

SPECTRUM PHARMACEUTICALS INC

Form 10-K

March 10, 2011

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

**Form 10-K**

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

For the fiscal year ended December 31, 2010

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

Commission File Number: 001-35006

**SPECTRUM PHARMACEUTICALS, INC.®**  
(Exact Name of Registrant as Specified in its Charter)

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

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

**11500 South Eastern Avenue, Suite 240  
Henderson, Nevada 89052**

(Address of principal executive offices)  
**(702) 260-7421**

(Registrant's telephone number, including area code)

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

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

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

**None**

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated  
filer

Accelerated filer

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

Smaller reporting  
company

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2010 was \$189,068,452 based on the closing sale price of such common equity on such date.

As of February 25, 2011 there were 52,003,514 shares of the registrant's common stock were outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

None

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**FORWARD-LOOKING STATEMENTS**

*Spectrum Pharmaceuticals, Inc.'s Annual Report on Form 10-K contains certain forward-looking statements. These forward-looking statements involve a number of risks and uncertainties. These forward-looking statements can generally be identified as such because the context of the statement will include certain words, including but not limited to, believes, may, will, expects, intends, estimates, anticipates, plans, seeks, continues, predicts, potential, likely, or opportunity, and also contains predictions, estimates and other forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and in reliance upon the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are based on the current beliefs of the Company's management, as well as assumptions made by and information currently available to the Company's management. Readers of this Annual Report on Form 10-K should not put undue reliance on these forward-looking statements, which speak only as of the time this Annual Report on Form 10-K was filed with the Securities and Exchange Commission, or SEC. 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. In addition, past financial or operating performance is not necessarily a reliable indicator of future performance, and you should not use our historical performance to anticipate results or future period trends. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our results of operations and financial condition. 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 Annual Report on Form 10-K.*

Unless the context otherwise requires, all references in this Annual Report on Form 10-K to the Company, we, us, or our 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.<sup>®</sup>, Fusilev<sup>®</sup>, Zevalin<sup>®</sup> and RenaZorb<sup>®</sup> are registered trademarks of Spectrum Pharmaceuticals, Inc. and its subsidiaries. Redefining Cancer Care<sup>™</sup>, Turning Insights Into Hope<sup>™</sup>, RIT Oncology, LLC<sup>™</sup>, RIT<sup>™</sup>, and our logos are trademarks owned by Spectrum Pharmaceuticals, Inc. and its subsidiaries. EOquin<sup>®</sup> is a registered trademark of Allergan, 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 biotechnology company with fully integrated commercial and drug development operations with a primary focus in oncology. Our strategy is comprised of acquiring, developing and commercializing a broad and diverse pipeline of late-stage clinical and commercial products. We market two oncology drugs, ZEVALIN® and FUSILEV® and have two drugs, apaziquone and belinostat, in late stage development along with a diversified pipeline of novel drug candidates. We have assembled an integrated in-house scientific team, including formulation development, clinical development, medical research, regulatory affairs, biostatistics and data management, and have established a commercial infrastructure for the marketing of our drug products. We also leverage the expertise of our worldwide partners to assist in the execution of our strategy. Apaziquone is presently being studied in two large Phase 3 clinical trials for non-muscle invasive bladder cancer, or NMIBC, under strategic collaborations with Allergan, Inc., or Allergan, Nippon Kayaku Co. Ltd., or Nippon Kayaku, and Handok Pharmaceuticals Co. Ltd., or Handok. Belinostat, is being studied in multiple indications including a Phase 2 registrational trial for relapsed or refractory peripheral T-cell lymphoma, or PTCL, under a strategic collaboration with TopoTarget A/S or TopoTarget.

Our business strategy is comprised of the following initiatives:

*Maximizing the growth potential of our marketed drugs, Zevalin and Fusilev.* Our near-term outlook largely depends on sales and marketing successes for our two marketed drugs. For Zevalin, we stabilized sales in 2009, increased sales in 2010 and believe we can continue to grow sales in 2011 and beyond. For Fusilev, which we launched in August 2008, we were able to benefit from broad utilization in community clinics and hospitals and recognized a dramatic increase in sales during 2010 due to a shortage of generic leucovorin. While we cannot predict how long the shortage may continue, our focus now is to obtain approval for Fusilev in advanced metastatic colorectal cancer. As part of its review of our supplemental new drug application (sNDA) for metastatic colorectal cancer, the FDA requested additional data to which we submitted a response on October 29, 2010. The FDA formally accepted the submission and established a decision date (PDUFA) of April 29, 2011.

For both Zevalin and Fusilev, we initiated and continue to stage appropriate infrastructure expansions and additional initiatives to facilitate broad customer reach and to address other market requirements, as appropriate. We have formed a dedicated commercial organization comprised of highly experienced and motivated sales representatives, account managers, and a complement of other support marketing personnel to manage the sales and marketing of these drugs. In addition our scientific department supports field activities through various MDs, PhDs and other medical science liaison personnel.

*Optimizing our development portfolio and maximizing the asset values of its components.* While over the recent few years, we have evolved from a development-stage to a commercial-stage pharmaceutical company, we have maintained a highly focused development portfolio. Our strategy with regard to our development portfolio is to focus on late-stage drugs and to develop them rapidly to the point of regulatory approval. We plan to develop some of these drugs ourselves or with our subsidiaries and affiliates, or secure collaborations such that we are able to suitably monetize these assets.



We have assembled a drug development infrastructure that is comprised of highly experienced and motivated MDs, PhDs, clinical research associates and a complement of other support personnel to rapidly develop these drugs. During 2009, this team achieved our goal of completing enrollment in the two Phase 3 apaziquone trials (with more than 1,600 patients enrolled). We expect to continue to maximize the value of apaziquone through further developmental efforts and initiation of additional trials.

We have several other exciting compounds in earlier stages of development in our portfolio. Based upon a criteria-based portfolio review, we are in the process of streamlining our pipeline drugs, allowing for greater focus and integration of our development and commercial goals.

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*Expanding our pipeline of late stage and commercial drugs through licensing and business development.* It is our goal to identify new strategic opportunities that will create strong synergies with our currently marketed drugs and identify and pursue partnerships for out-licensing certain of our 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. We believe our in-licensing of belinostat, a novel histone deacetylase (HDAC) inhibitor, is demonstrative of such licensing and business development efforts outlined above.

*Managing our financial resources effectively.* We remain committed to fiscal discipline, a policy which has allowed us to become well capitalized among our peers, despite a very challenging capital markets environment during 2009 and continuing through 2010. 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. Even with the continued build-up in operational infrastructure to facilitate the marketing of our two commercial drugs, we intend to be fiscally prudent in any expansion we undertake. In terms of revenue generation, we plan to become more reliant on sales from currently marketed drugs and intend to pursue out-licensing of 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, including termination of our existing development programs, especially if we do not expect value being driven from continued development. We ended 2010 with over \$100 million in cash, cash equivalents and investments which was net of the \$30 million license fee paid for belinostat in early 2010 offset by cash received from out-license of apaziquone of approximately \$17.5 million.

*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 previously held positions at both small to mid-size biotech companies, as well as large pharmaceutical companies. We have 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 2010 and early 2011, we have continued to execute on our business strategy described above. We discuss below the key developments during that period.

We recorded approximately \$61 million in sales of our products for the year 2010. We successfully increased Zevalin sales to approximately \$29 million in 2010 as compared to approximately \$16 million in 2009. We also recorded Fusilev sales of \$32 million in 2010, compared to approximately \$13 million in 2009. We believe that in 2011 and beyond, revenues from these products have the potential to grow. However future growth in Fusilev revenue will depend largely on its approval by the FDA for metastatic colorectal cancer indication (expected on April 29, 2011) and or a continuing shortage of leucovorin.

In September 2009, Zevalin received FDA approval in first-line setting; expanding its label for the treatment of patients with previously untreated follicular NHL who achieve a partial or complete response to first-line chemotherapy. This new and expanded indication supplements the 2002 FDA approval of Zevalin as treatment for

patients with relapsed or refractory, low-grade or follicular B-cell NHL. Additionally, in November 2009, the Centers for Medicare and Medicaid Services (CMS) decided that Zevalin should be reimbursed under an Average Sales Price (ASP) methodology in the Hospital Outpatient Prospective Payment System (HOPPS) and issued a corresponding proposed rule, which became effective on January 1, 2010. The ASP methodology is widely used for

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injectable chemotherapy drugs and creates a consistent reimbursement standard in the hospital setting. Effective January 1, 2011 Zevalin reimbursement rate increased from ASP plus 4% to ASP plus 5%.

In December 2010 at the Annual Meeting of the American Society of Hematology in Orlando, Florida, a total of 12 scientific papers on Zevalin were presented. Of these, 6 papers were selected by the program committee of ASH for oral presentations. These included a five year update on the progression free survival in the FIT (First-Line Indolent Trial), Zevalin's use in bone marrow conditioning regimen and the first results from an international Phase 2 clinical trial using Zevalin as a first line monotherapy treatment in certain newly diagnosed patients with follicular lymphoma.

We have been working with the FDA to remove the requirement for a bioscan prior to Zevalin administration and on January 20, 2011 we submitted a Post Approval Supplement (sBLA) with the FDA containing data supporting the removal of the bioscan. The FDA has up to sixty (60) days to accept or reject the submission.

In October 2009, the FDA issued a Complete Response letter regarding the sNDA for Fusilev in metastatic colorectal cancer indication. In the Complete Response letter, the FDA recommended that we meet with them to discuss options for continuing to seek approval of Fusilev in advanced metastatic colorectal cancer. We promptly requested such a meeting, which occurred in January 2010. In that meeting, the FDA requested additional data which we submitted on October 29, 2010. The FDA formally accepted the submission and we expect a decision by the FDA (PDUFA date) on April 29, 2011. In addition, on January 4, 2011, we submitted a sNDA with the FDA for a Ready-to-Use formulation of Fusilev for Injection. This submission is in support of Fusilev's use in colorectal cancer and the FDA has up to 60 days to formally accept or reject the submission.

As for apaziquone, in November 2009, we entered into a collaboration agreement with Nippon Kayaku Co. Ltd. for the development and commercialization of apaziquone in Asia, with the exception of North and South Korea. In exchange, Nippon Kayaku paid Spectrum an up-front payment of \$15 million and agreed to make additional payments of up to \$136.0 million based on the achievement of certain regulatory and commercialization milestones contained in the collaboration agreement, as well as royalties on net sales. Nippon Kayaku received exclusive rights to apaziquone for the treatment of NMIBC in Asia, including Japan and China. Under the terms of the Nippon Kayaku collaboration agreement, Nippon Kayaku will conduct the apaziquone clinical trials pursuant to a development plan, and will be responsible for all expenses relating to the development and commercialization of apaziquone in the Nippon Kayaku territory. As for South Korea, or the Republic of Korea, and North Korea, or the Democratic People's Republic of Korea, (collectively, Korea), we entered into a collaboration agreement with Handok Pharmaceuticals Co. Ltd. for the development and commercialization of apaziquone for the treatment of NMIBC. Under the terms of the Handok collaboration agreement, Handok paid us an up-front payment of \$1.0 million and there are potential milestone payments of approximately \$19 million, as well as royalties on net sales. The potential milestones will be based on the achievement of certain regulatory and commercialization milestones. Additionally, Handok will conduct the apaziquone clinical trials pursuant to a development plan and will be responsible for all expenses relating to the development and commercialization of apaziquone in North and South Korea.

In the fourth quarter of 2009, we completed enrollment of two Phase 3 pivotal clinical trials for apaziquone. The two trials enrolled more than 1,600 patients with non-muscle invasive bladder cancer and we expect top-line data in 2012. Per the terms of the collaboration agreement, we received a \$1.5 million milestone payment in January 2010 from Allergan for the completion of patient accrual in these clinical trials.

In February 2010, we entered into a licensing and collaboration agreement with TopoTarget, for the development and commercialization of belinostat, a drug being studied in multiple indications, including a Phase 2 registrational trial for patients with relapsed/refractory PTCL. The licensing and collaboration agreement provides that we have the exclusive right to make, develop and commercialize belinostat in North America and India, with an option for China. In consideration for the rights granted under the licensing and collaboration agreement, we paid TopoTarget an

up-front fee of \$30 million. In addition, we will pay up to \$313 million and one million shares of Spectrum common stock based on the achievement of certain development, regulatory and sales milestones, as well as double-digit royalties on net sales of belinostat.

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In January 2011 we signed a letter of agreement with Viropro, Inc., for the development of a biosimilar version of the monoclonal antibody drug rituximab. Biosimilars, or follow-on biologics, are terms used to describe officially-approved subsequent versions of innovator biopharmaceutical products made by a different sponsor following patent and exclusivity expiry.

We continued our efforts to build a global pharmaceutical organization in 2010. For two of our non-US business entities, Spectrum Pharma Canada, Inc., a Canadian affiliate headquartered in the Province of Quebec, Canada, and OncoRx Pharma Private Ltd., a wholly-owned Indian subsidiary headquartered in Mumbai, India, we continued to grow and establish 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 strive to maintain a robust pipeline of products under development to bring to the market.

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:

\* *Pivotal Trial under Special Protocol Assessment (SPA)*

Some of our drugs may prove to be beneficial in additional disease indications as we continue their study and development. 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 2010*, cancer is the second leading cause of death in the United States, accounting for approximately 25% of all deaths. In the United States, approximately 1.5 million new cancer cases were expected to be diagnosed in 2010 and over 569,000 persons were

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expected to die from the disease in 2010. 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.

*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 deemed to be 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., or CTI as 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.

Zevalin was approved by the FDA in February of 2002 as the first radioimmunotherapeutic agent for the treatment of NHL. Zevalin was approved 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. For reference, the term refractory refers to lymphoma that does not respond to a particular therapy. The term relapsed



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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 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 with other agents for the treatment of B-cell NHL.

The current Zevalin therapeutic regimen also requires a bioscan (also known as an imaging study) of the prospective patient prior to treatment with Y-90 Zevalin. For the bioscan, the patient is infused with In-111 Zevalin, the In-111 radioisotope 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. 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 healthcare providers throughout the world who provide Zevalin therapy do not believe that the In-111 bioscan is a necessary part of the Zevalin therapeutic regimen. In the EU, most countries do not perform the In-111 bioscan prior to the Y-90 Zevalin infusion. On January 20, 2011, we submitted a Post Approval Supplement with the FDA containing data supporting the removal of the bioscan. The FDA has up to sixty (60) days to accept or reject the submission.

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 are 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 65,540 people were expected to be newly diagnosed with NHL in 2010. Additionally, approximately 20,210 were expected to die from this disease in 2010.

In December 2008, the FDA accepted for filing and review, and granted priority review status for RIT Oncology, LLC's or RIT's, supplemental biologics license application (sBLA) for the use of Zevalin as first-line therapy for patients with a previously untreated follicular NHL who achieve a partial or complete response of first-line chemotherapy.

The sBLA was based upon data from the multinational, randomized Phase 3 First-line Indolent Trial (FIT) which evaluated the efficacy 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 18 months (control arm) to 38 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 almost two years, with a toxicity profile comparable to that seen with Zevalin's use in relapsed or refractory indications. In September 2009, we received FDA approval for the sBLA.

Additionally, in November 2009, the CMS decided that Zevalin should be reimbursed under an ASP methodology in the HOPPS and issued a corresponding proposed rule, which went into effect on January 1, 2010. The ASP methodology is widely used for injectable chemotherapy drugs and creates a consistent reimbursement standard in the hospital setting.

In December 2010 at the Annual Meeting of the American Society of Hematology in Orlando, Florida, a total of 12 scientific papers on Zevalin were presented. Of these, 6 papers were selected by the program committee of ASH for

oral presentations. These included a five year update on the progression free survival in the FIT (First-Line Indolent Trial), Zevalin's use in bone marrow conditioning regimen and the first results from an international Phase 2 clinical trial using Zevalin as a first line monotherapy treatment in certain newly diagnosed patients with follicular lymphoma.

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

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

Upon entering into the joint venture arrangement, 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 joint venture 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 entered into an agreement with CTI 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. CTI disputed the adjustments, but in a May 2009 arbitration proceeding, we were awarded approximately \$4.3 million. 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 joint venture arrangement, 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 initial capital contributions made by CTI and us), (ii) upon the December 2008 closing of the joint venture 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) was required to pay Biogen an additional amount of \$5.5 million if the milestone event occurred 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. As disclosed above, we received FDA approval for the treatment of patients with previously untreated follicular NHL who achieve a partial or complete response to first-line chemotherapy and in accordance with the amendment, we paid Biogen \$5.5 million. 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 us 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).

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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 new drug application (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.

Leucovorin is currently a standard combination agent with 5-FU in various colorectal cancer treatment regimens. 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™ 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 chondrosarcoma). 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 & Cie AG, a Swiss corporation, that we assumed in connection with the acquisition of the assets of Targent. Pursuant to the license agreement with Merck & Cie, 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. In addition, 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. Also, under the terms of the license agreement, we paid Merck & Cie \$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

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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 Merck & Cie. 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: 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 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 2010 incidence and prevalence of bladder cancer in the United States would be approximately 70,530 and over 500,000 respectively. According to Botteman et al., (PharmacoEconomics 2003), bladder cancer is the most expensive cancer to treat on a lifetime basis.

The initial treatment of this cancer is complete surgical removal of the tumor. However, bladder cancer is a highly recurrent disease with approximately 75% of patients recurring within 5 years, and a majority of patients recurring within 2 years. This high recurrence rate is attributed to: 1) the highly implantable nature of cancer cells that are dispersed during surgery, 2) incomplete tumor resection, and 3) tumors present in multiple locations in the bladder which may be missed or too small to visualize at the time of resection. Despite evidence in the published literature and guidance from the American and European Urology Associations, instillation of a chemotherapeutic agent immediately following surgery is not a standard clinical practice. Currently, there are no approved drugs for this indication which may, in part, explain the difference between the literature and urology guidelines and actual clinical management of this disease. For more than 30 years, no new drugs have been introduced in the market for 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 alkylating indoloquinone that is enzymatically activated by enzymes that are over expressed by bladder tumors. Pharmacokinetic studies have verified that apaziquone is not detectable in the bloodstream of patients when it is administered either after surgical resection or as a part of a delayed multi-instillation protocol. The proposed dose therefore carries a minimal risk of systemic toxicity which could 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 currently 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. At the two-year follow up, eighteen patients (38%) were disease free.

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. Apaziqone was well-tolerated over multiple instillations in this study of patients with high-risk superficial bladder cancer. At 18 months follow up 55% of the patients were recurrence free.



