of our common stock. In addition, INC is entitled to up to 25,000 additional shares of our common stock and an additional payment of $300,000 upon achievement of certain regulatory milestones.

*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.

Based on the results of the previous studies, we have initiated a multi-center, randomized, double-blind, placebo-controlled study to evaluate the efficacy of ozarelix compared to placebo in the treatment of lower urinary tract symptoms (LUTS) secondary to BPH in men as assessed by the IPSS at Week 14.

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 50% financial interest in any income Aeterna Zentaris derives from ozarelix in Japan. We are contingently obligated to pay amounts based upon achievement of milestones and a royalty based on any future net sales.

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## 4. Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents, and investments in marketable securities totaled $78.3 million and $55.8 million as of December 31, 2008 and 2007, 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 | Long Term |
| December 31, 2008 | | | | | | | |
| Cash and Equivalents | $ 9,860 | | | $ 9,860 | $ 9,860 | | |
| FDIC Insured Bank Certificates of Deposit | 10,509 | | | 10,509 | | $ 10,319 | $ 190 |
| Money Market Currency Funds | 128 | | | 128 | | 128 | |
| U.S. Government securities | 55,867 | | | 55,867 | | 55,867 | |
| Corporate debt securities | 2,000 | | 88 | 1,912 | | 1,912 | |
| Other securities | 104 | | 57 | 47 | | | 47 |
| Total investments | $ 78,468 | $ | $ 145 | $ 78,323 | $ 9,860 | $ 68,226 | $ 237 |
| 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 |

*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.

*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. Accounts Receivables and Revenues

The Company recorded revenues from sales of Fusilev and Zevalin during the year ended December 31, 2008. The Company s largest customers are Group Purchasing Organizations ( GPOs ) and Distributors of pharmaceutical products. GPOs accounted for approximately 30% and distributors for approximately 70% of the net sales. All sales were to customers in the United States.

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

Accounts receivable, net, consisted of the following:

| | December 31, 2008 | 2007 |
|---|---|---|
| | ($ in 000s) | |
| Accounts Receivable | $ 9,926 | $ 191 |
| Allowance for discounts, chargebacks and returns | (4,774) | |
| Allowance for doubtful accounts | (150) | |
| Accounts Receivables Net of Allowances | $ 5,002 | $ 191 |

While shipments of Fusilev for the year ended December 31, 2008 were approximately $10.8 (net of estimates for promotional, price and other adjustments), we deferred the recognition of approximately $3.1 million of such revenue until we have more experience with the amount of product returns.

**6. Inventories**

Inventories, net, consist of the following:

| | December 31, 2008 | 2007 |
|---|---|---|
| | ($ in 000s) | |
| Finished Goods | $ 1,492 | $ |
| Work In Process | 312 | |
| Raw Materials | 68 | |
| Less: inventory reserves | (31) | |
| | $ 1,841 | $ |

The Company periodically reviews product inventories on hand. Inventory levels are evaluated by management relative to product demand, remaining shelf life, future marketing plans and other factors, and reserves for obsolete and slow-moving inventories are recorded for amounts which may not be realizable.

**7. Property and Equipment**

As of December 31, 2008 and 2007, property and equipment consisted of:

| | December 31, | |
|---|---|---|
| | 2008 | 2007 |
| | (Amounts in thousands) | |
| Equipment | $ 2,286 | $ 1,435 |
| Leasehold improvements | 1,255 | 588 |
| Total property and equipment | 3,541 | 2,023 |
| Less: accumulated depreciation and amortization | (1,759) | (1,307) |
| **Property and equipment, net** | $ 1,782 | $ 716 |

For the years ended December 31, 2008, 2007 and 2006, the Company recorded depreciation expense of approximately $452,000, $255,000 and $198,000, respectively.