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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 evaluable patients with T<sub>a</sub>G1-G2 (low-grade) NMIBC. 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 European Medicines Agency (EMA) whereby the EMA agreed that the two Phase 3 studies as designed should be sufficient for a regulatory decision regarding European registration. In December 2009, we achieved our goal of completing enrollment for both Phase 3 clinical trials and we expect top-line data in 2012.

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<sup>®</sup>, formerly NDDO Research Foundation<sup>®</sup> (INC) 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 nominal amount of cash and issued them a nominal 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 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 with Allergan also 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 also entered into a co-promotion agreement with Allergan 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 elect to opt-out of the co-promotion agreement, 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. In addition, if we opt-out of the co-promotion agreement, 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 our license, development, supply and distribution agreements with Allergan, Allergan paid us an up-front fee of \$41.5 million. In addition, Allergan will pay us up to \$304.0 million based on the achievement of certain development, regulatory and sales milestones. For example, for completing enrollment of both aforementioned Phase III trials by year-end 2009, Allergan paid us a \$1.5 million milestone payment. 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. In November 2009, we entered into a collaboration agreement with the Nippon Kayaku Co., LTD. for the development and commercialization of apaziquone in Asia, except North and South Korea (the Nippon

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Kayaku Territory ). In exchange, Nippon Kayaku paid Spectrum an up-front payment of \$15 million and agreed to make additional payments of up to \$136.0 million based on the achievement of certain regulatory and commercialization milestones contained in the agreement. In addition, Nippon Kayaku received exclusive rights to apaziquone for the treatment of NMIBC in Asia (other than North and South Korea), including Japan and China. Nippon Kayaku will conduct apaziquone clinical trials in the Nippon Kayaku Territory pursuant to a development plan. In addition, Nippon Kayaku will be responsible for all expenses relating to the development and commercialization of apaziquone in the Nippon Kayaku Territory. In January 2011 Nippon Kayaku initiated a Phase 1 study with the first patient being dosed in Japan. The Phase 1 study is required by the local regulatory authorities and is designed to enroll up to 6 patients.

Also in November 2009, we entered into a collaboration agreement with Handok Pharmaceuticals for the development and commercialization of apaziquone in North and South Korea. Under the terms of the Handok collaboration agreement, Handok paid us an up-front payment of \$1.0 million and potential milestone payments totaling approximately \$19 million. The potential milestone payments will be based on the achievement of certain regulatory and commercialization milestones. Handok received rights to apaziquone for the treatment of NMIBC in North and South Korea. Additionally, Handok will conduct the apaziquone clinical trials in North and South Korea pursuant to a development plan and will be responsible for all expenses relating to the development and commercialization of apaziquone in North and South Korea.

***Belinostat:*** Belinostat is a histone deacetylase or HDAC inhibitor that is being studied in multiple clinical trials, both as a single drug and in combination with chemotherapeutic drugs for the treatment of various hematological and solid tumors. HDACs catalyze the removal of chemical groups known as acetyl groups from certain portions of human DNA, and thus regulate gene expression. By inhibiting this enzyme, belinostat induces cell cycle arrest, and leads to inhibition of cancer cell proliferation and induction of apoptosis, or cell death. Additional mechanisms of action thought to be responsible for belinostat's anti-cancer effect include inhibition of angiogenesis, or blood vessel growth, and the resensitization of cells that have overcome drug resistance to anticancer drugs, such as platinum and taxanes.

Belinostat is currently the only HDAC inhibitor in clinical development with multiple potential routes of administration, including intravenous administration, continuous intravenous infusion and oral administration, which we believe may afford belinostat with a significant competitive advantage.

Belinostat is currently in a registrational trial, under a special protocol assessment, as a monotherapy for relapsed/refractory Peripheral T-Cell Lymphoma or PTCL an indication which has been granted Orphan Drug and Fast Track designation by the FDA. The registrational trial is an open-label, multicenter, single arm efficacy and safety study, in which we plan to enroll approximately 120 patients with relapsed or refractory peripheral T-cell lymphoma, who have failed at least one prior systemic therapy. We expect to file an NDA for belinostat in PTCL in 2011/2012.

Belinostat is also currently in a randomized Phase 2 trial for carcinoma of unknown primary or CUP, in combination with carboplatin and paclitaxel being conducted by our collaborator, Topotarget. Target enrollment was reached in December 2010 and Topotarget expects top-line results of progression free survival and response rate in the third quarter of 2011. There are currently no approved therapies or drugs for treatment of CUP, which is an indication with a large patient population. The NCI estimated that for 2008, approximately 2 to 4% of all cancers are CUP.

Based on the data from past and ongoing studies, we believe there are many potential attributes associated with belinostat that separate it from other currently marketed HDACs, including efficacy when used alone and in combination, less toxicities (when compared to other currently-marketed HDACs), including less bone marrow toxicity, and a lack of other severe side effects, such as mucositis, that may enable full dose combinations of this drug with several other cytotoxic agents. Hence, belinostat is currently being investigated in multiple indications, both as

monotherapy and in combination with other treatment regimens. Numerous studies have been conducted, and are ongoing, through the NCI and other well-known oncologic academic institutions. Additionally, we plan on a comprehensive development program for belinostat, which includes both hematologic indications, such as PTCL, and solid tumor indications, such as ovarian cancer, colorectal cancer and CUP. Based upon the foregoing, we

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believe belinostat potentially has broad applicability and hence, commercial potential beyond that of currently marketed HDACs.

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

In February 2010, we entered into a licensing and collaboration agreement with TopoTarget, for the development and commercialization of belinostat, pursuant to which TopoTarget and we agreed to a collaboration for the development and commercialization of belinostat. The agreement provides that we have the exclusive right to make, develop and commercialize belinostat in North America and India, with an option for China. The agreement also grants TopoTarget a co-promote option if and only if we do not maintain a minimum number (subject to adjustment for certain events outside of our control) of field personnel (as defined in the agreement) for a certain number of years post-approval of the PTCL indication.

In consideration for the rights granted to us under the license and collaboration agreement with TopoTarget, we paid TopoTarget an up-front fee of \$30.0 million. In addition, we will pay up to \$313 million and one million shares of Spectrum common stock based on the achievement of certain development, regulatory and sales milestones, as well as certain royalties on net sales of belinostat.

Under the terms of the agreement, all development, including studies, will be conducted under a joint development plan and in accordance with a mutually agreed upon target product profile provided that we have final decision-making authority for all developmental activities in North America and India (and China upon exercise of the option for China) and TopoTarget has final decision-making authority for all developmental activities in all other jurisdictions. We will assume all responsibility for and future costs of the ongoing registrational PTCL trial while TopoTarget will assume all responsibility for and future costs of the ongoing Phase 2 CUP trial. We and TopoTarget will conduct future planned clinical trials pursuant to the joint development plan, of which we will fund 70% of the development costs and TopoTarget will fund 30% of the development costs.

We and TopoTarget will each pay 50% of the costs for chemical, pharmaceutical and other process development related to the manufacturing of the product that are incurred with a mutually agreed upon budget in the joint development plan. TopoTarget is responsible for supplying us with both clinical and commercial product.

*Ozarelix*: Ozarelix is a Luteinizing Hormone Releasing Hormone, or LHRH, antagonist (a substance that blocks the effects of a natural hormone found in the body). 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.

In January 2010, based upon the mixed results of our earlier Phase 2 study of ozarelix for the treatment of BPH and the recently announced failure of Aeterna Zentaris's large, Phase 3, registrational trial of cetrorelix (another LHRH antagonist), we discontinued development of ozarelix in BPH. We estimate that this discontinuation will result in substantial reduction in future clinical development expenses. Currently, we are conducting a phase II clinical trial of ozarelix in prostate cancer patients.

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. In November 2010, we amended the terms of the agreement to expand the territory covered by the exclusive license.

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, and where there is no generic competition in such country of the territory, whichever term is longer, although some obligations survive termination. In addition, the agreement may be terminated earlier by either party (in

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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 with Indena S.p.A. In clinical studies, 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 activity 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 bioavailability, 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 certain royalties on worldwide sales of ortataxel, if and when the product is approved. On October 11, 2010, we amended the agreement to extend payments of certain development and regulatory milestones.

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

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. We are currently working on the development plan for lucanthone.

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.

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



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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.

***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 in 2010, 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 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., 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.

In August 2009, we entered into an acquisition agreement with Altair, in which we acquired 100% of the rights to Renazorb and all of Altair's life science technology. Our acquisition of RenaZorb expands upon our prior license agreement with Altair, pursuant to which Altair granted us human uses. Our acquisition of RenaZorb provides us with access to all uses of and intellectual property for RenaZorb. In consideration for the acquisition, we paid Altair a total of \$750,000 in the form of restricted shares of our common stock.

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### **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, or 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 are in the process of qualifying additional contract manufacturers for 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. We believe that the market for such manufacturers and suppliers is such that we could quickly enter into another supply or manufacturing agreement, on substantially similar terms, if we were required to do so. However, in the event we are unable to manufacture our products, either directly or indirectly through others or on commercially acceptable terms, if at all, we may not be able to commercialize our products as planned. 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.

For Fusilev, we utilize a third-party logistics company to store and distribute this drug product. The same third party logistics company also stores and ships Zevalin kits containing the CD20 MAB.

For Zevalin, we changed the supply and distribution model in 2009. Previously, we sold Zevalin kits containing the CD20 MAB to radiopharmacies, who then in turn ordered the radioactive isotope (Y-90 or In-111) separately and radiolabeled (or attached) the radioactive isotope to the CD20 MAB. The radiopharmacy then sold the end user product to the consumer. Under the current model we do not sell the Zevalin kits containing the CD20 MAB to the radiopharmacies, but instead contract with them, as a fee-for-service, to radiolabel the individual components of the CD20 MAB to the radioactive isotope, and then, also under a fee-for-service arrangement, have them distribute the end use product to the end user, which are clinics, hospitals or other medical settings. In this regard, we now sell the CD20 MAB together with the radioactive isotope as the end user product directly to the healthcare service provider.

### **Customers**

Our product sales are concentrated in a limited number of customers. Sales to Customer A for the years ended December 31, 2010, 2009 and 2008 were 45.7%, 21.7 and 35.7% respectively, of our total consolidated gross product sales. No other single customer generates over 10% of our consolidated gross product sales.

We are exposed to risks associated with extending credit to our customers related to the sale of products. We do not require collateral or other security to support credit sales, however, we maintain reserves for potential bad debt and to date, credit losses have been within management's expectations. Customer A owed us 56.1% of net receivables as of December 31, 2010 and no customer owed us more than 10% of net receivables as of December 31, 2009. 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

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developing our own treatments. In the event that one or more of those programs are successful, the market for some of our drug products could be reduced or eliminated. Any product for which we obtain FDA approval must also compete for market acceptance and market share.

Competing in the branded product business requires us to identify and quickly bring to market new products embodying therapeutic innovations. Successful marketing of branded products depends primarily on the ability to communicate the effectiveness, safety and value of the products to healthcare professionals in private practice, group practices, hospitals and academic institutions, and managed care organizations. Competition for branded drugs is less driven by price and is more focused on innovation in treatment of disease, advanced drug delivery and specific clinical benefits over competitive drug therapies. Unless our 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, among others, Abraxis Bioscience, Inc., Astra Zeneca LP, Bayer AG, Endo Pharmaceuticals, 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., Genta Incorporated, Merck, Celgene Corporation, Allos Therapeutics, Inc., BiPar Sciences, Inc., Genzyme Corporation, Shire Pharmaceuticals, Abbott Laboratories, Poniard Pharmaceuticals, Inc., Roche Pharmaceuticals and Johnson & Johnson 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<sup>®</sup> (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<sup>®</sup> 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<sup>®</sup> (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 prednisone 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.

For more information regarding competition to our products, please also read our discussion of competition matters in Item 1A Risk Factors of this report.

**Table of Contents****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. Our development focus is primarily based on acquiring and developing late-stage development drugs as compared to new drug discovery, which is very uncertain and lengthy.

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, 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 but not including amortization of intangibles or expensing of in-process research and development costs, are expensed as we incur them and were approximately \$57.3 million, \$21.1 million and \$26.7 million, respectively, in 2010, 2009 and 2008 broken out by product as follows:

	<b>Year Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
	<b>(\$ in 000 s)</b>		
Apaziquone	\$ 6,165	\$ 10,915	\$ 5,477
Ozarelix	1,916	1,168	2,435
Ortataxel	716	311	150
Fusilev	1,281	1,125	2,096
Zevalin	421	563	151
Belinostat	36,045		
Other development drugs	3,469	1,535	1,304
<b>Total Direct Costs</b>	<b>50,013</b>	<b>15,617</b>	<b>11,613</b>
Indirect Costs (including non-cash share-based compensation of \$2.4 million, \$3.2 million and \$4.0 million, respectively)	14,838	16,652	15,070
Partner Reimbursement	(7,550)	(11,211)	
<b>Total Research &amp; Development</b>	<b>\$ 57,301</b>	<b>\$ 21,058</b>	<b>\$ 26,683</b>

**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, lucanthone, belinostat and SPI-1620, in each case for the remaining life of the applicable patents. Except for Zevalin, Fusilev, belinostat 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 Zevalin, apaziquone and RenaZorb, 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 neither conclusive as to its validity nor as to the enforceable scope of the claims of the patent. Accordingly,



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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 Zevalin, we have sublicensed United States patents that cover the processes and tools for making monoclonal anti-bodies or 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 belinostat, there are composition of matter patents that cover belinostat and related compounds that do not begin to expire until 2021. Currently, there are multiple United States and foreign patent applications pending that cover belinostat formulations, uses and manufacturing and synthesis processes. We plan to file additional United States and foreign patent applications covering new formulations, uses and manufacturing and synthesis processes, where appropriate. For apaziquone, there is 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 multiple manufacturing and synthesis patents that do not begin to expire till 2021, 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 expired in 2010. For lucanthone, there is a United States method of use patent that expires in 2019. For RenaZorb, there is one method of use patent that expires in 2024 and 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. We also have multiple United States method of use patents that expire in 2021 and 2022, and there is ongoing prosecution for their 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

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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<sup>®</sup>, Fusilev<sup>®</sup>, Turning Insights Into Hope<sup>™</sup>, Zevalin<sup>®</sup> and RenaZorb<sup>®</sup>. 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<sup>®</sup> is a registered trademark of Allergan.

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 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 Hatch 1984, or 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.

### ***Product Exclusivity***

Under the Hatch-Waxman Act, drug products are provided exclusivity whereby the FDA will not accept applications to market a generic form of an innovator reference listed drug product until the end of the prescribed period. A product is granted a five-year period of exclusivity if it contains a chemical entity never previously approved by the FDA either alone or in combination, although generic applications may be submitted after four years if they contain a certification of patent invalidity or non-infringement as further discussed below. A three-year period of exclusivity is granted to a previously approved product based on certain changes, *e.g.*, in strength, dosage form, route of administration or conditions of use, where the application is supported by new clinical investigations that are essential to approval. In addition, in 1997 Congress amended the law to provide an additional six months of

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exclusivity as a reward for studying drugs in children. This pediatric exclusivity, which can be obtained during the approval process or after approval, effectively delays the approval of a generic application until six months after the expiration of any patent or other exclusivity that would otherwise delay approval, thus providing an additional six months free of generic competition. In order to qualify for pediatric exclusivity, the FDA must make a written request for pediatric studies, the application holder must agree to the request and complete the studies with required timeframe, and the studies must be accepted by the FDA based on a determination that the studies fairly respond to the request. The provisions were enacted with a five-year sunset date, and have been reauthorized in 2002 and 2007. The current provisions are set to expire in October 2012, and Congress is likely to consider reauthorizing the statute again.

### ***Generic Approval and Patent Certification***

The Hatch-Waxman Act also created the abbreviated new drug application, or ANDA, approval process, which permits the approval of a generic version of a previously approved branded drug without the submission of a full new drug application, or NDA, and based in part on the FDA's finding of safety and effectiveness for the reference listed drug. Applicants submitting an NDA are required to list patents associated with the drug product, which are published in the FDA Orange Book, and the timing of an ANDA approval depends in part on patent protection for the branded drug. When an ANDA is filed, the applicant must file a certification for each of the listed patents for the branded drug, stating one of the following: (1) that there is no patent information listed; (2) that such patent has expired; (3) that the patent will expire on a particular date (indicating that the ANDA may be approved on that date); or (4) that the drug for which approval is sought either does not infringe the patent or the patent is invalid, otherwise known as paragraph IV certification. If an ANDA applicant files a paragraph 4 certification, it is required to provide the patent holder with notice of that certification. If the patent holder brings suit against the ANDA applicant for patent infringement within 45 days of receiving notice, the FDA may not approve the ANDA until the earlier of (i) 30 months from the patent holder's receipt of the notice (the 30-month stay) or (ii) the issuance of a final, non-appealed, or non-appealable court decision finding the patent invalid, unenforceable or not infringed.

The Hatch-Waxman Act also provided an incentive for generic manufacturers to file paragraph 4 certifications challenging patents that may be invalid unenforceable, or not infringed, whereby the first company to successfully challenge a listed patent and receive ANDA approval is protected from competition from subsequent generic versions of the same drug product for 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. These 180-day exclusivity provisions have been the subject of litigation and administrative review, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, amended the provisions in several ways, including by providing that an ANDA applicant entitled to 180-day exclusivity may lose such exclusivity if any of the following events occur: (1) failure to market; (2) withdrawal of the ANDA; (3) change in patent certification; (4) failure to obtain tentative approval; (5) illegal settlement agreement; and (6) patent expiration.

With respect to the illegal settlement prong, the MMA amendments require that 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. In addition, Congress has considered enacting legislation that would prohibit such settlements between brand name and generic drug manufacturers. Such a provision was considered as part of the recently enacted healthcare reform, the Patient Protection and Affordable Care Act or PPACA signed into law on March 23, 2010.

However, Congress removed the provision prior to passage. It is possible that Congress will again consider a ban on such settlements between brand name and generic drug manufacturers in the future.

With the passage of the PPACA, there are now exclusivity protections for certain innovator biological products and a framework for FDA review and approval of biosimilar and interchangeable versions of innovator biologic

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products. The PPACA provides that no application for a biosimilar product may be approved until 12 years after the date on which the innovator product was first licensed, and no application may be submitted until four years after the date of first licensure. Products deemed interchangeable (as opposed to biosimilar) are also eligible for certain exclusivity.