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

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

**8. Zevalin related intangible assets**

In connection with the formation of RIT Oncology LLC in December 2008, as described in Note 3, we recorded certain intangible assets in connection with the acquisition of Zevalin as follows:

| | December 31, 2008 | | |
|---|---|---|---|
| | Gross Carrying Amount | Accumulated Amortization | Net Carrying Amount |
| Developed technology | $ 23,100 | $ (98) | $ 23,002 |
| Core technology | 14,100 | (60) | 14,040 |
| Acquired in-process research and development | 4,700 | (4,700) | |
| | $ 41,900 | $ (4,858) | $ 37,042 |

Identifiable intangible assets with definite lives are amortized on a straight-line basis over their estimated useful lives. The developed and core technology assets will be amortized over 10 years, or approximately $3.7 million annually through 2018. Included in the intangible assets was an amount of $4.7 million of IPR&D for a medical indication still awaiting approval by the FDA. Such amount was completely written off during the year ended December 31, 2008.

**9. Income Taxes**

In July 2006, 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, 2008 are as follows:

| | For the Years Ended December 31, | | |
|---|---|---|---|
| | 2008 | 2007 | 2006 |
| | (Amounts in thousands) | | |

| | | | |
|---|---|---|---|
| Current: | | | |
| Federal | | | |
| State | $ 5 | $ 5 | $ 5 |
| Foreign | | | |
| | 5 | 5 | 5 |
| Deferred: | | | |
| Federal | | | |
| State | | | |
| Foreign | | | |
| | $ 5 | $ 5 | $ 5 |

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

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

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

| | 2008 | 2007 | 2006 |
|---|---|---|---|
| | (Amounts in thousands) | | |
| Computed at statutory tax rate | $ (7,956) | $ (14,890) | $ (9,904) |
| Non-utilization of net operating losses | 7,956 | 14,890 | 9,904 |
| **Tax expense using effective tax rate** | $ | $ | $ |

Significant components of our deferred tax assets and liabilities as of December 31, 2008 and 2007 are shown below. A valuation allowance has been recognized to fully offset the net deferred tax assets as of December 31, 2008, 2007 and 2006 as realization of such assets is uncertain.

| | 2008 | 2007 | 2006 |
|---|---|---|---|
| | (Amounts in thousands) | | |
| Deferred tax assets: | | | |
| Net operating loss and business credit carry forwards | $ 79,936 | $ 76,869 | $ 66,426 |
| Stock-based Compensation | 2,755 | 2,459 | 1,596 |
| Depreciation and amortization differences | 698 | 340 | 318 |
| **Net deferred tax assets** | **83,389** | **79,668** | **68,340** |
| Valuation allowance for deferred tax assets | $ (83,389) | $ (79,668) | $ (68,340) |
| **Total deferred tax assets** | **$** | **$** | **$** |

At December 31, 2008 and 2007, we had Federal and California income tax loss carry-forwards of approximately $167 million and $90 million, respectively. The Federal and California tax loss carry-forwards will begin to expire in 2010 and 2009, respectively. Both Federal and California law limit the use of net operating loss carry-forwards 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 carry-forwards to the point that they may never be utilized. In addition, at December 31, 2008 we had research and development credit carry-forwards of approximately $9 million which will begin to expire in 2008 and also had foreign loss carry-forwards of approximately $41 million.

**10. Commitments and Contingencies**

***Facility and Equipment Leases***

As of December 31, 2008 we were obligated under a facility lease and operating equipment leases. Our facility lease expires in June 2009. We are evaluating options open to us to reconsider the renewal of the lease or to consider the use of alternative premises to conduct our business. We do not anticipate a major disruption in our business operations should we decide not to renew the lease and move to an alternative location.

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

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

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

| | Lease Commitments | Capital Lease Commitments |
|---|---|---|
| | (Amounts in thousands) | |
| Year ending December 31: | | |
| 2009 | $ 239 | $ 50 |
| 2010 | 2 | 51 |
| 2011 | | 50 |
| 2012 | | 50 |
| 2013 | | |
| Thereafter | | |
| | $ 241 | $ 201 |

Rent expense for the years ended December 31, 2008, 2007 and 2006 amounted to approximately $583,000, $579,000 and $343,000, respectively, and was net of sub-lease rent income of $225,000 during the years ended December 31, 2006.