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 may grant orphan drug designation to a drug intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, and a drug may also be considered an orphan even if the drug treats a disease or condition affecting more than 200,000 individuals in the United States where the drug has no expected profitability. Orphan drug designation does not necessarily convey any advantage in, or shorten the duration of, the regulatory review and process for marketing approval. If a product with an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to seven years of orphan drug exclusivity, during which time FDA will not approve any other application to market the same drug for the same indication except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Also, competitors are not prohibited from receiving approval to market the same drug or biologic for a different indication than that which received orphan approval.

Under European Union medicines laws, the criteria for designating an orphan medicinal product are similar in principle to those in the United States. Criteria for orphan designation are set out in Article 3 of Regulation (EC) 141/2000 on the basis of two alternative conditions. A medicinal product may be designated as orphan if it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10 thousand persons in the European Union, or EU, when the application is made. This is commonly known as the disease prevalence criterion. Alternatively, a product may be so designated if it is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the EU and if without incentives it is unlikely that the marketing of the product in the EU would generate sufficient return to justify the necessary investment. This is commonly known as the insufficient return criterion.

These two alternative criteria must cumulatively meet the second condition that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition. Significant benefit is defined in Regulation (EC) 847/2000 as a clinically relevant advantage or a major contribution to patient care.

Upon grant of a marketing authorization, orphan medicinal products are entitled to ten years of market exclusivity in respect of the approved therapeutic indication. Within the period of market exclusivity, no competent authority in the EU is permitted to accept an application for marketing authorization, a variation or a line-extension for the same approved therapeutic indication in respect of a similar medicinal product pursuant to Article 8.1 of Regulation 141/2000 unless one of derogations set out in Article 8.3 of the same Regulation applies. In order to determine whether two products are considered similar, Regulation 847/2000 requires an assessment of the principal molecular structure and the underlying mode of action. Any minor variation or modification of the principal molecular structure would not ordinarily render the second product dissimilar to the first authorized product.

In order for the second applicant to break the market exclusivity granted to the first authorized similar medicinal product in respect of the same therapeutic indication, the second applicant would principally rely upon data to demonstrate that his product is safer, more efficacious or clinically superior to the first product pursuant to Article 8.3I

of Regulation 141/2000. Ordinarily, such an assessment will require a head-to-head comparative clinical trial for the purpose of demonstrating clinical superiority.



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The 10-year market exclusivity may be reduced to 6 years if at the end of the fifth year it is established that the product no longer meets the criteria for orphan designation on the basis of available evidence.

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). In addition, belinostat has been granted an orphan drug designation for PTCL. As discussed above, a drug with orphan designation status may obtain orphan exclusivity upon marketing approval under specified conditions set out in the applicable laws and regulations.

## **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 there under, as well as other federal and state statutes and regulations, govern, among other things, the development, approval, manufacture, safety, labeling, storage, record keeping, distribution, promotion, and advertising of our products. Product development and approval within this regulatory framework, including for drugs already at a clinical stage of development, can take many years and require the expenditure of substantial resources, and to obtain FDA approval, a product must satisfy mandatory procedures and safety and efficacy requirements. In addition, each drug-manufacturing establishment must be registered with the FDA. Domestic manufacturing establishments must comply with the FDA's current good manufacturing practice, or cGMP, regulations and are subject to 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 inspections 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, or 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.

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*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 and report any adverse reactions that may result from long-term use of the drug on a large, more widespread, patient population. During the phase 3 clinical trials, typically the drug candidate is compared to either a placebo or a standard treatment for the target disease.

*New Drug Application:* After completion of all three clinical trial phases, if the data indicates that the drug is safe and effective, a 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:* An ANDA is the abbreviated review and approval process for generic drugs created by the Hatch-Waxman Act. 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. 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, or FDAAA, which was 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, or 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 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.

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### **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.

The Patient Centered Outcomes Research Institute, a private, non-profit corporation created as a result of the PPACA, is tasked with assisting patients, clinician, purchasers, and policy-makers in making informed health decisions. One of the Institute's initiatives will be to conduct comparative clinical effectiveness research, which is defined as research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more medical treatments, services, and items. It is important to note that the Institute would not be permitted to mandate coverage, reimbursement, or other policies for any public or private payer, however the outcome of the Institute's initiatives could influence prescriber behavior.

### **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/region to country/region, 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/region to country/region.

Under the EU regulatory systems, we may submit marketing authorization applications either under a centralized procedure or decentralized procedure or the mutual recognition procedure. The centralized procedure is mandatory for medicines produced by a biotechnological process. The procedure is also mandatory for new active substances which are indicated for treatment of several diseases or conditions, including cancer and orphan conditions. Companies may apply for centralized assessment if the product contains a new active substance or the

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product constitutes significant therapeutic, scientific or technical innovation or the granting of authorization under the centralized procedure is in the interests of the EU patients. A centralized marketing authorization is valid in all European Union member states. This marketing authorization is issued in the form of a Commission decision which is legally binding in its entirety to which it is addressed.

Directive 2004/27/EC introduced two parallel procedures to the centralized procedure to allow a product to be progressively authorized in each of the member states of the EU. They are the decentralized procedure and the mutual recognition procedure. The mutual recognition procedure applies where the product has already been authorized in a member state of the EU that will act as reference member state. The national marketing authorization granted by the reference member state forms the basis for mutual recognition in the member states chosen by the applicant. In the decentralized procedure, the product in question is not authorized in any one the EU member states. In such a situation, the applicant company will request a member state to act as the reference member state to lead the scientific assessment for the benefit/risk balance for agreement by the concerned member states. In both cases, the concerned member states have up to 90 days to accept or raise reasoned objections to the assessment made by the reference member state.

In addition, pricing and reimbursement is subject to negotiation and regulation in most countries outside the United States. Increasingly, adoption of a new product for use in national health services is subject to health technology assessment under the national rules and regulations to establish the clinical effectiveness and cost-effectiveness of a new treatment. In some countries, in order to contain health care expenditures, reference price is introduced in order for the national healthcare providers to achieve a price comparable to the reference price in the same therapeutic category. We may therefore 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.

The PPACA enacted significant reforms, including revising the definition of average manufacturer price for reporting purposes, increasing Medicaid rebates, expanding the 340B drug discount program, and making changes to affect the Medicare Part D coverage gap, or donut hole. In the coming years, additional significant changes could be made 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 EU, 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, 2010, we had 139 employees, of which 10 held a M.D. degree and 8 held a Ph.D. degree. We cannot be sure that we will be able to attract and retain qualified personnel in sufficient numbers to meet our needs. Our employees are not subject to any collective bargaining agreements, and we regard our relations with our employees to be good.



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### **Corporate Background and Available Information**

We are 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 websites located at <http://www.sppirx.com> and <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**

In addition to other information included in this Annual Report on Form 10-K, the following factors, among others, could cause actual results to differ materially from those contained in forward-looking statements contained in this Annual Report on Form 10-K, and thus should be considered carefully in evaluating our business and future prospects. The following risk factors are not an exhaustive list of the risks associated with our business. New factors may emerge or changes to these risks could occur that could materially affect our business.

#### **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, 2010 were approximately \$310.4 million. Our net losses in 2010, 2009 and 2008 were approximately \$48.8 million, \$19.0 million and \$14.2 million, respectively, after recording approximately \$2.7 million, \$8.1 million and \$1.3 million, respectively, of warrant based income. 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.

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***Our drug product Fusilev may not be more cost-effective 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.

***Our revenue from Fusilev sales may not be sustainable and our customer concentration is significant***

Most of the Fusilev revenue the Company recorded in 2010 resulted from the leucovorin drug shortage, the depth of which we cannot predict. Even with approval for colorectal cancer a possibility in 2011, there is not surety that Fusilev sales will be sustainable. Our customer concentration of Fusilev is high. Sales to Customer A for the years ended December 31, 2010, 2009 and 2008 were 45.7%, 27.1%, and 35.7% respectively, of our total consolidated gross product sales. If our relationship with our top distributors is impaired our sales of Fusilev would be negatively impacted.

***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.

***Adverse economic conditions may have material adverse consequences on our business, results of operations and financial condition.***

Unpredictable and unstable changes in economic conditions, including recession, inflation, increased government intervention, or other changes, may adversely affect our general business strategy. If the current equity and credit markets further deteriorate, or do not continue to improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. While we believe we have adequate capital resources to meet current working capital and capital expenditure requirements, a radical economic downturn, a double-dip recession, or an increase in our expenses could require additional financing on less than attractive rates or on terms that are excessively dilutive to existing stockholders. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans or plans to acquire additional technology.

These economic conditions not only limit our access to capital, but also make it difficult for our customers and us to accurately forecast and plan future business activities, and they could cause businesses to slow spending on our products, which would delay and lengthen sales cycles. Furthermore, during challenging economic times, our customers may face issues gaining timely access to sufficient credit, which could result in an impairment of their ability to make timely payments to us. In addition, the recent economic crisis could also adversely impact our suppliers' ability to provide us with materials which would negatively impact on our business, financial condition and results of 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.

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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 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 maintain or obtain improved reimbursement rates for Zevalin, the product's sales may be harmed, which could adversely affect our financial and operating results.***

Effective January 1, 2010, the Centers for Medicare & Medicaid Services finalized a policy to allow reimbursement for Zevalin in the Hospital Outpatient Prospective Payment System, or HOPPS, based on the average sales price methodology applicable to other injectable drugs and biologicals. If we are not able to maintain this reimbursement methodology in the HOPPS setting, we could face significant difficulty in getting health care providers to prescribe Zevalin, which will have an adverse impact on the product's expected sales, and in turn adversely impact 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.***

Sales of Zevalin in the United States 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 in the future. However, implementation of the sales and marketing strategy for Zevalin, and the efforts to expand approved usage of Zevalin, will require a continued 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 commercial team 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 commercial personnel or the inability of us to dedicate the necessary resources to those efforts.

***We are aware of several competitors attempting to develop and market products competitive to Zevalin, which may reduce or eliminate our commercial opportunity.***

The pharmaceutical and biotechnology industries are intensely competitive and subject to rapid and significant technological changes, and a number of companies are pursuing the development of pharmaceuticals and products that

target the same diseases and conditions that Zevalin targets. We cannot predict with accuracy the timing or impact of the introduction of potentially competitive products or their possible effect on our sales. Certain potentially competitive products to Zevalin are in various stages of development, some of which have been filed for approval with the FDA or have been approved by regulatory authorities in other countries. Also, there are many ongoing studies with currently marketed products including Rituxan<sup>®</sup>, Treanda<sup>®</sup> and other developmental products,

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which may yield new data that could adversely impact the use of Zevalin in specific states for which it has obtained FDA approval. The introduction of competitive products to Zevalin could significantly reduce the sales of Zevalin, which, in turn would adversely impact our financial and operating results.

***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, it 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 primarily consist of the Zevalin-related intellectual property. The security agreement secures certain payment, indemnification and other obligations of RIT to Biogen related to Zevalin. If RIT were to default on certain of its obligations to Biogen or generally become bankrupt or insolvent, Biogen could seek to foreclose on the collateral under the security agreement to satisfy RIT's obligations. 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.

Additionally, we are a guarantor on 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 as a result of any such default could have a material and adverse effect on our financial condition and results of operations.

***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 of our territories.***

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 other companies' actions, negative publicity is associated with either product, our own efforts to successfully market and sell such products in our markets may be adversely impacted.

***Our supply of active pharmaceutical ingredients, or APIs, and drug products will be dependent upon the production capabilities of contract manufacturing organizations, or CMOs, component and packaging supply sources, other third-party suppliers, and other providers of logistical services, some of whom are based overseas and, if these parties are not able to meet our demands and FDA scrutiny, 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 APIs or our drug products, and, therefore, we have entered into agreements with CMOs and other suppliers to supply us with APIs and our finished dose drug products. Success in the development and marketing of our drug products depends, in part, upon our ability to maintain, expand and enhance our existing relationships and establish new sources of supply. Some of the third-party manufacturing facilities used in the production of APIs and our drug products are located outside the United States. The manufacture of APIs and finished drug products, including the acquisition of compounds used in the manufacture of the finished drug product, may require considerable lead times. We have little or no control over the production processes of third-party manufacturers, CMOs or other suppliers. Our ability to source APIs and drug products is also dependent on providers of logistical services who may be subject to disruptions that we cannot predict or sufficiently plan around. Accordingly, while we do not currently anticipate shortages of supply, circumstances could arise 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.

Additionally, all of our regular suppliers are sole-source suppliers, including for Zevalin and Fusilev, and no currently qualified alternative suppliers exist. Our efforts to qualify additional suppliers of Fusilev may take longer than anticipated and the timing for securing necessary regulatory approvals is uncertain. If problems arise during the



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production of a batch of our drug products, that batch of product may have to be discarded. This could, among other things, lead to increased costs, lost revenue, damage to customer relations, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred. To the extent that one of our suppliers experiences significant manufacturing problems, this could have a material adverse effect on our revenues and profitability.

Finally, 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.

***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 and may have disagreements with our partner. 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.

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

TopoTarget licensed to us the rights to develop and market belinostat in the United States, Canada, Mexico and India. TopoTarget is currently fully funding and overseeing one clinical study underway with belinostat. In addition, TopoTarget has agreed to partially fund other development expenses for belinostat. We do not fully control the drug development process under our agreement with TopoTarget and may have disagreements with our partner. TopoTarget, or its partners, may conduct their own clinical trials on belinostat 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 belinostat may be adversely impacted if TopoTarget's efforts are not successful.

*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 to us the rights to develop and market ozarelix worldwide except Japan, Korea, Indonesia, Malaysia, the Philippines, and Singapore. Aeterna Zentaris, or its partners, may conduct their own clinical trials on ozarelix for regulatory approval in all these countries. We will not have control over such

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development activities and our ability to attain regulatory approvals for ozarelix may be adversely impacted if Aeterna Zentaris efforts are not successful.

***Our dependence on key executives, scientists and sales and marketing personnel could impact the development and management of our business.***

We are highly dependent upon our ability to attract and retain qualified scientific, technical sales and marketing and managerial personnel. There is intense competition for qualified personnel in the pharmaceutical and biotechnology industries, and we cannot be sure that we will be able to continue to attract and retain the qualified personnel necessary for the development and management of our business. Although we do not believe the loss of one individual would materially harm our business, our business might be harmed by the loss of the services of multiple existing personnel, as well as the failure to recruit additional key scientific, technical and managerial personnel in a timely manner. Much of the know-how we have developed resides in our scientific and technical personnel and is not readily transferable to other personnel. While we have an employment agreement with our Chief Executive Officer, we do not have employment agreements with any of our other key scientific, technical and managerial employees.

***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 and complete commercial team. 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 are not able to effectively manage our growth, our product sales and resulting revenues will be negatively impacted.

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

We regularly evaluate and, as appropriate, may make selective acquisitions of businesses that we believe complement or augment our existing business. We may not be able to integrate any acquired business successfully or operate any acquired business profitably. Issues that could delay or prevent integration of the acquired business into our own include:

- conforming standards, controls, procedures and policies, business cultures and compensation structures;
- conforming information technology and accounting systems;
- consolidating corporate and administrative infrastructures;
- consolidating sales and marketing operations;
- retaining existing customers and attracting new customers;
- retaining key employees;

identifying and eliminating redundant and underperforming operations and assets;

minimizing the diversion of management's attention from ongoing business concerns;

coordinating geographically dispersed organizations;

managing tax costs or inefficiencies associated with integrating operations; and

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making any necessary modifications to operating control standards to comply with the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated thereunder.

If we are unable to successfully integrate our acquisitions with our existing business, we may not obtain the advantages that the acquisitions were intended to create, which may materially adversely affect our business, results of operations, financial condition and cash flows, our ability to develop and introduce new products and the market price of our stock. Actual costs and sales synergies, if achieved at all, may be lower than we expect and may take longer to achieve than we anticipate. Furthermore, the products of companies we acquire may overlap with our products or those of our customers, creating conflicts with existing relationships or with other commitments that are detrimental to the integrated businesses.

***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.

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

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

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

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

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

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

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

attempts by either party to terminate the collaboration;

our ability 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 its development and commercialization efforts due to internal reorganizations, mergers, consolidations and otherwise;

unwillingness of a partner to fully fund or commit sufficient resources to the testing, marketing, distribution or development of our products;

unwillingness or ability of a partner to fulfill their obligations to us due to the pursuit of alternative products, conflicts of interest that arise or changes in business strategy or other business issues; and/or

we may not be able to guarantee supplies of development or marketed products.

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.***

To remain competitive and 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 in-license and we may not be successful in locating and acquiring, or in-licensing, additional desirable drug products on acceptable terms.

To accomplish our acquisition and in-license strategy, we intend to commit efforts, funds and other resources to research and development and business development. Even with acquired and in-licensed drug products, a high rate of failure is inherent in the development of such products. We must make ongoing substantial expenditures without any assurance that our efforts will be commercially successful. Failure can occur at any point in the process, including after significant funds have been invested. For example, promising new drug product candidates may fail to reach the market or may only have limited commercial success because of efficacy or safety concerns, failure to



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achieve positive clinical outcomes, inability to obtain necessary regulatory approvals, limited scope of approved uses, excessive costs to manufacture, the failure to establish or maintain intellectual property rights or infringement of the intellectual property rights of others.

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. Finally, while it is not feasible to predict the actual cost of acquiring and developing additional drug products, that cost could be substantial and we may need to raise additional financing for such purpose, which may further dilute existing stockholders.

***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, among others, Abraxis Bioscience, Inc., Astra Zeneca LP, Bayer AG, Endo Pharmaceuticals, 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., Genta Incorporated, Merck, Celgene Corporate, Allos Therapeutics, Inc., BiPar Sciences, Inc., Genzyme Corporation, Shire Pharmaceuticals, Abbott Laboratories, Poniard Pharmaceuticals, Inc., Roche Pharmaceuticals and Johnson & Johnson who may be more advanced in the development of competing drug products or are more established. Many of our competitors are large and well-capitalized companies focusing on a wide range of diseases and drug indications, and have substantially greater financial, research and development, marketing, human and other resources than we do. Furthermore, large

pharmaceutical companies have significantly more experience than we do in pre-clinical testing, human clinical trials and regulatory approval procedures, among other things.

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***Our 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 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 twelve 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 believe that 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.

***Earthquakes or other natural or man-made disasters and business interruptions could adversely affect our business.***

Our operations are vulnerable to interruption by fire, power loss, floods, telecommunications failure and other events beyond our control. In addition, our operations are susceptible to disruption as a result of natural disasters such as

earthquakes. So far we have never experienced any significant disruption of our operations as a result of earthquakes or other natural disasters. Although we have a contingency recovery plan, any significant business interruption could cause delays in our drug development and future sales and harm our business.

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**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.

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.