***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 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.

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.

***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.

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, 2008, we were committed under such contracts for up to approximately $13.7 million, for future goods and services, including approximately $8.5 million due within one year. 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 contracts due to the

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

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

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.

***Supply Agreements***

In connection with our acquisition of Zevalin, RIT Oncology assumed a supply agreement with Biogen Idec Inc. ( Biogen ) to manufacture Zevalin for sale in the United States pursuant to which we would purchase from Biogen, and Biogen would provide to us, kits to make Zevalin doses for sale to end-users in the United States at a cost plus manufacturing price. RIT Oncology also assumed a manufacturing and supply agreement with MDS (Canada) Inc., MDS Nordion Division, or MDS (Canada), for yttrium-90, a radioisotope used in connection with the administration of Zevalin.

In connection with Fusilev, we have a single source API supplier as well as a single source finished product manufacturer.

***Employment Agreement***

We have entered into an employment agreement with Dr. Shrotriya, our President and Chief Executive Officer, which expires January 2, 2011. The employment agreement automatically renews for a one-year calendar 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 agreement requires Dr. Shrotriya to devote his full working time and effort to the business and affairs of the Company during the term of the agreement. The employment agreement provides 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.

Dr. Shrotriya s employment may be terminated due to non-renewal of his employment agreement by us, mutual agreement, death or disability, or by us for cause (as that term is defined in the employment agreement) or without cause, or by Dr. Shrotriya for no reason, good reason (as defined in the agreement) or non-renewal. The employment agreement provides for various guaranteed severance payments and benefits if: (i) the agreement is not renewed by us, (ii) Dr. Shrotriya s employment is terminated without cause, (iii) Dr. Shrotriya resigns for good reason, (iv) the agreement is terminated due to death or disability of Dr. Shrotriya, (v) if Dr. Shrotriya voluntarily resigns his employment for no reason or (vi) if Dr. Shrotriya s employment is terminated (other than by Dr. Shrotriya) without cause within twelve months after a change in control, or Dr. Shrotriya is adversely affected in connection with a change in control and resigns within twelve months. If the agreement is terminated due to mutual agreement, Dr. Shrotriya s non-renewal of the agreement, or by us for cause, Dr. Shrotriya shall not be entitled to any severance.

If any payment or distribution by us to or for the benefit of Dr. Shrotriya is subject to the excise tax imposed by Section 4999 of the Internal Revenue Code (IRC) or any interest or penalties are incurred by Dr. Shrotriya with respect to such excise tax, then Dr. Shrotriya shall be entitled to receive an additional payment in an amount such that after payment by Dr. Shrotriya of all taxes (including any interest and penalties imposed with respect thereto) and excise tax imposed upon such payment, Dr. Shrotriya retains an amount of the payment equal to the excise tax imposed upon the payment.

If we determine that any payments to Dr. Shrotriya under the agreement fail to satisfy the distribution requirement of Section 409A(a)(2)(A) of the IRC, the payment schedule of that benefit shall be revised to the extent necessary so that the benefit is not subject to the provisions of Section 409A(a)(1) of the IRC. We may attach conditions to or adjust the amounts so paid to preserve, as closely as possible, the economic consequences that would have applied in the absence of this adjustment; provided, however, that no such condition or adjustment shall result in the payments being subject to Section 409A(a)(1) of the IRC.

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

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

***Litigation***

At December 31, 2008, 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.

## 11. 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, 2008, 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 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, 2008, 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

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

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

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***

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 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 FUSILEV. 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.

In March 2008, we issued to Targent, LLC 125,000 shares of the Company s common stock for payment of a milestone pursuant to the asset purchase agreement with Targent in connection with the approval of FUSILEV by the FDA. The fair value of the stock, $305,000, was recorded as a stock-based research and development charge for the year ended December 31, 2008.