In the United States, there have been, and we expect there will continue to be, a number of state and federal proposals that limit the amount that private insurance plans may pay to reimburse the cost of drugs, including our products. We believe the increasing emphasis on managed care in the United States has and will continue to put pressure on the price and usage of our products, which may also impact sales of our products. In addition, current third-party reimbursement policies for our products may change at any time. Negative changes in reimbursement or our failure to obtain reimbursement for our products may reduce the demand for, or the price of, products, which could result in lower sales of our products, thereby weakening our competitive position and negatively impacting our results of operations.

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.

*Wholesaler actions could increase competitive and pricing pressures on pharmaceutical manufacturers, including us.*

*We sell Fusilev primarily through wholesalers.* These wholesale customers comprise a significant part of the distribution network for pharmaceutical products in the United States. A small number of large wholesale distributors control a significant share of the market, which can 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.

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***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. 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.

***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 outside of the United States. In order to market our existing and future product candidates in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals according to the applicable domestic laws and regulations. We have had limited interactions with foreign 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 guarantee approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not necessarily ensure approval by regulatory authorities in other countries or by the FDA. The foreign 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 foreign regulatory approvals on a timely basis, if at all. We may not be able to file for foreign 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 impact 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;



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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 such as the Centers for Medicare & Medicaid Services promulgate regulations, and issue guidelines, directly applicable to us and to our products. In addition, third parties such as professional societies, practice management groups, insurance carriers, physicians, private health/science foundations and organizations involved in various diseases from time to time may publish guidelines or recommendations to healthcare providers, administrators and payers, and patient communities. Recommendations 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. Third-party organizations like the above 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.

***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 related to the drug development process through lengthy and rigorous 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, the contract research organizations or contract manufacturers with which we have relationships, 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, 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 an application seeking approval to market a drug product, 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.

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;

finer;

changes in advertising;

revocation or suspension of regulatory approvals of products;

product recalls or seizures;

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

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civil or criminal sanctions;

suspension or termination of ongoing clinical trials;

imposition of restrictions on our operations;

close the facilities of our contract manufacturers; and

refusals to approve new products.

***The discovery of previously unknown safety risks with drug products approved to go to market may raise costs or prevent us from marketing such products or change the labeling of our products or take other potentially limiting or costly actions if we or others identify safety risks after our products are on the market.***

The later discovery of previously unknown safety risks with our products may result in the imposition of restrictions on distribution or use of the drug product, including withdrawal from the market. 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 products at issue. 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.

The Food and Drug Administration Amendments Act of 2007 significantly added to the FDA's authority, including allowing the FDA to:

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;

mandate labeling changes to products, at any point in a product's lifecycle, based on new safety information; and

require sponsors to implement a Risk Evaluation and Mitigation Strategy, or 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).

Failure to comply with a REMS could result in significant civil monetary 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 United States, 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.

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,

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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 related to pricing and reimbursement that could impact our ability to sell our products profitably. The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 were signed into law on March 23, 2010 and March 30, 2010, respectively, and are referred to collectively as the Healthcare Reform Acts. The Healthcare Reform Acts enacted provisions including a revision to the definition of average manufacturer price for reporting purposes, increasing Medicaid rebates, expanding the 340B drug discount program, and making changes to affect the Medicare Part D coverage gap, or donut hole. These reforms will significantly impact the pharmaceutical industry. The full effects of these provisions will become apparent as these laws are implemented and the Centers for Medicare & Medicaid Services and other agencies issue applicable regulations or guidance as required by the Acts. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products.

The sales of our products depend in part on the availability of reimbursement from third-party payors such as government health administration authorities, private health insurers, health maintenance organizations including pharmacy benefit managers and other health care-related organizations. Both the federal and state governments in the United States and foreign governments continue to propose and pass new legislation 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.

The high cost of pharmaceuticals continues to generate substantial government interest. Various governmental entities may focus on pharmaceutical prices by holding hearings or launching investigations regarding the pricing for drugs by pharmaceutical companies such as ours and the ability of patients to obtain drugs. In December 2009, the Government Accounting Office released its report on the growing cost of brand-name prescription drugs. In addition, in July 2008, the Joint Economic Committee of Congress held hearings on the pricing of drugs for rare conditions. Future developments may require us to decrease the price that we charge for our products, thereby negatively affecting our financial results.

In some foreign countries, particularly in the European Union, prescription drug pricing is subject to governmental control. Drug pricing may be made against a reference price set by the healthcare providers as a measure for healthcare cost containment. 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 seeks to address the clinical effectiveness and cost-effectiveness of our product candidate as compared with other available therapies as part of the health technology assessment. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels for the purpose of adoption of these products in the national health services in these jurisdictions, our profitability will likely be negatively affected.

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***If we market products in a manner that violates health care anti-kickback or other anti-fraud and anti-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. The Healthcare Reform Acts make several important changes to the federal anti-kickback statute, false claims laws, and health care fraud statute for example, by weakening the intent requirement under the anti-kickback and health care fraud statutes that may make it easier for the government, or whistleblowers to charge such fraud and abuse violations. In addition, the Healthcare Reform Acts increase penalties for fraud and abuse violations. In addition, the Healthcare Reform Acts increases penalties for fraud and abuse violations. 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 negatively impact 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



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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 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:

in certain jurisdictions, 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.

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We also rely on trade secret protection and contractual protections for our unpatented, confidential and proprietary technology. Trade secrets are difficult to protect. While we enter into confidentiality agreements with our employees, consultants and others, these agreements may not successfully protect our trade secrets or other confidential and proprietary information. It is possible that these agreements will be breached, or that they will not be enforceable in every instance, and that we will not have adequate remedies for any such breach. 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.

We also rely on trademarks to protect the names of our products. These trademarks may be challenged by others. If we enforce our trademarks against third parties, such enforcement proceedings may be expensive. Some of our trademarks, including Zevalin are owned by, or assignable to, our licensors and, upon expiration or termination of the applicable license agreements, we may no longer be able to use these trademarks.

If we are unable to adequately protect our technology, trade secrets or proprietary know-how, or enforce our patents and trademarks, 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. We believe that there is significant litigation in the pharmaceutical and biotechnology industry regarding patent and other intellectual property rights. A patent does not provide the patent holder with freedom to operate in a way that infringes the patent rights of others. We may be accused of patent infringement at any time. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents in the United States.

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, including trademarks and copyrights, relevant to our drug products of which we are not aware. Third parties may assert patent or other intellectual property infringement claims against us, or our licensors and collaborators, with products. Any claims that might be brought against us relating to infringement of patents may cause us to incur significant expenses and, if successfully asserted against us, may cause us to pay substantial damages and result in the loss of our use of the intellectual property that is critical to our business strategy.

In the event that we or our partners are found to infringe any valid claim of a patent held by a third party, we may, among other things, be required to:

pay damages, including up to treble damages and the other party's attorneys' fees, which may be substantial;

cease the development, manufacture, use and sale of our products that infringe the patent rights of others through a court-imposed sanction such as an injunction;

expend significant resources to redesign our products so they do not infringe others' patent rights, which may not be possible;

discontinue manufacturing or other processes incorporating infringing technology; or

obtain licenses to the infringed intellectual property, which may not be available to us on acceptable terms, or at all.

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***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. The pharmaceutical field is characterized by a large number of patent filings involving complex legal and factual questions, and, therefore, we cannot predict with certainty whether our licensed patents will be enforceable. Competitors may have filed applications for or have been issued patents and may obtain additional patents and proprietary rights related to products or processes that compete with or are similar to ours. We may not be aware of all of the patents potentially adverse to our interests that may have been issued to others. 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. We have not conducted an extensive search of patents issued to other parties and such patents which contain claims relating to our technology and products may exist, may have been filed, or could be issued. If such patents do exist, we may 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 and we cannot be certain that we will have the required resources to pursue litigation or otherwise to protect our proprietary rights. 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 which may not be available on commercially reasonable terms, or at all, in order to continue to develop or market certain of our products. If we need but cannot obtain a license, we may be prevented from marketing the affected product.

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

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

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

We may be held liable if any product we or our partners develop causes injury or is found otherwise unsuitable during product testing, manufacturing, clinical trials, 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 \$15.0 million in the aggregate, it is possible that this coverage will be insufficient to protect us from future claims. Additionally, 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

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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 financial condition.

***The use of hazardous materials, including radioactive and biological materials, in our research and development and commercial 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, manufacturing (including a radiolabeling step for Zevalin) and administration of our drugs involves the controlled use of hazardous materials, including chemicals, radioactive and biological materials, such as radioactive isotopes. However, we do not physically handle these radioactive isotopes or such 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 cleanup and removal. Currently the costs of complying with federal, state and local regulations are not significant, and consist primarily of waste disposal expenses, however, they could become expensive, and current or future environmental regulations may impair our research, development, production and commercialization efforts.

## **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 December 31, 2010, there were approximately 51,459,284 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 12.6 million additional shares of common stock. However, we would receive over \$62 million from the issuance of shares of common stock upon the exercise of all of the options and warrants. A substantial number of those shares, when we issue them upon vesting, conversion or exercise, will be available for immediate resale in the public market. In addition, we may sell additional shares of common stock or securities convertible or exercisable into common stock in public or private offerings, 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 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.



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Factors that may cause the market price and volume of our common stock to decrease include:

- recognition on up-front licensing or other fees or revenues;
- payments of non-refundable up-front or license fees, or payment for cost-sharing expenses, to third parties;
- adverse results or delays in our clinical trials;
- fluctuations in our results of operations;
- timing and announcements of our 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;
- changes in recommendations or guidelines of government agencies or other third parties regarding the use of our drug products;
- 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;
- 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, 2010 through February 25, 2011, the price of our common stock ranged between \$7.10 and \$3.70, and the daily trading volume was as high as 5,960,800 shares and as low as 83,900 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.

***If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results, and current and potential stockholders may lose confidence in our financial reporting.***

We are required by the SEC to establish and maintain adequate internal control over financial reporting that provides reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. We are likewise required, on a quarterly basis, to evaluate the effectiveness of our internal controls and to disclose any changes and material weaknesses in those internal controls.

As described in our Annual Report on Form 10-K for the year ended December 31, 2009, we identified a material weakness with regard to accounting for warrant instruments in our internal control over financial reporting for such period. Given this material weakness with regard to warrants, management was unable to conclude that we maintained effective internal control over financial reporting as of December 31, 2009. Since the determination regarding this material weakness, we devoted significant effort and resources to the remediation and improvement of our internal control over financial reporting. As described in Item 9A of this Annual Report on Form 10-K for the year ended December 31, 2010, no new or existing material weaknesses were identified and we determined that our internal control over financial reporting was effective as of December 31, 2010.

Any failure to maintain such internal controls in the future could adversely impact our ability to report our financial results on a timely and accurate basis. If our financial statements are not accurate, investors may not have a complete understanding of our operations. Likewise, if our financial statements are not filed on a timely basis as required by the SEC and NASDAQ, we could face severe consequences from those authorities. In either case, there could result a material adverse affect on our business. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

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

The reports of publicly-traded companies are subject to review by the 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, and 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.

***Changes in our effective income tax rate could adversely affect our results of operations.***

We are subject to federal and state income taxes in the United States and our tax liabilities are dependent upon the distribution of income among these different jurisdictions. Various factors may have favorable or unfavorable effects on our effective income tax rate. These factors include, but are not limited to:

- interpretations of existing tax laws,
- the accounting for stock options and other share-based compensation,
- changes in tax laws and rates,
- future levels of research and development spending,
- changes in accounting standards,
- changes in the mix of earnings in the various tax jurisdictions in which we operate,
- the outcome of examinations by the Internal Revenue Service and other jurisdictions,
- the accuracy of our estimates for unrecognized tax benefits,
- realization of deferred tax assets, and
- changes in overall levels of pre-tax earnings.

The impact on our income tax provision resulting from the above-mentioned factors may be significant and could have an impact on our results of operations.

***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. If we do not pay dividends, our stock may be less valuable to investors because a return on their investment will only occur if our stock price appreciates.

**Item 1B. *Unresolved Staff Comments***

None.

**Item 2. *Properties***

We sublease our principal executive office in Henderson, Nevada under a non cancelable operating lease expiring April 30, 2014. We lease our research and development facility in Irvine, California under a non cancelable operating lease expiring June 30, 2016. 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. We believe that our leased facilities are adequate to meet our needs at this time.

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**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. *[Reserved]***

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

As of February 25, 2011 there were 52,003,514 shares of common stock outstanding and 382 stockholders of record. On February 25, 2011, the closing sale price of our common stock was \$6.80 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 2010 and 2009 were as follows:

	<b>High</b>	<b>Low</b>
<b>Year 2010:</b>		
First Quarter	\$ 5.48	\$ 4.28
Second Quarter	\$ 5.24	\$ 3.79
Third Quarter	\$ 4.66	\$ 3.67
Fourth Quarter	\$ 7.08	\$ 4.05
<b>Year 2009</b>		
First Quarter	\$ 2.10	\$ 1.39
Second Quarter	\$ 8.15	\$ 1.75
Third Quarter	\$ 10.00	\$ 4.76
Fourth Quarter	\$ 6.74	\$ 3.97



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**Stock Performance Graph (1)**

The graph below compares the cumulative total stockholder return on \$100 invested, assuming the reinvestment of all dividends, on December 31, 2005, the last trading day before our 2005 fiscal year, through the end of fiscal 2010 with the cumulative total return on \$100 invested for the same period in the Russell 2000 index and a Peer Group.

**COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\***

Among Spectrum Pharmaceuticals, Inc., the Russell 2000 Index,  
and a Peer Group

\* \$100 invested on 12/31/05 in stock or index, including reinvestment of dividends. Fiscal year ending December 31.

The Peer Group included the following companies:

Affymax Inc	Immunomedics Inc
Allos Therapeutics Inc	Intermune Inc
Amicus Therapeutics Inc	Isis Pharmaceuticals Inc
Arena Pharmaceuticals Inc	Mannkind Corp
Biocryst Pharmaceuticals Inc	Medivation Inc
Biomarin Pharmaceutical Inc	Onyx Pharmaceuticals Inc
Cell Therapeutics Inc	Sangamo Biosciences Inc
Cytokinetics Inc	Seattle Genetics Inc
Dendreon Corp	Supergen Inc
Enzon Pharmaceuticals Inc	Theravance Inc
Exelixis Inc	Vertex Pharmaceuticals Inc

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	<b>12/31/05</b>	<b>12/31/06</b>	<b>12/31/07</b>	<b>12/31/08</b>	<b>12/31/09</b>	<b>12/31/10</b>
Spectrum Pharmaceuticals, Inc.	100.00	130.73	64.30	35.22	104.96	162.41
Russell 2000	100.00	118.37	116.51	77.15	98.11	124.46
Peer Group	100.00	123.99	126.64	92.09	128.95	134.43

(1) The information in this section is not soliciting material, is not deemed filed with the SEC and is not to be incorporated by reference in any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

**Unregistered Equity Issuances**

We did not issue any unregistered securities during the year ended December 31, 2010 that were not otherwise disclosed in a previously filed Quarterly Report on Form 10-Q or a Current Report on Form 8-K.

**Equity Repurchases**

We did not repurchase any of our securities during the quarter ended December 31, 2010.

**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.

**Item 6. Selected Financial Data**

The following table presents selected historical financial data. We derived the selected statements of operations data for the years ended December 31, 2010, 2009, and 2008 and balance sheet data as of December 31, 2010 and 2009 from our audited consolidated financial statements and notes thereto that are included elsewhere in this annual report. We derived the selected statements of operations data for the years ended December 31, 2007 and 2006 and the balance sheet data as of December 31, 2008, 2007 and 2006 from our audited consolidated financial statements that do not appear in this annual report.

You should read the following financial information together with the information under Management's Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and related notes included elsewhere in this annual report. The information set forth below is not necessarily indicative of our future financial condition or results of operations.

<b>Statement of Operations Data:</b>	<b>Years ended December 31,</b>				
	<b>2010</b>	<b>2009</b>	<b>2008</b>	<b>2007</b>	<b>2006</b>
	<b>(In thousands, except per share data)</b>				
Total revenues	\$ 74,113	\$ 38,025	\$ 28,725	\$ 7,672	\$ 5,673
Operating expenses:					

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Cost of product sales (excludes amortization of purchased intangible assets)	17,439	8,148	1,193		97
Selling, general and administrative	48,550	33,607	15,156	11,577	7,736
Research and development	57,301	21,058	26,683	33,285	23,728
Amortization of purchased intangibles	3,720	3,720	158		
Acquired in-process research and development			4,700		
Loss from operations	(52,897)	(28,508)	(19,165)	(37,190)	(25,888)
Change in fair value of common stock warrant liability	2,731	8,075	1,271	12,055	(2,485)
Other income, net	1,279	662	1,165	3,139	2,606
Loss before provision for income taxes	(48,887)	(19,771)	(16,729)	(21,996)	(25,767)
Benefit (Provision) for income taxes	43	(421)	(5)	(5)	(5)
Net loss attributable to non-controlling interest		1,146	2,538	20	3
<b>Net loss attributable to Spectrum Pharmaceuticals, Inc. stockholders</b>	<b>\$ (48,844)</b>	<b>\$ (19,046)</b>	<b>\$ (14,196)</b>	<b>\$ (21,981)</b>	<b>\$ (25,769)</b>
Net loss per share basic and diluted	\$ (0.99)	\$ (0.48)	\$ (0.45)	\$ (0.76)	\$ (1.06)

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Balance Sheet Data:	2010	2009	As of December 31,		
			2008	2007	2006
	(In thousands)				
Cash, cash equivalents and investments	\$ 104,243	\$ 113,341	\$ 75,938	\$ 55,659	\$ 50,967
Working capital	58,543	86,758	54,677	48,813	46,054
Total assets	163,631	173,133	129,509	57,540	53,117
Common stock warrant liability (at fair value)	3,904	6,635	765	2,035	14,090
Long term obligations, less current portion	25,833	25,310	42,822	992	1,035
Total stockholders' equity (including non-controlling interest)	74,476	108,324	53,116	46,714	31,759

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

*This Annual Report on Form 10-K contains forward-looking statements within the meaning of the federal securities laws. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those expressed or implied by such forward-looking statements. For a detailed discussion of these risks and uncertainties, see the Risk Factors section in Item 1A of Part I of this Form 10-K. We caution the reader not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Form 10-K. We undertake no obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Form 10-K.*

**Overview**

We are a biotechnology company with fully integrated commercial and drug development operations with a primary focus in oncology. Our strategy is comprised of acquiring, developing and commercializing a broad and diverse pipeline of late-stage clinical and commercial products. We market two oncology drugs, ZEVALIN® and FUSILEV® and have two drugs, apaziquone and belinostat, in late stage development along with a diversified pipeline of novel drug candidates. We have assembled an integrated in-house scientific team, including formulation development, clinical development, medical research, regulatory affairs, biostatistics and data management, and have established a commercial infrastructure for the marketing of our drug products. We also leverage the expertise of our worldwide partners to assist in the execution of our strategy. Apaziquone is presently being studied in two large Phase 3 clinical trials for non-muscle invasive bladder cancer, or NMIBC, under strategic collaborations with Allergan, Inc., (Allergan), Nippon Kayaku Co. Ltd., (Nippon Kayaku), and Handok Pharmaceuticals Co. Ltd., (Handok). Belinostat, is being studied in multiple indications including a Phase 2 registrational trial for relapsed or refractory peripheral T-cell lymphoma, or PTCL, under a strategic collaboration with TopoTarget A/S or TopoTarget.

Our business strategy is comprised of the following initiatives:

**Maximizing the growth potential of our marketed drugs, Zevalin and Fusilev.** Our near-term outlook largely depends on sales and marketing successes for our two marketed drugs. For Zevalin, we stabilized sales in 2009, increased sales in 2010 and believe we can continue to grow sales in 2011 and beyond. For Fusilev, which we launched in August 2008, we were able to benefit from broad utilization in community clinics and hospitals and recognized a dramatic increase in sales during 2010 due to a shortage of generic leucovorin. While we cannot predict how long the shortage may continue, our focus now is to obtain approval for Fusilev in advanced metastatic colorectal cancer. As part of its review of our supplemental new drug application, or

sNDA, for metastatic colorectal cancer, the FDA requested additional data to which we submitted a response on October 29, 2010. The FDA formally accepted the submission and established a decision date, or PDUFA, of April 29, 2011.

For both Zevalin and Fusilev, we initiated and continue to stage appropriate infrastructure expansions and additional initiatives to facilitate broad customer reach and to address other market requirements, as appropriate. We have formed a dedicated commercial organization comprised of highly experienced and motivated sales representatives, account managers, and a complement of other support marketing personnel

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to manage the sales and marketing of these drugs. In addition our scientific department supports field activities through various MDs, PhDs and other medical science liaison personnel.

***Optimizing our development portfolio and maximizing the asset values of its components.*** While over the recent few years, we have evolved from a development-stage to a commercial-stage pharmaceutical company, we have maintained a highly focused development portfolio. Our strategy with regard to our development portfolio is to focus on late-stage drugs and to develop them rapidly to the point of regulatory approval. We plan to develop some of these drugs ourselves or with our subsidiaries and affiliates, or secure collaborations such that we are able to suitably monetize these assets.

We have assembled a drug development infrastructure that is comprised of highly experienced and motivated MDs, PhDs, clinical research associates and a complement of other support personnel to rapidly develop these drugs. During 2009, this team achieved our goal of completing enrollment in the two Phase 3 apaziquone trials (with more than 1,600 patients enrolled). We expect to continue to maximize the value of apaziquone through further developmental efforts and initiation of additional trials.

We have several other exciting compounds in earlier stages of development in our portfolio. Based upon a criteria-based portfolio review, we are in the process of streamlining our pipeline drugs, allowing for greater focus and integration of our development and commercial goals.

***Expanding our pipeline of late stage and commercial drugs through licensing and business development.*** It is our goal to identify new strategic opportunities that will create strong synergies with our currently marketed drugs and identify and pursue partnerships for out-licensing certain of our 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. We believe our in-licensing of belinostat, a novel histone deacetylase, or HDAC, inhibitor, is demonstrative of such licensing and business development efforts outlined above.

***Managing our financial resources effectively.*** We remain committed to fiscal discipline, a policy which has allowed us to become well capitalized among our peers, despite a very challenging capital markets environment during 2009 and continuing through 2010. 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. Even with the continued build-up in operational infrastructure to facilitate the marketing of our two commercial drugs, we intend to be fiscally prudent in any expansion we undertake. In terms of revenue generation, we plan to become more reliant on sales from currently marketed drugs and intend to pursue out-licensing of 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, including termination of our existing development programs, especially if we do not expect value being driven from continued development. We ended 2010 with over \$100 million in cash, cash equivalents and investments which was net of the \$30 million license fee paid for belinostat in early 2010 offset by cash received from an out-license of apaziquone of approximately \$17.5 million.

***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 previously held positions at both small to mid-size biotech companies, as well as large pharmaceutical companies. We have 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.

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**Financial Condition**

***Liquidity and Capital Resources***

Our cumulative losses, since inception in 1987 through December 31, 2010, are approximately \$310.4 million. We expect to continue to incur additional losses for at least the next few years, as we implement our growth strategy of commercializing marketed drugs, while continuing to develop our portfolio of late-stage drug products. Our long-term strategy is to generate profits from the sale and licensing of our drug products. Accordingly, in the next several years, we expect to supplement our cash position with sales of Zevalin and Fusilev and generate licensing revenue from out-licensing our other drug products.

While we believe that the approximately \$104 million in cash, cash equivalents and investments, which includes long term marketable securities, we had available on December 31, 2010 will allow us to fund our current planned operations for at least the next twelve to eighteen months, we may, however, 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. We may be unable to obtain such additional capital when needed, or on terms favorable to us or our stockholders, if at all. If we raise additional funds 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.

Zevalin sales growth is largely dependent on the successful launch of Zevalin for use as part of first-line therapy for follicular NHL, continued use in its initial indication, and establishing a consistent and accurate reimbursement standard. As noted above, we recently obtained a CMS decision for a reimbursement standard based on ASP methodology in the HOPPS setting. As discussed earlier, during 2010 our sales of Fusilev grew considerably over prior years because of a shortage of generic leucovorin. We are unable to predict how long this current shortage may last and we believe that the growth of future Fusilev sales largely depends upon obtaining FDA approval for use of Fusilev in combination with 5-FU containing regimens for the treatment of colorectal cancer and favorable reimbursement. The FDA stated in their October 2009 Complete Response letter that the submission did not demonstrate that Fusilev is non-inferior to leucovorin; and at our January 2010 meeting the FDA requested additional data which we submitted in late 2010. The FDA formally accepted the submission and established a decision date (PDUFA) of April 29, 2011. 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.

Our expenditures for research and development (R&D ) 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 (such as personnel costs, rent, and utilities, among others). The following summarizes our research and development expenses for the periods indicated and include related stock-based charges but not amortization of intangibles or expensing of in-process research and development costs. We charge all research and development expenses to operations as incurred.



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	<b>Year Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
	(\$ in 000 s)		
Apaziquone	\$ 6,165	\$ 10,915	\$ 5,477
Ozarelix	1,916	1,168	2,435
Ortataxel	716	311	150
Fusilev	1,281	1,125	2,096
Zevalin	421	563	151
Belinostat	36,045		
Other development drugs	3,469	1,535	1,304
<b>Total Direct Costs</b>	<b>50,013</b>	<b>15,617</b>	<b>11,613</b>
Indirect Costs (including non-cash share-based compensation of \$2.4 million, \$3.2 million and \$4.0 million, respectively)	14,838	16,652	15,070
Partner Reimbursement	(7,550)	(11,211)	
<b>Total Research &amp; Development</b>	<b>\$ 57,301</b>	<b>\$ 21,058</b>	<b>\$ 26,683</b>

Our primary focus areas for the foreseeable future, and the programs that are expected to represent a significant part of our R&D expenditures, are the on-going registrational clinical trials of apaziquone and belinostat and additional clinical studies in supporting the expanded utilization of our FDA products (ZEVALIN and FUSILEV). While we are currently focused on advancing these key product development programs, we continually evaluate our R&D programs of other pipeline products in response to the scientific and clinical success of each product candidate, as well as an ongoing assessment as to the product candidate's commercial potential. Our anticipated net use of cash for R&D in the fiscal year ending December 31, 2011, excluding the cost of in-licensing or acquisitions of additional drugs, if any, is expected to range between approximately \$30 and \$40 million.

Under our various existing licensing agreements, we are contingently obligated to make various regulatory and business milestone payments. In connection with the development of certain in-licensed drug products, we anticipate the occurrence of certain of these milestones during 2011. Upon successful achievement of these milestones, we will likely become obligated to pay up to approximately \$5.0 million during 2011, payable in cash or stock at our discretion.

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 has borne 65% of the development costs of apaziquone. Additionally, we entered into a collaboration agreement with TopoTarget, whereby, commencing February 2, 2010, TopoTarget bears, for belinostat, 100% of the CUP trial costs and 30% of other development costs unrelated to the PTCL study.

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**

Net cash used in operating activities was \$22.5 million for 2010 which includes the non-recurring \$30.0 million upfront payment for in licensing a novel drug belinostat in late stage pivotal clinical trials. The principal components of such cash usage was a net loss in the period of \$48.8 million adjusted for net non-cash credits of \$1.3 million, offset by changes in working capital of \$25.0 million during the period.

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***Net Cash used for Investing Activities***

Net cash used in investing activities of \$9.8 million in 2010 was primarily due to the \$8.3 million net purchase of marketable securities and a \$1.6 million increase in property and equipment acquisitions, of which \$1.0 million relates to landlord contributions to tenant improvements.

***Net Cash provided by Financing Activities***

Net cash provided by financing activities of \$3.6 million in 2010, primarily relates to proceeds from the issuance of common stock as a result of the exercise of stock options and purchases of shares under our Employee Stock Purchase Plan.

**Results of Operations**

***Results of Operations for Fiscal 2010 Compared to Fiscal 2009***

*Net Revenues.* Net revenues increased \$36.1 million, or 94.9%, to \$74.1 million in 2010 (net of estimates for promotional, price and other adjustments including distributor chargebacks, rebates and returns reserves) from \$38.0 million in 2009. We recorded approximately \$60.9 million of revenue from the sales of Zevalin and Fusilev as compared to approximately \$28.2 million in 2009. Zevalin and Fusilev revenues in 2010 were approximately \$28.9 and \$32.0 million respectively, compared to approximately \$15.7 million and \$12.5 million, respectively in 2009. The increase in Zevalin revenues included both an increase in unit sales and average selling prices. Revenues from the sales of Fusilev have fluctuated in 2009 and 2010. During the first half of 2009, Fusilev sales were higher due to a supply disruption of leucovorin. The disruption in supply abated in the second quarter of 2009, and subsequent Fusilev sales were significantly lower than experienced in the first half of 2009. Commencing late in the second quarter of 2010, a similar disruption emerged and accordingly, in the second, third and fourth quarters of 2010, sales of Fusilev grew significantly. Looking forward we are unable to predict how long this disruption may continue and cannot predict our ability to manufacture sufficient quantities to meet fluctuating commercial demand.

We also recorded \$13.2 million in 2010 and \$9.8 million in 2009 of licensing revenues from the amortization of the upfront payments received from Allergan in 2008 and from Nippon Kayaku and Handok payments received in 2010. In January 2007, we received approximately \$0.9 million, representing our 50% share of an economic interest that Aeterna Zentaris had from an arrangement with Nippon Kayaku for certain rights to ozarelix in Japan and recognized the amount as deferred revenue. In early 2010 we reevaluated the basis for deferral having determined that there are no further ongoing obligations and recorded the approximately \$0.9 million as license revenue during 2010.

*Cost of Product Sales.* As a result of increased product revenues and a reserve for expiring inventory of \$50,000, the cost of product sales increased \$9.3 million to \$17.4 million in 2010 from \$8.1 million in 2009. As a percentage of revenue, the cost of product sales increased from 21.4% in 2009 to 23.5% in 2010.

*Selling, General and Administrative.* Selling, general and administrative expenses increased \$15.0 million, or 44.5%, to \$48.6 million in 2010, from \$33.6 million in 2009. The increase is primarily due to approximately:

\$13.6 million increase attributable to sales and marketing expenses, including payroll costs, incurred with the sales of Zevalin and Fusilev. We expect sales and marketing expenses related to Zevalin and Fusilev to increase in 2011

\$1.8 million increase in non-cash compensation expenses.

*Research and Development.* Total research and development expenses increased \$36.2 million, or 172.1%, to \$57.3 million in 2010, from \$21.1 million in 2009. The increase is primarily due to the \$30.0 million upfront payment for the licensing of belinostat, and a one-time charge of \$3.1 million, representing the fair value of 751,956 shares of our common stock issued as consideration for the acquisition and licensing of compounds. We anticipate research and development expenses in 2011 to be higher than 2010, before any payments for drug licensing, primarily due to continued development of belinostat through our collaboration with TopoTarget.

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*Change in Fair Value of Common Stock Warrant Liability.* We recorded income of \$2.7 million for the change in the fair value of the warrant obligations during 2010 compared to income of \$8.1 million in the same period of 2009. The decrease from 2009 is due to the expiration of 6,931,607 common stock warrants issued in 2009, which expired unexercised and a decrease in the fair value of 3,747,312 warrants expiring in September 2011.

*Other Net Income.* The principal components of other income of \$1.3 million and \$662,000 during 2010 and 2009, respectively, consisted of \$977,000 related to grants under the Qualifying Therapeutic Discovery Project Program administered under section 48D of the Internal Revenue Code as well as currency gains and losses and net interest income. We have lower investment yields 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.

***Results of Operations for Fiscal 2009 Compared to Fiscal 2008***

In 2009, we incurred a net loss of approximately \$19.0 million as compared to a net loss of \$14.2 million in 2008. The principal components of the year-to-year changes in line items are discussed below.

*Net Revenues.* We recognized revenue of approximately \$38.0 million in 2009 as compared to \$28.7 million in 2008. During 2009, we recorded approximately \$28.2 million of revenue from the sales of Zevalin and Fusilev as compared to approximately \$8.0 million in 2008. Zevalin and Fusilev revenues in 2009 were approximately \$15.7 and \$12.5 million respectively, compared to approximately \$0.3 million and \$7.7 million, respectively in 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 had deferred the recognition of approximately \$3.1 million of such revenue until we had more experience with product returns. We also recognized approximately \$0.3 million net sales of Zevalin from the consolidation of RIT Oncology, LLC (RIT) effective December 15, 2008. During 2009, we also recognized \$8.3 million of licensing revenues from the amortization of the \$41.5 million up-front payment we received from Allergan in 2008. We also recognized a milestone payment from Allergan of \$1.5 million on the completion of enrollment of our two pivotal clinical trials for apaziquone. No similar revenues were recognized in 2008. 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 2009.

*Selling, General and Administrative.* Selling, general and administrative expenses increased by approximately \$18.4 million, from approximately \$15.2 million in 2008 to approximately \$33.6 million in 2009, primarily due to approximately:

\$10.6 million increase attributable to sales and marketing expenses, including payroll costs, incurred with the launch of Zevalin and Fusilev.

\$3.3 million increase in general and administrative costs due to increased activities, including payroll costs and higher professional costs due to business development activities

\$1.6 million increase in non-cash compensation expenses.

*Research and Development.* Research and development expenses decreased by approximately \$5.7 million, from approximately \$26.7 million in 2008 to approximately \$21 million in 2009, which included non-cash amortization and write off of Zevalin related intangibles and in-process research, and development charges of approximately \$3.7 million and \$4.9 million in 2009 and 2008, respectively. Research and development expenses also reduced

primarily due to sharing of apaziquone related development costs by our development partner, Allergan, of approximately \$11.2 million. In addition, we incurred reduced development expense in other development products, including ozarelix. During 2009, 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 Zevalin and Fusilev and prioritized our research and development efforts to complete the rapid enrollment in the apaziquone clinical studies.

As reported above, we recorded approximately \$3.7 million of expense from amortization of Zevalin related intangibles for the year ended December 31, 2009 as compared to \$0.2 million during the same period in 2008. This

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was a full year's amortization expense as compared to 15 days prorated amortization during 2008, since Zevalin was acquired in December 2008. During the year 2008, we recorded expense of \$4.7 million for in-process research and development, or IPRD, on the Zevalin related intangibles; no similar expense was recorded in 2009.

*Change in Fair Value of Common Stock Warrant Liability.* We recorded approximately \$8.1 million of income from warrant obligations in 2009 as compared to \$1.3 million in 2008, in connection with the restatement of our previously reported financial statements.

*Other Net Income.* Other income consisted of net interest income of approximately \$0.7 million and \$1.2 million for the years ended December 31, 2009 and 2008, respectively and in 2008 included approximately \$200,000 realized investment gains. The decrease in interest income was primarily due to lower investment yields in 2009 due to the shift in our investment strategy to more conservative US Treasury investments.

**Nature of each accrual that reduces gross revenue to net revenue**

Provisions for product returns, sales discounts and rebates, distribution and data fees, and estimates for chargebacks are established as a reduction of product sales revenue at the time revenues are recognized. Management considers various factors in determination of such provisions, which are described more in detail below. Such estimated amounts are deducted from our gross sales to determine our net revenues. Provisions for bad and doubtful accounts are deducted from gross receivables to determine net receivables. Changes in our estimates, if any, would be recorded in the statement of operations in the period the change is determined. If we materially over or under estimate the amount, there could be a material impact on our consolidated financial statements.

For the periods ended December 31, 2010 and 2009, the following is a roll forward of the provisions for product returns, discounts and rebates, data and distribution fees and chargeback allowances and estimated doubtful account allowances:

	<b>Chargebacks and Discounts</b>	<b>Rebates</b>	<b>Returns</b>	<b>Data and Distribution Fees</b>	<b>Doubtful accounts</b>	<b>Total</b>
	(\$ in 000 s)					
<b>Period ended December 31, 2010:</b>						
Balances at beginning of the period	\$ 860	388	\$ 1,176	\$ 213	\$ 150	\$ 2,787
Add provisions:	1,750	14,721	3,540	3,029	359	23,389
Less: Credits or actual allowances:	(1,935)	(635)	(2,716)	(1,368)	(170)	(6,824)
Balances at the close of the period	\$ 675	\$ 14,474	\$ 2,000	\$ 1,874	\$ 339	\$ 19,352
<b>Period ended December 31, 2009:</b>						
Balances at beginning of period	\$ 1,631	\$	\$ 3,144	\$	\$ 150	\$ 4,925
Add provisions:	3,760	469	95	1,212		5,536
	(4,531)	(81)	(2,063)	(999)		(7,674)

Less: Credits or actual allowances:

Balances at the close of the period	\$	860	\$	388	\$	1,176	\$	213	\$	150	\$	2,787
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Amounts recorded as allowances on our consolidated balance sheets for 2010 and 2009 are reflected in the table above. The basis and methods of estimating these allowances, used by management, are described below.