In October 2008, we issued 75,000 shares of the Company s common stock in connection with the assignment to us of certain intellectual property rights related to EOquin. The fair value of the stock, $74,000, was recorded as a stock-based research and development charge for the year ended December 31, 2008.

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

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

***Common Stock Reserved for Future Issuance***

As of December 31, 2008, approximately 12.7 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:

| | |
|---|---|
| **Reserved stock** | |
| Conversion of Series E preferred shares | 136,000 |
| Exercise of stock options | 7,115,772 |
| Exercise of warrants | 5,444,555 |
| **Total shares of common stock reserved for future issuances** | **12,696,327** |

***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, 2008. A summary of warrant activity follows:

| | 2008 | | 2007 | | 2006 | |
|---|---|---|---|---|---|---|
| | Common Stock Warrants | Weighted Average Exercise Price | Common Stock Warrants | Weighted Average Exercise Price | Common Stock Warrants | Weighted Average Exercise Price |
| Outstanding at beginning of year | 9,652,051 | $ 6.51 | 9,917,077 | $ 6.71 | 9,920,703 | $ 7.20 |
| Granted | 50,000 | 1.79 | | | 50,000 | 5.25 |
| Repurchased | | | | | | |
| Exercised | | | (161,145) | 3.22 | (17,750) | 3.00 |
| Forfeited | (157,450) | 6.62 | | | | |
| Expired | (4,100,046) | 5.43 | (103,881) | 30.54 | (35,876) | (143.44) |
| **Outstanding, at the end of year** | 5,444,555 | $ 7.28 | 9,652,051 | $ 6.51 | 9,917,077 | $ 6.71 |
| **Exercisable, at the end of year** | 5,432,055 | $ 7.29 | 9,572,051 | $ 6.52 | 9,782,077 | $ 6.73 |

During the years ended December 31, 2008 and 2006, 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, 2008 and 2006 were valued at $52,000 and $177,000, respectively using the Black-Scholes option pricing model, with the following assumptions: dividend yield of 0%; expected volatility of 67% (2008) and 80% (2006); risk free interest rate of 3.14% (2008) and 5.21% (2006); 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

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

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

vesting period of the related grants. The following table summarizes information about warrants outstanding at December 31, 2008:

| Range of Exercise Price | Warrants Outstanding 12/31/2008 | Weighted Average Remaining Life | Weighted Average Exercise Price | Warrants Exercisable 12/31/2008 | Weighted Average Exercise Price |
|---|---|---|---|---|---|
| $0.00 to $2.99 | 50,000 | 5.00 | $ 1.79 | 37,500 | $ 1.79 |
| $3.00 to $5.00 | | | | | |
| $5.01 to $10.00 | 5,369,555 | 2.74 | $ 7.31 | 5,369,555 | $ 7.31 |
| $10.01 to $87.50 | 25,000 | 1.05 | $ 11.50 | 25,000 | $ 11.50 |
| | 5,444,555 | | | 5,432,055 | |

## 12. Share-Based Compensation

***Stock Options***

We have two stock incentive plans: the 1997 Stock Incentive Plan (the 1997 Plan ) and the 2003 Amended and Restated Incentive Award Plan (the 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, 2008, approximately 1 million incentive awards were available for grant under the 2003 Plan.

During each of the three years in the period ended December 31, 2008, 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 2008, 2007 and 2006, respectively: risk-free interest rates of 2.66% (2008), 4.57% (2007), and 4.58% (2006); zero expected dividend yields; expected lives of 5 years; expected volatility of 65.9% (2008), 68.3% (2007), and 75.2% (2006). 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 2008, 2007 and 2006, was $1.19, $3.54 and $3.26, respectively.