***Chargebacks, discounts and rebates***

Chargebacks represent a provision against gross accounts receivable and related reduction to gross revenue. A chargeback is the difference between the price the wholesale customer, in our case the wholesaler or distributor, pays (the wholesale acquisition cost, or WAC) and the price (contracted price) that a contracted customer (e.g., a Group Purchasing Organization, or GPO, member) pays for a product. We accrue for chargebacks in the relevant



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period on the presumption that all units of product sold to members of the GPOs will be charged back. We estimate chargebacks at the time of sale of our products to the members of the GPOs based on:

- (1) volume of all products sold via distributors to members of the GPOs and the applicable chargeback rates for the relevant period;
- (2) applicable WAC and the contract prices agreed with the GPOs; and
- (3) the information of inventories remaining on hand at the wholesalers and distributors at the end of the period, actual chargeback reports received from our wholesalers and distributors as well as the chargebacks not yet billed (product shipped less the chargebacks already billed back) in the calculation and validation of our chargeback estimates and reserves.

Discounts (generally prompt payment discounts) are accrued at the end of every reporting period based on the gross sales made to the customers during the period and based on their terms of trade for a product. We generally review the terms of the contracts, specifically price and discount structures, payment terms in the contracts between the customer and the Company to estimate the discount accrual.

Customer rebates are estimated at every period end, based on direct purchases, depending on whether any rebates have been offered. The rebates are recognized when products are purchased and a periodic credit is given. Medicaid rebates are based on the data we receive from the public sector benefit providers, which is based on the final dispensing of our product by a pharmacy to a benefit plan participant.

We record Medicaid and Medicare rebates based on estimates for such expense. However, such amount have not been material to the financial statements.

### ***Product returns allowances***

Customers are typically permitted to return products within thirty days after shipment, if incorrectly shipped or not ordered, and within a window of time six months before and twelve months after the expiration of product dating, subject to certain restocking fees and preauthorization requirements, as applicable. The returned product is destroyed if it is damaged, quality is compromised or past its expiration date. Based on our returns policy, we refund the sales price to the customer as a credit and record the credit against receivables. In general, returned product is not resold. As of each balance sheet date, we estimate potential returns, based on several factors, including: inventory held by distributors, sell through data of distributor sales to end users, customer and end-user ordering and re-ordering patterns, aging of accounts receivables, rates of returns for directly substitutable products and pharmaceutical products for the treatment of therapeutic areas similar to indications served by our products, shelf life of our products and based on experience of our management with selling similar oncology products. We record an allowance for future returns by debiting revenue, thereby reducing gross revenues and crediting a reserve for returns to other accrued liabilities.

### ***Distribution and Data Fees***

Distribution and data fees are paid to authorized wholesalers and specialty distributors of Fusilev as a percentage of WAC for products sold. The services provided include contract administration, inventory management, product sales reporting by customer, returns for clinics and hospitals. We accrue distribution and data fees based on a percentage of Fusilev revenues that are set and governed by distribution agreements.

### ***Doubtful Accounts***

An allowance for doubtful accounts is estimated based on the customer payment history and a review by management of the aging of the accounts receivables as of the balance sheet date. We accrue for doubtful accounts by recording an expense and creating an allowance for such accounts. If we are privy to information on the solvency of a customer or observe a payment history change, we estimate the accrual for such doubtful receivables or write the receivable off.

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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, 2010, approximately:

(\$ in 000 s)	Total	Less than 1 Year	2-3 Years	4-5 Years	After 5 Years
<b>Contractual Obligations(1)</b>					
Capital Lease Obligations(2)	90	45	45		
Operating Lease Obligations(3)	3,245	568	1,233	1,152	292
Purchase Obligations(4)	6,323	5,931	392		
Contingent Milestone Obligations(5)	204,043	6,089	69,058	37,926	90,970
<b>Total</b>	<b>213,701</b>	<b>12,633</b>	<b>70,728</b>	<b>39,078</b>	<b>91,262</b>

- (1) The table of contractual and commercial obligations excludes contingent payments that we may become obligated to pay upon the occurrence of future events whose outcome is not readily determinable. Such significant contingent obligations are described below under *Employment Agreement*.
- (2) The capital lease obligations are related to leased office equipment.
- (3) The operating lease obligations are primarily related to the facility lease for our principal executive office in Henderson, Nevada expiring April 30, 2014; and for our research and development facility in Irvine, California expiring June 30, 2016
- (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, 2010. 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, 2010, 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 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 relevant for us: 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.

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### ***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. 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, 2012. 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 ninety 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, or 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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### **Critical Accounting Policies, Estimates and Assumptions**

Our discussion and analysis of our consolidated financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in conformity with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities reported in our consolidated financial statements. The estimation process requires assumptions to be made about future events and conditions, and is consequently inherently subjective and uncertain. Actual results could differ materially from our estimates. We regularly 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.

#### ***Revenue Recognition***

We sell our products to wholesalers and distributors of oncology products and directly to the end user, directly or through GPOs (e.g., certain hospitals or hospital systems and clinics with whom we have entered into a direct purchase agreement). Our wholesalers and distributors purchase our products and sell the products directly to the end users, which include, but are not limited to, hospitals, clinics, medical facilities, managed care facilities and private oncology based practices etc. Revenue from product sales is recognized upon shipment of product when title and risk of loss have transferred to the customer, and the following additional criteria specified by ASC No. 605-15, Revenue Recognition: Products are met:

- (i) the price is substantially fixed and determinable;
- (ii) our customer has economic substance apart from that provided by us;
- (iii) our customer's obligation to pay us is not contingent on resale of the product; and
- (iv) we do not have significant obligations for future performance to directly bring about the resale of our product; and
- (v) we have a reasonable basis to estimate future returns.

Generally, revenue is recognized when all four of the following criteria are met:

- (i) persuasive evidence that an arrangement exists;
- (ii) delivery of the products has occurred, or services have been rendered;
- (iii) the selling price is both fixed and determinable; and
- (iv) collectibility is reasonably assured.

Provisions for estimated product returns, sales discounts, rebates and charge backs are established as a reduction of gross product sales at the time such revenues are recognized. Thus, revenue is recorded, net of such estimated

provisions. Our estimates for product returns are based our review of inventory in the channels and review of historical rates of actual returns.

Consistent with industry practice, our product return policy permits our customers to return products within thirty days after shipment, if incorrectly shipped or not ordered, and within a window of time six months before and twelve months after the expiration of product dating, subject to certain restocking fees and preauthorization requirements, as applicable. Currently, our returns policy does not allow for replacement of product. The returned product is destroyed if it is damaged, its quality is compromised or it is past its expiration date. Based on our returns



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policy, we refund the sales price to the customer as a credit and record the credit against receivables. In general returned product is not resold. We generally reserve the right to decline granting a return and to decide on product destruction. As of each balance sheet date, we estimate potential returns, based on several factors, including: inventory held by distributors, sell through data of distributor sales to end users, customer and end-user ordering and re-ordering patterns, aging of accounts receivables, rates of returns for directly substitutable products and other pharmaceutical products for the treatment of therapeutic areas similar to indications served by our products, shelf life of our products and the extensive experience of our management with selling the same and similar oncology products. We record an allowance for future returns by debiting revenue, thereby reducing gross revenues and crediting a reserve for returns to reduce gross receivables. If allowances exceed the related accounts receivables, we reclassify such allowances to accrued obligations.

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.

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.

### ***Fair Value of Acquired Assets***

The fair value of acquired tangible and identifiable intangible assets and liabilities assumed based on their estimated fair values at the acquisition date requires extensive accounting estimates and judgments, including in process research and development. 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. Additionally, we must determine whether an acquired entity considered to be a business or a set of net assets because a portion of the purchase price can only be allocated to goodwill in a business combination.

### ***Research and Development***

Research and development expenses include 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. Research and development costs are expensed as incurred. In certain instances we enter into agreements with third parties for research and development activities, where we may prepay fees for services at the initiation of the contract. We record such 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 connection with the October 2008 co-development agreement, Allergan bears 65% of the development costs incurred for apaziquone in NMIBC, commencing January 1, 2009. During the year ended December 31, 2010 and December 31, 2009, approximately \$7.5 million \$11.2 million, respectively, of development costs were reimbursed by Allergan, and credited against total related research and development expense.

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As of each balance sheet date, we review purchase commitments 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.

### ***Amortization and impairment of intangible assets***

Identifiable intangible assets with definite lives are amortized on a straight-line basis over their estimated useful lives, ranging from 1 to 10 years.

We evaluate the recoverability of intangible assets whenever events or changes in circumstances indicate that an intangible asset's carrying amount may not be recoverable. Such circumstances could include, but are not limited to the following:

- (i) a significant decrease in the market value of an asset;
- (ii) a significant adverse change in the extent or manner in which an asset is used; or
- (iii) an accumulation of costs significantly in excess of the amount originally expected for the acquisition of an asset.

We measure the carrying amount of the asset against the estimated undiscounted future cash flows associated with it. Should the sum of the expected future net cash flows be less than the carrying value of the asset being evaluated, an impairment loss would be recognized. The impairment loss would be calculated as the amount by which the carrying value of the asset exceeds its fair value.

### ***Share-Based Compensation***

We recognize compensation expenses for all share-based awards to employees and directors. In estimating the fair value of share-based compensation, we use the quoted closing market price, based on the date prior to our grant date, 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 historical volatility of our common stock, and we estimate the expected life of options based on several criteria, including the vesting period of the grant and the expected volatility.

Share based compensation is recognized only for those awards that are ultimately expected to vest, and we have applied or estimated forfeiture rate to unvested awards for purposes of calculating compensation costs. These estimates will be revised in future periods if actual forfeitures differ from the estimates. Changes in forfeiture estimates impact compensation cost in the period in which the change in estimate occurs.

We account for registered common stock warrants pursuant to applicable accounting guidance on the understanding that in compliance with applicable securities laws, the registered warrants require the issuance of registered securities upon exercise and do not sufficiently preclude an implied right to net cash settlement. We classify registered warrants on the consolidated balance sheet as a current liability which is revalued at each balance sheet date subsequent to the initial issuance. Determining the appropriate fair-value model and calculating the fair value of registered warrants requires considerable judgment, including estimating stock price volatility and expected warrant life. We develop our estimates based on historical data. A small change in the estimates used may have a relatively large change in the estimated valuation. We use the Black-Scholes pricing model to value the registered warrants. Changes in the fair market value of the warrants are reflected in the consolidated statement of operations as Change in fair value of common stock warrant liability.

***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.

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**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 (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 investing in highly liquid, highly rated instruments and not investing in long-term maturity 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, 2010 and December 31, 2009, were primarily in money market accounts, short-term corporate bonds, certificate of deposits, 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 and without penalty, 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, 2010 or December 31, 2009, any decline in the fair value of our investments would not be material in the context of our consolidated 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.

**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***

Our principal executive officer and principal financial officer have provided certifications filed as Exhibits 31.1 and 32.1, and 31.2 and 32.2, respectively. Such certifications should be read in conjunction with the information contained in this Item 9A for a more complete understanding of the matters covered by such certifications.

**(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 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 Acting Chief Financial Officer (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

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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 Acting Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2010, the end of the period covered by this report (the Evaluation Date ). Based on the foregoing, our Chief Executive Officer and Acting Chief Financial Officer concluded that our disclosure controls and procedures, as of the end of the period covered by this report, were effective in timely alerting them to material information relating to the Company required to be included in our periodic SEC filings.

**(ii) Internal Control Over Financial Reporting**

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

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

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

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

Our independent registered public accounting firm, Ernst & Young LLP, has issued a report on our internal control over financial reporting. Ernst & Young LLP's report appears below under Item 9A(ii)(b) and expresses an unqualified opinion on the effectiveness of our internal control over financial reporting.

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

During the quarter ended December 31, 2010, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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**Report of Ernst & Young LLP, Independent Registered Public Accounting Firm**

The Board of Directors and  
Stockholders of Spectrum Pharmaceuticals, Inc.

We have audited Spectrum Pharmaceuticals, Inc. and Subsidiaries' internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Spectrum Pharmaceuticals, Inc. and Subsidiaries' management is responsible 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 the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

In our opinion, Spectrum Pharmaceuticals, Inc. and Subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2010 based on the COSO criteria.

We also have audited in accordance with standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Spectrum Pharmaceuticals Inc. and Subsidiaries as of December 31, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2010 of Spectrum Pharmaceuticals, Inc. and Subsidiaries and our report dated March 9, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Irvine, California



March 9, 2011

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**Item 9B. *Other Information***

None.

**PART III**

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

**Directors**

Our board of directors consists of six directors, each of whom serves for a one-year term expiring at the following annual meeting and until his successor has been duly elected and qualified. The names of our directors and certain biographical information about them are set forth below:

***Krishan K. Arora, Ph.D.***

Dr. Arora, 70, has been a director of Spectrum since June 2010. Prior to his election, Dr. Arora had been providing consulting services to Spectrum since February 2010. Dr. Arora is a business executive with global experience in driving strategic thinking, management and implementation of operations for drug development worldwide. Dr. Arora has provided consulting services to senior management at several pharmaceutical companies, including Astellas Pharma Global Development, Inc., for global drug development, from May 2008 to June 2009, and UCB, Inc., for applications in global regulatory affairs, electronic document management, pharmacovigilance and worldwide quality assurance and compliance, from November 2003 to February 2006. Prior to that, Dr. Arora held senior management positions with several pharmaceutical companies, including Vice President of R&D Global Regulatory Affairs for Management Information at Pfizer Inc. from 1998 to 2003, Senior Director of Regulatory Affairs at Novartis AG from 1993 to 1998 and Group Director of Biometrics Operations at Sanofi-Aventis. In addition, from 1994 to 2003, Dr. Arora served as Chairman of the Electronic Regulatory Submissions Working Group at PhRMA, which consisted of business and information technology experts from the FDA and 20 biopharmaceutical companies and was the PhRMA lead at ICH on establishing electronic standards for submission of marketing applications to regulatory authorities. Dr. Arora received a B.Sc. in Mathematics, Physics and Chemistry from Lucknow University in India, a B.Sc. (Honors) in Agriculture and a M.Sc. in Animal Genetics from G. B. Pant University of Agriculture & Technology in India and a Ph.D. in Population Genetics from Iowa State University. Dr. Arora has significant experience in the pharmaceutical industry, which includes 11 years' experience in global regulatory affairs and 18 years' experience in biometrics operations, including statistics, clinical data systems, clinical data management and medical writing. Furthermore, Dr. Arora has operational management experience, a keen understanding of the regulatory environment in which pharmaceutical companies operate and extensive knowledge in drug development operations and regulatory submissions and approvals. As a result, Dr. Arora is well qualified to serve on our board of directors.



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***Stuart M. Krassner,  
Sc.D., Psy.D***

Dr. Krassner, 75, has been a director of Spectrum since December 2004 and was previously a member of our Scientific Advisory Board from 1996 to 2001. Dr. Krassner's career spans four decades of experience in various positions at the University of California, Irvine, or UCI, most recently as Professor Emeritus of Developmental and Cell Biology at the School of Biological Sciences. While at UCI, he developed and reinforced FDA and NIH compliance procedures for UCI-sponsored human clinical trials, established UCI's first Institutional Review Board, and at one time headed all contract and grant activities. Dr. Krassner has also been retained by a number of public and private pharmaceutical, medical device and other companies to provide scientific and regulatory advisory services, including FDA compliance. Dr. Krassner's work has been published in numerous peer-reviewed U.S. journals. Dr. Krassner has been awarded grants from the National Institute of Health, the National Science Foundation and the World Health Organization. Dr. Krassner has been a member of the American Society of Protozoology, the American Society of Tropical Medicine and Hygiene, the Corporation of the Marine Biological Laboratories, Woods Hole, MA, and Sigma Xi, among others. Dr. Krassner received a B.S. in Biology from Brooklyn College and an Sc.D. from the Bloomberg School of Public Health at Johns Hopkins University.

Dr. Krassner's extensive and distinctive experience in business and academia brings valuable perspective to our board. He has a strong background in research in the area of developmental and cell biology and his work in the area has been published in numerous peer-reviewed U.S. journals. Moreover, his expertise in scientific and regulatory advisory services, including FDA compliance, makes him well qualified to serve on our board of directors.

***Luigi Lenaz, M.D.***

Dr. Lenaz, 70, has been a director of Spectrum since June 2010. Dr. Lenaz served as Spectrum's Chief Scientific Officer from February 2005 to June 2008 and as President of Spectrum's Oncology Division from 2000 to 2005. Since retiring as Spectrum's Chief Scientific Officer in June 2008, Dr. Lenaz provided consulting services to Spectrum from June 2008 to June 2010. From 1997 to 2000, Dr. Lenaz served as Senior Vice President of Clinical Research, Medical Affairs at SuperGen, Inc., a NASDAQ listed pharmaceutical company dedicated to cancer drug development. From 1978 to 1997, Dr. Lenaz held several senior management positions with Bristol-Myers Squibb, a NYSE-listed pharmaceutical company, including Senior Vice President of Oncology Franchise Management from 1990 to 1997 and Director of Scientific Affairs, Anti-Cancer from 1985 to 1990. Dr. Lenaz is also a prominent researcher, having conducted research in the areas of pharmacology, experimental chemotherapy, histology, general physiology, and experimental therapeutics at various institutions for cancer research, including Roswell Park Memorial Institute, Memorial Sloan-Kettering Cancer Center and the National Cancer Institute in Milan. He is a member of several scientific societies, including the American Association for Cancer Research, American Association for Clinical Oncology, European Society for Medical Oncology, and International Association for the Study of Lung Cancer. Dr. Lenaz has served as a director of Pharmaco-Kinesis Corporation, a privately held medical

device company, since January 2009. Dr. Lenaz is a graduate of Liceo Scientifico A. Righi in Bologna, Italy and he received a medical degree from the University of Bologna Medical School in 1966.

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Dr. Lenaz is a renowned and accomplished oncologist who will bring to the board of directors over 35 years' experience in the pharmaceutical industry and a wealth of knowledge in the field of cancer drug development. Dr. Lenaz's qualifications to serve on the board of directors include his expertise in the development of cancer drugs, his tenure as our Chief Scientific Officer, as well as his subsequent consulting services for our company, his significant management experience with Bristol-Myers Squibb, and his prominent research in the field of oncology. As a result, Dr. Lenaz is well qualified to serve on our board of directors.

***Anthony E. Maida, III,  
M.A., M.B.A., Ph.D.***

Dr. Maida, 59, has been a director of Spectrum since December 2003. Dr. Maida is currently Vice President of Clinical Research and General Manager, Oncology, world-wide for PharmaNet, Inc. Dr. Maida has been the acting Chairman of Dendri Therapeutics, Inc., a startup company focused on the clinical development of therapeutic vaccines for patients with cancer, since 2003. Dr. Maida has been serving as Chairman, Founder and Director of BioConsul Drug Development Corporation and Principal of Anthony Maida Consulting International since 1999, providing consulting services to large and small biopharmaceutical firms in the clinical development of oncology products and product acquisitions and to venture capital firms evaluating life science investment opportunities. Additionally, Dr. Maida formerly served as a member of the board of directors of Sirion Therapeutics, Inc., a privately held ophthalmic-focused company, and GlycoMetrix, Inc., a startup company focused on the development of tests to identify carbohydrates that can indicate cancer. Dr. Maida served as the President and Chief Executive Officer of Replicon NeuroTherapeutics, Inc., a biopharmaceutical company focused on the therapy of patients with tumors (both primary and metastatic) of the central nervous system, where he successfully raised financing from both venture capital and strategic investors and was responsible for all financial and operational aspects of the company, from June 2001 to July 2003. From 1999 to 2001, Dr. Maida held positions as Interim Chief Executive Officer for Trellis Bioscience, Inc., a privately held biotechnology company that addresses high clinical stage failure rates in pharmaceutical development, and President of CancerVax Corporation, a biotechnology company dedicated to the treatment of cancer. From 1992 until 1999, Dr. Maida served as President and CEO of Jenner Biotherapies, Inc., a biopharmaceutical company. From 1980 to 1992, Dr. Maida held senior management positions with various companies including Vice President Finance and Chief Financial Officer of Data Plan, Inc., a wholly owned subsidiary of Lockheed Corporation. Dr. Maida serves on the Advisory Boards of EndPoint BioCapital and Sdn Bhd (Kuala Lumpur, Malaysia) and serves or has served as a consultant and technical analyst for several investment firms, including CMX Capital, LLC, Sagamore Bioventures, Roaring Fork Capital, North Sound Capital, The Bonnie J. Addario Lung Cancer Foundation and Pediatric BioScience, Inc. Additionally, Dr. Maida has been retained by Abraxis BioScience, Inc., Northwest Biotherapeutics, Inc., Takeda Chemical Industries, Ltd. (Osaka, Japan), and Toucan Capital to conduct corporate and technical due diligence on investment opportunities. Dr. Maida is a speaker at industry conferences and is a member

of the American Society of Clinical Oncology, the American Association for Cancer Research, the Society of Neuro-Oncology, the International Society for Biological Therapy of Cancer, the American Association of Immunologists and the American Chemical Society. Dr. Maida received a B.A. in History from Santa Clara University in 1975, a B.A. in Biology from San Jose State University in 1977, an M.B.A. from Santa Clara University in 1978, an M.A. in Toxicology from San Jose State University in 1986 and a Ph.D. in Immunology from the University of California in 2010.

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Dr. Maida's qualifications to serve on the board of directors include the extensive experience he has gained holding senior management positions, including chairman, president, chief financial officer and chief executive officer, at various biotechnology and biopharmaceutical companies. He has successfully raised financing from venture capital and strategic investors for biopharmaceutical companies and he currently provides consulting services to hedge funds, venture capital firms interested in biopharmaceutical firms. Furthermore, Dr. Maida's vast knowledge in the area of clinical development of oncology products and product acquisitions, in addition to his continuous research in the field of oncology, provides unique and valuable insight to our board of directors. As a result, Dr. Maida is well qualified to serve on our board of directors.

***Dilip J. Mehta, M.D., Ph.D.***

Dr. Mehta, 78, has been a director of Spectrum since June 2010. Dr. Mehta served on Spectrum's board of directors from June 2003 to July 2007. Dr. Mehta has been self-employed as a pharmaceutical consultant since 1998 and provided consulting services to Spectrum from July 2007 to June 2010. Dr. Mehta is a venture partner at Radius Ventures, LLC in New York. From 1982 until his retirement in 1997, Dr. Mehta held several senior management positions with Pfizer Inc., including Senior Vice President, U.S. Clinical Research, with responsibility for clinical research (Phases 1, 2 and 3) including data processing and statistical analysis for Pfizer's drugs in the U.S., as well as supervised submissions of new drug applications for Cardura, Norvasc, Zolof, Zithromax, Diflucan, Unasyn, Trovan, Viagra, Geodon, and a number of other drugs/supplements. Dr. Mehta served as Chairman of the board of directors of Quintiles Spectral (India) Limited (Ahmedabad, India) from 1998 to 2001 and as a member of the board of directors of Bharat Serums & Vaccines Limited (Mumbai, India) from 2006 to 2008 and Targanta Therapeutics Corporation, a NASDAQ-listed biopharmaceutical company acquired by The Medicines Company in February 2009, from 2005 to 2009. From 1993 to 1997, Dr. Mehta served as Chair, Efficacy Section for the Pharmaceutical Research and Manufacturers of America, or PhRMA, in the International Conference on Harmonization and was a PhRMA topic leader for one of the Expert Working Group in Efficacy. From 1966 to 1982, Dr. Mehta held the position of Group Director, Clinical Research in the U.S. for Hoechst AG with supervision of Internal Medicine, Metabolic and Infectious Diseases and Cardiovascular groups. Dr. Mehta received an M.D., an M.B.B.S. (Bachelor of Medicine and Bachelor of Surgery equivalent to an M.D. degree in the U.S.) and a Ph.D. from the University of Bombay. Dr. Mehta was a Research Fellow in Clinical Pharmacology at Cornell University Medical College. Dr. Mehta brings to the board of directors over 28 years' experience in the pharmaceutical industry and a wealth of knowledge in the field of clinical research and drug development. Dr. Mehta's qualifications to serve on the board of directors include his expertise in clinical research, drug development and FDA matters, his prior service on Spectrum's board of directors, as well as his service on the boards of directors of other publicly traded and privately held biopharmaceutical companies and his significant management experience with Pfizer. As a result, Dr. Mehta is well qualified to serve on our board of



directors.

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**Table of Contents*****Rajesh C. Shrotriya, M.D.***

Dr. Shrotriya, 66, has been Chairman of the Board, Chief Executive Officer and President since August 2002 and a director of Spectrum since June 2001. From September 2000 to August 2002, Dr. Shrotriya served as President and Chief Operating Officer of Spectrum. Dr. Shrotriya also serves as a member of the board of directors of Antares Pharma, Inc., an AMEX-listed drug delivery systems company. Prior to joining Spectrum, Dr. Shrotriya held the position of Executive Vice President and Chief Scientific Officer from November 1996 until August 2000, and as Senior Vice President and Special Assistant to the President from November 1996 until May 1997, for SuperGen, Inc., a publicly-held pharmaceutical company focused on drugs for life-threatening diseases, particularly cancer. From August 1994 to October 1996, Dr. Shrotriya held the positions of Vice President, Medical Affairs and Vice President, Chief Medical Officer of MGI Pharma, Inc., an oncology-focused biopharmaceutical company. Dr. Shrotriya spent 18 years at Bristol-Myers Squibb Company in a variety of positions, most recently as Executive Director, Worldwide CNS Clinical Research. Previously, Dr. Shrotriya held various positions at Hoechst Pharmaceuticals, most recently as Medical Advisor. Dr. Shrotriya was an attending physician and held a courtesy appointment at St. Joseph Hospital in Stamford, Connecticut. In addition, he received a certificate for Advanced Biomedical Research Management from Harvard University. Dr. Shrotriya received an M.D. from Grant Medical College, Bombay, India, in 1974; a D.T.C.D. (Post Graduate Diploma in Chest Diseases) from Delhi University, V.P. Chest Institute, Delhi, India, in 1971; an M.B.B.S. (Bachelor of Medicine and Bachelor of Surgery – equivalent to an M.D. degree in the U.S.) from the Armed Forces Medical College, Poona, India, in 1967; and a B.S. in Chemistry from Agra University, Aligarh, India, in 1962.

Dr. Shrotriya is a demonstrated leader in the biopharmaceutical industry. His significant leadership experience includes 8 years of serving as our Chairman and Chief Executive Officer as well as his service on the board of directors of Antares Pharma, Inc. Dr. Shrotriya has held prior leadership roles in the biopharmaceutical industry including his positions as our President and Chief Operating Officer, as the executive vice president and chief scientific officer for a publicly-held pharmaceutical company, and 18 years of experience in various positions he held in Bristol-Myers Squibb. Dr. Shrotriya's significant leadership experience in the biopharmaceutical sector, along with his experience as a physician and his expertise in drug development, position him well to serve on our board of directors.

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**Executive Officers**

Each of our executive officers serves at the discretion of the board of directors. The names of our executive officers and certain biographical information about them are set forth below:

**Name and Age**

<p><i>Rajesh C. Shrotriya, M.D. (66)</i> Chairman of the Board, Chief Executive Officer and President</p>	<p>Information regarding Dr. Shrotriya is provided above.</p>
<p><i>George Tidmarsh, M.D, Ph.D. (51)</i> Senior Vice President, Chief Scientific Officer &amp; Head of Research &amp; Development Operations</p>	<p>Dr. Tidmarsh has served as Senior Vice President, Chief Scientific Officer and Head of Research &amp; Development at Spectrum since July 2010. Before joining Spectrum, Dr. Tidmarsh served as the Chief Executive Officer of Metronome Therapeutics, a privately held biopharmaceutical company focused on novel cancer drug development from 2006 until 2010. From 2005 through 2008, he was the Founder and Chief Executive Officer of Horizon Therapeutics, Inc., a venture funded private company, where he successfully completed four Phase 1 and two large Phase 3 trials, and authored all patent applications. Dr. Tidmarsh also has published over twenty articles. He earned his Bachelor of Science, M.D., and Ph.D. from Stanford University and is currently an Associate Professor of Pediatrics and Neonatology at Stanford University.</p>
<p><i>James E. Shields (59)</i> Senior Vice President, Chief Commercial Officer</p>	<p>Mr. Shields has served as Senior Vice president, Chief Commercial Officer since May 2010. Previously Mr. Shields served as Area Business Director for a Division of TEVA Pharmaceutical Industries Limited from September 2007 through April 2010 and Regional Business Director and National Director of Sales for Commercial Divisions of Altana AG from March 2001 until the US Commercial Division was dissolved in December 2006. Mr. Shields also held positions of increasing responsibility with several pharmaceutical companies, including Centocor, Bristol-Myers Squibb, and ICI Stuart Pharmaceuticals. Mr. Shields earned his Bachelor's Degree from the University of Kentucky.</p>
<p><i>Shyam Kumaria (61)</i> Senior Vice President of Finance</p>	<p>Mr. Kumaria has served as Vice President of Finance since December 2003. From 1996 to 2003, he provided financial and management consulting services to private companies. From 1984 to 1996, he served in senior executive and management positions for several companies including Deloitte &amp; Touche. Mr. Kumaria became a Chartered Accountant in London, England in 1973 and a Certified Public Accountant in 1978. He received an Executive M.B.A. from Columbia University in 1984.</p>
<p><i>Brett L. Scott (60)</i> Senior Vice President and Acting Chief Financial Officer</p>	<p>Mr. Scott has served as Senior Vice President and Acting Chief Financial Officer since October 2010. Previously Mr. Scott served as Chief Financial Officer at Biolase Technology a Southern California-based medical device company. Prior to Biolase, Mr. Scott was Executive Vice President and Chief Financial Officer of North American Scientific, Inc., a Southern California-based medical device company. In March 2009, North American Scientific sought protection under Chapter 11 of the U.S. Bankruptcy Code, and as part of an orderly plan to sell its assets, during the following two months successfully completed the sale of its prostate and breast cancer businesses to Best Theratronics, Ltd. and Portola Medical Inc. respectively.</p>

Prior to North American Scientific, Mr. Scott was Chief Financial Officer of Irvine, California-based Alsius Corporation from January 2006 to August 2008. Mr. Scott is a Certified Public Accountant and received a bachelor of science degree in business administration from the University of Southern California.

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There are no family relationships between any director or executive officer and any other director or executive officer.

### **Section 16(A) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Exchange Act requires our executive officers and directors, and persons who beneficially own more than ten percent of our common stock, to file initial reports of ownership and reports of changes in ownership with the SEC and NASDAQ. Executive officers, directors and persons who beneficially own more than ten percent of our common stock are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file.

Based solely upon our review of the copies of reporting forms furnished to us, and written representations that no other reports were required, we believe that all filing requirements under Section 16(a) of the Exchange Act applicable to our directors, officers and any persons holding 10% or more of our common stock with respect to our fiscal year ended December 31, 2010 were satisfied on a timely basis with the exception of Mr. George Tidmarsh, our Chief Scientific Officer, who filed a Form 5 on February 14, 2011 to report an earlier acquisition of shares of the Company's common stock in connection with an asset purchase transaction that closed in July 2010.

### **Code of Business Conduct and Ethics**

We have adopted a Code of Business Conduct and Ethics that applies to all of our directors, officers and employees, including the principal executive officer, principal financial officer, principal accounting officer, controller or persons performing similar functions. A copy of the Code of Business Conduct and Ethics will be provided to any person, without charge, upon oral request to (949) 788-6700 or upon written request to Investor Relations, Spectrum Pharmaceuticals, Inc., 157 Technology Drive, Irvine, CA 92618. Amendments to the Code of Business Conduct and Ethics that apply to our principal executive officer, principal financial officer, principal accounting officer, controller or persons performing similar functions, if any, will be posted on our website at [www.sppirx.com](http://www.sppirx.com). We will disclose any waivers of provisions of our Code of Business Conduct and Ethics that apply to our directors and principal executive, financial and accounting officers by disclosing such information on Form 8-K.

### **Audit Committee**

We have a standing Audit Committee that is currently comprised of Drs. Maida (Chair), Arora and Krassner, each of whom satisfies the NASDAQ and SEC rules for Audit Committee membership. Our board of directors has determined that Drs. Maida, Arora and Krassner are each Audit Committee financial experts within the meaning of SEC rules and that all three are independent within the meaning of the NASDAQ director independence standards and SEC Rule 10A-3.

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

### **Compensation Discussion and Analysis**

#### ***Executive summary***

In 2010, the company established aggressive plans for future growth, including strategic business milestones maximizing the growth potential of our marketed drugs, Zevalin® and Fusilev®, managing multiple large, late-stage clinical trials for apaziquone and belinostat, as well as developing a pipeline of anti-cancer drugs. In addition, we targeted to grow our Zevalin revenues by 25% to approximately \$20 million and continue to create shareholder value.

Our results in 2010 reflect achievement of certain key strategic and financial objectives:

Record product revenues of both of our marketed, proprietary anticancer drugs ZEVALIN® and FUSILEV®

Overall revenue for the company grew by almost 95% to \$74 million from \$38 million in 2009

Closing the year with \$104 million in cash, cash equivalents and investments during difficult economic times and market conditions,

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Strengthening the leadership and streamlining operations at each of the Company's functions,

Growing the Company's market capitalization by approximately 40% to levels which greatly exceeded the Board's expectations and peer company performance.

As a result, the Company is transforming from a small drug development company to a biotechnology company with fully integrated commercial and drug development operations.

These accomplishments are testaments to our Chairman and Chief Executive Officer, Dr. Rajesh Shrotriya's consistently demonstrated clear vision and leadership in directing the affairs of the Company through the past eight years. In alignment with the its compensation philosophy, the Compensation Committee determined that Dr. Shrotriya's reward for this performance would be in the form of an increased equity incentive opportunity, the details of which are provided within the Compensation Discussion and Analysis, or CD&A, and the accompanying compensation table disclosures.

In addition, our transformation necessitated that we add three newly appointed executive officers to our leadership team in 2010 to lead our sales, research & development, and finance functions in the future. The specific compensation programs that we established for each of these executive officers are provided within the CD&A and accompanying compensation table disclosures.

***Compensation Philosophy and Objectives***

The Compensation Committee's executive compensation philosophy is to attract and retain professionals of the highest caliber, capable of leading us to fulfillment of our ambitious business objectives, by offering competitive compensation opportunities that reward executives for their individual contributions towards both our long-term and short-term goals. Competition for attracting the best talent in the pharmaceutical industry is very intense, and such competition is national in scope. Accordingly, in light of the intense competition for highly qualified executives, our executive officers are eligible for competitive salary adjustments, cash bonuses and equity compensation based upon periodic evaluations of individual and company performance, relative to goals established at the start of the year.

The Compensation Committee believes that three principal compensation elements—base salary, annual bonus, and equity incentive awards—in combination effectively support the company's overall compensation objectives of attracting top talent for executive positions, incentivizing such executive officers, rewarding them for achievement of individual and company goals, and aligning the interests of executive officers with those of our stockholders. The Compensation Committee has not established specific competitive market levels to target for each element, but has strived to position the total compensation delivered by the three elements as follows:

Chairman & CEO; between the 75th and 90th percentile of the peer group and industry in general

Other Named Executive Officers: between the median and 75th percentile of the peer group and industry in general

The different positioning strategies reflect the contributions made since 2002 by our current Chairman and CEO, as well as his significant impact on our current and future business success. In contrast, three of the four other named executive officers were hired into their current roles in 2010. Finally, executive officer total compensation is delivered primarily through the annual bonus and equity incentive awards, hence actual achievement of our desired compensation positioning vs. market is largely dependent upon pay-for-performance.

The Compensation Committee believes that its compensation philosophy aligns the interests of our executive officers with those of our stockholders, and is necessary to incentivize individual executives to peak performance in advancing our short-term and long-term business objectives. It is designed to reward hard work, dedication and the achievement of both individual and company goals.

**Named Executive Officers**

For 2010, our named executive officers were as follows:

<b>Executive Name</b>	<b>Title</b>
Rajesh Shrotriya	Chairman and Chief Executive Officer



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<b>Executive Name</b>	<b>Title</b>
George Tidmarsh	Chief Scientific Officer
Jim Shields	Chief Commercial Officer
Brett Scott	Acting Chief Financial Officer
Shyam Kumaria	Senior Vice President, Finance

**Determining Competitive Practices*****Peer Group for Compensation Benchmarking***

In 2010, as part of our business transformation, we worked with Grant Thornton LLP to develop a revised peer group consisting of 22 companies used for evaluating competitive total compensation levels. This peer group represents a mix of companies in which we would likely compete for business and talent, with revenues and market capitalization similar to that of Spectrum. Specifically, for 2009 (the most recent year in which compensation benchmarking data is available) the peer group companies had median revenue of approximately \$63 million and a market capitalization of \$564 million compared to Spectrum's revenue of \$74 million and market capitalization of approximately \$354 million as of December 31, 2010. We used this peer group specifically to review the level of base salaries, mix and size of annual and long-term incentives, and other benefits and perquisites provided to executives of similar-sized companies.