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

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

A summary of stock option activity for each of the three years in the period ended December 31, 2008, is as follows:

| | 2008 | | 2007 | | 2006 | |
|---|---|---|---|---|---|---|
| | 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 | 6,482,260 | $ 5.91 | 4,640,252 | $ 5.86 | 3,661,682 | $ 6.98 |
| Granted | 2,148,000 | 2.10 | 1,974,700 | 5.85 | 1,277,000 | 5.10 |
| Exercised | | | (81,438) | 1.48 | (1,500) | 2.12 |
| Forfeited | (294,521) | 4.38 | (39,425) | 5.04 | (66,002) | 3.70 |
| Expired | (1,219,967) | 6.08 | (11,829) | 8.80 | (230,928) | 20.11 |
| **Outstanding, at end of year** | 7,115,772 | $ 4.80 | 6,482,260 | $ 5.91 | 4,640,252 | $ 5.86 |
| **Exercisable at end of year** | 5,097,835 | $ 5.22 | 4,185,273 | $ 5.89 | 3,045,015 | $ 5.88 |

The following table summarizes information about stock options outstanding under all plans at December 31, 2008:

| Range of Exercise Price | Options Outstanding 12/31/08 | Weighted Average Remaining Term (In Years) | Weighted Average Exercise Price | Options Exercisable 12/31/08 | Weighted Average Exercise Price |
|---|---|---|---|---|---|
| $1.00 - $2.50 | 1,443,750 | 7.39 | $ 1.58 | 585,125 | $ 1.71 |
| $2.51 - $5.00 | 2,235,950 | 7.23 | $ 3.38 | 1,719,450 | $ 3.49 |
| $5.01 - $10.00 | 3,409,832 | 6.71 | $ 6.25 | 2,771,020 | $ 6.22 |
| $10.01 - $325.00 | 26,240 | 1.97 | $ 114.00 | 22,240 | $ 107.24 |
| | 7,115,772 | | | 5,097,835 | |

Presented below is the aggregate intrinsic value of the stock options outstanding, vested and expected to vest, and exercisable as of December 31, 2008. The intrinsic value represents the total difference between the Company s closing common stock price on December 31, 2008 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, 2008. This amount changes based on the fair market value of the Company s common stock.

| | Common Stock Options | Weighted Average Exercise Price | Weighted Average Remaining Term (In Years) | Aggregate Intrinsic Value (In thousands) |
|---|---|---|---|---|
| Stock Options as of December 31, 2008 Outstanding | 7,115,772 | $ 4.80 | 6.46 | $ 219.67 |
| Vested and expected to vest | 6,772,723 | $ 4.85 | 6.40 | $ 193.83 |
| Exercisable | 5,097,835 | $ 5.22 | 6.05 | $ 67.69 |

During the years ended December 31, 2008, 2007 and 2006, the share-based charge in connection with the expensing of stock options was $5.5 million, $4.6 million and $3.5 million, respectively. As of December 31, 2008, there was $3.7 million of unrecognized share-based compensation cost related to stock options, which is expected to be recognized over a weighted average period of 1.5 years.

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

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

***Restricted Stock***

A summary of the status of the Company s restricted stock awards as of December 31, 2008 and of changes in unvested shares outstanding is as follows:

| | 2008 | | 2007 | | 2006 | |
|---|---|---|---|---|---|---|
| | Restricted Stock Awards | Average Grant date Fair Value | Restricted Stock Awards | Average Grant date Fair Value | Restricted Stock Awards | Average Grant date Fair Value |
| Nonvested at beginning of period | 277,500 | $ 5.03 | 146,250 | $ 4.25 | 115,000 | $ 4.26 |
| Granted | 372,500 | $ 1.65 | 265,000 | $ 5.56 | 80,000 | $ 4.23 |
| Vested | (272,500) | $ 3.17 | (133,750) | $ 5.22 | (48,750) | $ 4.25 |
| Forfeited | | | | | | |
| Nonvested at the end of period | 377,500 | $ 3.04 | 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, 2008, 2007 and 2006, the stock-based charge in connection with the expensing of restricted stock awards was approximately $862,000, $842,000 and $296,000, respectively. As of December 31, 2008, there was approximately $0.8 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 1.3 years.

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

During the years ended December 31, 2008, 2007 and 2006, we issued 166,430, 44,118 and 39,906 shares of common stock as the Company s match of approximately $274,000, $211,000 and $176,000 on the 401(k) contributions of its employees during those periods.

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

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

## 13. 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, 2008 (in thousands, except share and per share data):

| | March 31 | June 30 | September 30 | December 31 |
|---|---|---|---|---|
| | (Amounts in thousands except share and per share data) | | | |
| **Fiscal 2008** | | | | |
| Revenues | $ | $ 20,676 | $ | $ 8,049 |
| Total operating expenses | 8,967 | 9,977 | 9,092 | 19,859 |
| Net loss | $ (8,666) | $ 10,678 | $ (8,816) | $ (8,663) |
| Basic and diluted loss per share | $ (0.28) | $ 0.34 | $ (0.28) | $ (0.27) |
| Shares used in calculation | 31,271,281 | 31,462,522 | 31,538,023 | 31,928,778 |
| **Fiscal 2007** | | | | |
| 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) | $ (12,504) |
| Basic and diluted loss per share | $ (0.31) | $ (0.22) | $ (0.24) | $ (0.40) |
| Shares used in calculation | 25,290,717 | 28,442,904 | 31,034,241 | 31,207,861 |

## 14. Subsequent Event

As described in Note 3, on December 15, 2008, we established RIT as a 50/50 joint venture with CTI, whereby we acquired a 50% ownership interest in RIT. As part of that transaction, CTI also had the option to sell its remaining 50% membership interest in RIT to us, subject to adjustment for any amounts owed between RIT and CTI at the time of sale. CTI exercised this Put option in February 2009. On March 15, 2009, we and CTI entered into an agreement to complete such sale for an aggregate amount of $16.5 million subject to certain adjustments for among other things payables determined to be owed between CTI and RIT. As a result of the sale, we own 100% of RIT and are its sole member and therefore, we have, through licenses, all of the U.S. rights to Zevalin.

On an unaudited pro forma basis, assuming that we had acquired 100% of RIT on January 1, 2008, the Company s results for 2008 would have been approximately as follows:

| | | Twelve Months Ended December 31, 2008 (unaudited) |
|---|---|---|
| Revenues | $ | 40 million |
| Net loss | $ | 29 million |
| Loss per share | $ | 0.92 |

These pro forma amounts do not purport to show the exact results that would have actually been obtained if the acquisition had occurred as of the beginning of the period presented or that may be obtained in the future.

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## Index to Exhibits

| Exhibit No. | Description |
|---|---|
| 2.1 | Asset Purchase Agreement by and between the Registrant, Targent Inc. and Certain Stockholders of Targent, Inc., dated March 17 2006. (Filed as Exhibit 2.1 to Form 10-K/A, Amendment No. 1, as filed with the Securities and Exchange Commission on May 1, 2006, and incorporated herein by reference.) |
| 2.2 | Asset Purchase Agreement by and between the Registrant and Par Pharmaceutical, Inc., dated as of May 6, 2008. (Filed as Exhibit 2.1 to Form 10-Q, as filed with the Securities and Exchange Commission on August 11, 2008, and incorporated herein by reference.) |
| 2.3# | Purchase and Formation Agreement, dated as of November 26, 2008, by and among the Registrant, Cell Therapeutics, Inc. and RIT Oncology, LLC. (Filed as Exhibit 2.1 to Form 8-K, as filed with the Securities and Exchange Commission on December 19, 2008, and incorporated herein by reference.) |
| 3.1 | Amended Certificate of Incorporation, as filed. (Filed as Exhibit 3.1 to Form 10-Q, as filed with the Securities and Exchange Commission on August 8, 2006, and incorporated herein by reference.) |
| 3.2 | Form of Amended and Restated Bylaws of the Registrant. (Filed as Exhibit 3.1 to Form 10-Q, as filed with the Securities and Exchange Commission on August 16, 2004, and incorporated herein by reference.) |
| 4.1 | Rights Agreement, dated as of December 13, 2000, between the Registrant and ComputerShare Trust Company, N.A. (formerly 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 | Amendment No. 1 to the Rights Agreement dated as of December 13, 2000 by and between the Registrant and ComputerShare Trust Company, N.A. (formerly 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.) |
| 4.3 | 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.) |
| 4.4 | 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.) |
| 4.5 | 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.) |
| 4.6 | Amendment No. 2 to the Rights Agreement dated as of December 13, 2000 by and between the Registrant and ComputerShare Trust Company, N.A. (formerly 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.) |
| 4.7 | Amendment No. 3 to the Rights Agreement dated as of December 13, 2000 by and between the Registrant and ComputerShare Trust Company, N.A. (formerly 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.) |
| 4.8 | 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.) |
| 4.9 | |

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.)

4.10 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.)

4.11 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.)

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| Exhibit No. | Description |
|---|---|
| 4.12 | 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.) |
| 4.13 | 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.) |
| 4.14 | 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.) |
| 4.15 | 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.) |
| 4.16 | Amendment No. 5 to the Rights Agreement dated as of December 13, 2000 by and between the Registrant and ComputerShare Trust Company, N.A. (formerly 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.) |
| 4.17 | 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.) |
| 4.18 | Warrant issued by the Company to a Consultant, dated as of April 28, 2008. (Filed as Exhibit 4.1 to Form 10-Q, as filed with the Securities and Exchange Commission on August 11, 2008, 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 | 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.) |
| 10.5 | 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.) |
| 10.6 | 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.) |
| 10.7 | 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.) |
| 10.8 | 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.) |

| | |
|---|---|
| 10.9# | 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.) |
| 10.10# | 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.) |

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| Exhibit No. | Description |
|---|---|
| 10.11 | 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.) |
| 10.12* | 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.) |
| 10.13# | 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.) |
| 10.14# | 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.) |
| 10.15* | 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.) |
| 10.16# | 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.) |
| 10.17 | 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.) |
| 10.18* | 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.) |
| 10.19# | 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.) |
| 10.20* | 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.) |
| 10.21# | 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.) |
| 10.22 | 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.) |
| 10.25 | 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.) |
| 10.26* | 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.) |
| 10.27* | 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.) |
| 10.28# | 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.) |

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|---|---|
| 10.29# | License Agreement by and between the Registrant and Indena, S.p.A. dated July 17, 2007. (Filed as Exhibit 10.4 to Form 10-Q, as filed with the Securities and Exchange Commission on November 9, 2007.) |
| 10.30* | Executive Employment Agreement by and between the Registrant and Rajesh C. Shrotriya, M.D., entered into June 20, 2008 and effective as of January 2, 2008. (Filed as Exhibit 10.1 to Form 8-K, as filed with the Securities and Exchange Commission on June 26, 2008, and incorporated herein by reference.) |
| 10.31 | Consulting Agreement by and between the Registrant and Luigi Lenaz, M.D., effective as of July 1, 2008. (Filed as Exhibit 10.2 to Form 10-Q, as filed with the Securities and Exchange Commission on August 11, 2008, and incorporated herein by reference.) |

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| Exhibit No. | Description |
|---|---|
| 10.32*+ | Form of Indemnity Agreement of the Registrant. |
| 10.33#+ | License, Development, Supply and Distribution Agreement dated October 28, 2008 by and among the Registrant and Allergan Sales, LLC, Allergan USA, Inc. and Allergan, Inc. |
| 21+ | Subsidiaries of Registrant. |
| 23.1+ | Consent of Kelly & Company. |
| 31.1+ | Certification of Chief Executive Officer, pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934. |
| 31.2+ | Certification of Vice President Finance, pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934. |
| 32.1+ | Certification of Chief Executive Officer, pursuant to Rule 13a-14(b)/15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350. |
| 32.2+ | Certification of Vice President Finance, pursuant to Rule 13a-14(b)/15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350. |

* 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.