The compensation peer group included the following companies:

Affymax Inc	Immunomedics Inc
Allos Therapeutics Inc	Intermune Inc
Amicus Therapeutics Inc	Isis Pharmaceuticals Inc
Arena Pharmaceuticals Inc	Mannkind Corp
Biocryst Pharmaceuticals Inc	Medivation Inc
Biomarin Pharmaceutical Inc	Onyx Pharmaceuticals Inc
Cell Therapeutics Inc	Sangamo Biosciences Inc
Cytokinetics Inc	Seattle Genetics Inc
Dendreon Corp	Supergen Inc
Enzon Pharmaceuticals Inc	Theravance Inc
Exelixis Inc	Vertex Pharmaceuticals Inc

***Other Competitive Benchmarks***

To supplement compensation data gathered from our peer group companies, compensation for our named executive officers is also compared to published survey data from the Radford Life Sciences Survey. This survey includes data from various companies within the same industry and of similar size to Spectrum.

***Key Elements of Executive Compensation***

The principal elements of compensation for our executive officers are:

Base salary;

Annual bonuses; and

Equity incentive awards.

Base Salary. The base salaries of our executive officers are established as part of an annual compensation adjustment cycle. Base salaries for the year are established either at the end of the prior year or the beginning of the current year, i.e. the base salary for 2010 was set at the end of 2009. In establishing those salaries, the Compensation Committee considers the executive's level of responsibility, experience and individual performance, impact on company results, and company performance, as well as information regarding salary levels paid to executives with comparable duties in companies at a similar stage as ours.

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***Annual Bonuses.*** The Compensation Committee typically awards cash bonuses to executives as part of their annual overall compensation at the beginning of the next year for prior year performance, i.e. the cash bonus for 2010 performance was set in early 2011. Such cash bonuses are a reward for company results, individual achievement of goals, as well as achievement of key milestones. We have not established formal bonus target levels for our executive officers; however, the actual bonus awarded is determined based upon the Committee's evaluation of each executive's performance along with a review of bonus opportunities and actual bonuses paid to executives with similar duties and impact on results working in comparable companies.

***Equity Incentive Awards.*** Cash compensation is viewed as a reward for annual performance vs. goals, Equity incentive awards are important long-term compensation tools for employee retention as well as incentivizing future performance. In addition, equity incentive awards are an important compensation tool to utilize in attracting and retaining high caliber executive talent. The Compensation Committee believes that granting equity incentive awards, including stock options and restricted stock, to our executive officers is very beneficial to stockholders because it aligns management's interests in the enhancement of stockholder value. An executive officer receives value from these grants only if he or she remains employed by us during the vesting period, and, with regard to stock options, only if our common stock appreciates from the fair market value of our common stock on the date of the grant. In determining the number of shares subject to an equity incentive award, the Compensation Committee takes into account the executive officer's position and level of responsibility, the executive officer's past performance and potential future contribution, the executive officer's existing stock and unvested restricted stock holdings, the competitiveness of the executive officer's total compensation, including equity awards, and with reference to equity award levels of executives with comparable duties in comparable companies.

Typically, the Compensation Committee grants a lesser grant value of restricted stock than stock options because when restricted stock vests, it provides immediate value to the recipient, with less risk than stock options. In deciding whether to grant stock options or restricted stock, the Compensation Committee will review market factors such as our stock price, the different benefits offered by each type of award, past equity grants and the desired balance between performance and retention. Typically, the Compensation Committee grants equity incentive awards once annually; however, it may make additional grants based upon a number of factors, including company results and individual achievements.

## ***Benefits and Perquisites***

The named executive officers are eligible for benefits that are generally available to all Spectrum employees and are subject to favorable tax treatment by the IRS under the current tax code. Such benefits include health insurance, life insurance, vacation, and 401(k) retirement savings. Named executive officers and employees are required to contribute to offset a portion of the cost of certain plans.

We maintain a 401(k) Plan and an Employee Stock Purchase Plan, each available to all employees, to encourage employees to save for retirement and to provide incentives for our employees to exert maximum effort for our success. The 401(k) Plan provides matching employee contributions in shares of our common stock and the Employee Stock Purchase Plan provides employees with the opportunity to purchase common stock through accumulated payroll deductions, each in order to, among other things, align employees' interests with our stockholders.

## ***Fiscal 2010 Compensation***

The company's achievement of the strategic, financial and share value objectives in 2010 shaped the Compensation Committee's decisions with respect to 2010 base salary changes, annual bonuses and equity incentive awards.

## ***Base Salaries***

We provide base salaries to compensate executives for the services rendered during the fiscal year. In setting base salaries for the CEO and other named executive officers, the Compensation Committee considers various factors including competitive market data, the experience, skills and impact of the individual, the compensation of

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the individual relative to other members of the executive team; and performance of the executive and the company in the prior year.

Based on these factors, the Compensation Committee determined that the base salaries for selected named executive officers in 2009 and 2010 were as follows:

<b>Executive</b>	<b>2009</b>	<b>2010</b>
Rajesh Shrotriya	\$ 600,000	\$ 650,000
George Tidmarsh		\$ 400,000
Jim Shields		\$ 240,000
Brett Scott		\$ 225,000
Shyam Kumaria	\$ 275,000	\$ 290,000

*Annual Bonus*

The Board of Directors set stretch goals for the Company at the start of 2010, which constitute the performance objectives for the Chief Executive Officer and the Company's other executive officers. In January 2011, the Compensation Committee determined that the Company's executive officers met or exceeded each of the above-listed business objectives, as follows:

**Goals For 2010****Results For 2010****Marketed Products**

**ZEVALIN:** Grow sales 25% over 2009 sales of \$15.7M; Submit data to FDA for bioscan removal; Arrange alternate back-up supplier for Yttrium; Reduce cost of goods; Secure reimbursement in HOPPs and community setting.

**FUSILEV:** Maximize FUSILEV sales, with a goal of \$4 million for 2010; while advancing an sNDA for its use in the treatment of colorectal cancer.

All of the Zevalin goals have been accomplished, including Sales of \$29 million representing an 84% increase, compared to a target growth of 25%, for a drug that had experienced a declining sales trend prior to our acquisition of rights to the drug in 2009. Zevalin cost of goods was reduced significantly in 2010.

All of the Fusilev goals have been accomplished: Sales of \$32 million represent an increase of over 150% compared 2009 sales; and the FDA has established a PDUFA date of April 29, 2011 for a decision on our sNDA for colorectal cancer. Achieved profitability in the fourth quarter of 2010 Fourth quarter 2010 product revenues in excess of \$30 million, up 500% as compared to approximately \$5 million in the fourth quarter of 2009 Fiscal year 2010 product revenues in excess of \$60 million, up 114% as compared to approximately \$28 million in fiscal year 2009.

**Development pipeline**

Acquire a late stage (in Phase II or III/pivotal trial) or marketed drug

We in-licensed rights to belinostat, a HDAC inhibitor from TopoTarget Inc. and have

Continue active monitoring of apaziquone clinical trials

Active management of alliances with drug development partners

accelerated the clinical trial timeline in a difficult to enroll study, with the objective of filing an NDA in 2011, or early 2012.

The apaziquone clinical trials are on track for NDA submission in 2012.

We have continued to maintain excellent relations with our alliance partners.

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**Goals For 2010**

**Results For 2010**

**Financial Resources**

Maintain tight control over the Company's expenses.

Continue to manage expenses and capital such that we close 2010 with at least \$50M in the bank (if we do acquire an asset for about \$30 million cash)

**Human Resources**

Enhance leadership capabilities of personnel.

Hire appropriate personnel to support ZEVALIN sales growth; and personnel to support development of belinostat and other pipeline drugs.

**Investor Relations**

Continue to present at strategic healthcare and partnership conferences.

Continue to build a base of strategic investors while maintaining relationships with NASDAQ and current investors.

We continued to exercise tight control over cash used in operations. In spite of the approximately \$30 million paid for the licensing of belinostat, we closed the year with \$104 million cash, cash equivalents and investments, compared to \$125 million at the start of the year; a net decrease of \$21 million.

During the fourth quarter cash, cash equivalents and investments increased from \$92 million as of September 30, 2010 to approximately \$104 million as of December 31, 2010, reflecting a net increase of approximately \$12 million.

Maintained the companywide training and employee development to enhance corporate communication and teamwork; and also one-on-one training for key individuals in leadership roles to enable desired levels of performance to advance corporate objectives

During 2010 we reviewed our staffing and strengthened the leadership in all functions Commercial, Development, Legal and compliance, Finance and Business Development; at the same time reduced headcount by approximately 20 personnel compared to the start of the year.

The Company presented at several strategic healthcare and partnership conferences and continued to build on its investor base.

During 2010, the Company experienced an increase in its market capitalization of approximately 40%.

Based upon results versus established goals, for fiscal 2010, the Compensation Committee determined that the individual performance of Dr. Shrotriya, the Company's Chairman, President and Chief Executive Officer, exceeded expectations.

In making its determination regarding Dr. Shrotriya's total compensation in 2010, the Compensation Committee took into account the fact that Dr. Shrotriya had the principal authority and executive decision-making ability required to execute, or to oversee the execution of, the Company's goals and objectives and to lead the Company's transformation from a small drug development company to its current status as a biotechnology company with fully integrated commercial and drug development operations by, among other things, building the Company's research and development, sales and marketing and managerial infrastructure, attracting and retaining key management talent. In addition, the Compensation Committee acknowledged Dr. Shrotriya's success in continuing to build a base of strategic

investors, who have expressed interest and desire to invest additional capital to spur the Company's future growth. For these accomplishments, the Compensation Committee reasoned, and the Board of Directors endorsed, that the level of Dr. Shrotriya's achievements was far in excess of the achievements of principal executive officers of peer companies and thus merited a superior bonus commensurate with preceding years. Accordingly, the Committee awarded Dr. Shrotriya a cash bonus of \$950,000.



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In making decisions related to the annual bonus for the other named executive officers, the Compensation Committee, based primarily on Dr. Shrotriya's recommendations, concluded as follows:

**Shyam Kumaria** Mr. Kumaria's 2010 goals were aligned with Spectrum's overall objectives, with an emphasis on supporting attainment of the financial objectives. Based upon results achieved, Dr. Shrotriya determined that Mr. Kumaria's individual performance exceeded expectations as follows: financial management and reporting achievements, with a focus on cost containment; completing value-added corporate projects such as successfully obtaining approximately \$1 million in Government grant funds, gross margin improvements on Zevalin, and optimizing tax planning. Based on Dr. Shrotriya's recommendations, the Compensation Committee determined that Mr. Kumaria's contributions to the achievement of the Company's goals merited a cash bonus of \$100,000 based on 2010 performance.

**George Tidmarsh** Mr. Tidmarsh joined us in July 2010 and, in the short period that he has been with the Company, has made contributions to achievement of Spectrum's strategic milestones. The Compensation Committee determined that Mr. Tidmarsh's contributions to the achievement of the Company's goals merited a cash bonus of \$50,000 based on 2010 performance.

**Jim Shields** Mr. Shields joined us in May 2010. As Chief Commercial officer, he participates in Spectrum's established sales incentive plan; and earned a commission of \$51,975 from such participation. In addition, the Compensation Committee determined that Mr. Shields's contributions to the achievement of the Company's goals merited a cash bonus of \$35,000 based on 2010 performance.

**Brett Scott** Mr. Scott joined us in October 2010. In view of the limited service period in 2010, the Compensation Committee determined that Mr. Scott would not receive a cash bonus for 2010.

***Equity Incentive Opportunities***

Spectrum reviews the mix of the equity-based awards, which primarily consist of stock options and restricted stock awards, each year to ensure that the optimal balance on performance and retention is met for each executive officer. The Compensation Committee considers the performance of Spectrum and each executive in determining the appropriate level of equity incentive opportunity granted to each executive officer in 2010, which is summarized in the Grants of Plan-based Awards table on page 87.

In addition, based on the factors previously discussed, the Compensation Committee approved stock option and restricted awards to each named executive officer on January 3, 2011 as follows:

Executive	Stock Options		Restricted Stock	
	# Granted	Exercise price	# Granted	Fair Market Value
Rajesh Shrotriya	1,000,000	\$ 6.87	250,000	\$ 6.87
George Tidmarsh	50,000	\$ 6.87	20,000	\$ 6.87
Jim Shields	50,000	\$ 6.87	20,000	\$ 6.87
Brett Scott(1)				
Shyam Kumaria	50,000	\$ 6.87	20,000	\$ 6.87

(1) Mr. Scott was not awarded stock options or restricted Stock due to his limited tenure with the Company.

***Payments upon Termination of Employment or Change-in-Control***

Dr. Shrotriya has an employment agreement that provides for certain payments and benefits upon separation from the Company. The payments and benefits as provided within the agreement are designed to achieve the following objectives: protect earned benefits in the case that Dr. Shrotriya is terminated without cause or as may result from a change in control of Spectrum, and to act in the best interests of the stockholders at all times. The level of benefits provided under Dr. Shrotriya's agreement reflects the Compensation Committee's assessment of market conditions to provide a competitive level of compensation if he is impacted by a termination without cause or a change of control of Spectrum as well as a recognition of the results achieved by Dr. Shrotriya over his time of service to us.

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Dr. Shrotriya would receive certain severance benefits if he is terminated by Spectrum at the expiration of the term of the agreement (if not renewed), if his employment is terminated by us without cause, if his employment is terminated as a result of a change in control or his position is adversely affected due to a change in control and he resigns, or if he voluntarily terminates from Spectrum. The benefits are described in greater detail in this annual report under the heading Executive Employment Agreements, Termination of Employment and Change-in-Control Arrangements.

We currently do not provide any severance benefits to the other named executive officers, other than would be provided under general policies that apply to all of our other employees.

### ***Impact of Accounting and Tax Considerations on Compensation***

#### ***Stock based compensation***

The fair value of stock-based compensation, which includes equity incentives such as stock options and restricted stock, is measured in accordance with authoritative guidance. We measure compensation cost for all stock-based awards at fair value on the date of grant and recognize compensation expense over the service period over which the awards are expected to vest.

#### ***162(m)***

Section 162(m) of the Internal Revenue Code limits the Company's ability to deduct compensation paid in any given year to a named executive officer in excess of \$1.0 million. Performance-based compensation plans are not subject to this restriction. In the event the proposed compensation for any of the Company's named executive officers is expected to exceed the \$1.0 million limitation, the Compensation Committee will, in making a decision, balance the benefits of tax deductibility with its responsibility to hire, retain and motivate executive officers with competitive compensation programs. In light of our significant net operating losses, Section 162(m) is not considered a significant factor in executive officer compensation decisions at this time.

#### ***280G and 4999***

Sections 280G and 4999 of the Internal Revenue Codes relate to a 20% excise tax that may be levied on a payment made to an executive as a result of a change-in-control if the payment exceeds 2.99 times the executive's base earnings (as defined by the code section). Our agreement with Dr. Shrotriya provides that we will compensate him for any excise taxes as might arise upon a change-in-control of Spectrum. The decision to provide Dr. Shrotriya with this tax gross-up reflects the relatively low cash compensation Dr. Shrotriya received in prior years (which increases his potential 280G tax liability should a change in control occur), and to encourage Dr. Shrotriya to hold his stock options awarded in prior years for an extended period (which he has done). We do not currently provide similar tax protection to its other named executive officers, should a change-in-control occur.

### **Risk Assessment of Compensation Policies and Practices**

Our Compensation Committee has considered the concept of risk as it relates to the Company's compensation program, and based on such consideration, the Compensation Committee does not believe our compensation program encourages excessive or inappropriate risk-taking for the following reasons:

We structure our pay to consist of both fixed and variable compensation. The fixed (or salary) portion of compensation is designed, in part, to provide a steady income regardless of stock price performance so that executives do not feel pressured to focus exclusively on stock price performance to the detriment of other important business metrics. The variable (cash bonus and equity) portions of compensation are designed to reward both short and

long-term corporate performance. For short-term performance, a cash bonus is awarded based on the achievement of the performance criteria established for the Company and/or each executive officer based on performance criteria that the Compensation Committee believes to be challenging, yet does not encourage risk-taking, such as the achievement of product development and regulatory milestones, the acquisition of new products and the continuation of strategic corporate collaborations. For long-term performance, our stock option awards generally vest over four years and are only valuable if the Company's stock price increases over time, which further

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aligns the interests of our executives with those of our stockholders. The Compensation Committee believes that these variable elements of overall compensation are a sufficient percentage of overall compensation to motivate executive officers to produce superior short and long-term corporate results, while the fixed element is also sufficiently high such that the executive officers are not encouraged to take unnecessary or excessive risks. In addition, our internal controls and ethics code also help mitigate risks associated with our compensation program.

Based on the foregoing, the Compensation Committee concluded that risks arising from the Company's compensation program are not reasonably likely to have a material adverse effect on the Company and do not encourage or incentivize excessive or inappropriate risk-taking by the Company's employees.

**Role of Executives in Setting Compensation**

The Company's CEO makes recommendations on changes to compensation to the Compensation Committee for all executive officers except himself. Executives are not involved in decisions regarding their own compensation. The Compensation Committee has overall responsibility for the compensation programs for the CEO and other named executive officers.

**Role of the Compensation Consultant**

In 2010, management engaged Grant Thornton LLP to develop our compensation peer group, perform total compensation benchmarking analysis and make recommendations on potential annual and equity incentive opportunity levels for each named executive officer. Grant Thornton also assisted the Company in complying with the SEC proxy disclosure requirements as it relates to the preparation of the CD&A and related tabular calculations. Grant Thornton is independent and all work performed by Grant Thornton is subject to review and approval of the Compensation Committee.

**Compensation of Directors**

The following table shows fiscal 2010 compensation for our non-employee directors.

Name	Fees Earned or Paid in Cash (1)(\$)	Option Awards (2)(\$)	Total (\$)
Krishan K. Arora(5)	25,000	69,000	94,000
Stuart M. Krassner(3)	85,000	157,200	242,200
Luigi Lenaz(4)(6)	50,000	69,000	119,000
Anthony E. Maida(3)	85,000	157,200	242,200
Dilip J. Mehta(3)(7)	60,000	69,000	129,000

1. This column reports the dollar amount of cash compensation paid in 2011 for board and committee service. Effective as of June 26, 2009, each non-employee director received annual retainers for the period of service from the date of election (or reelection) as a director to the subsequent annual stockholder meeting, each retainer being payable on annually or semi-annually at the election of the director as follows: \$25,000 director retainer, \$25,000 retainer in lieu of meeting fees of the board and committees of the board, and \$10,000 each to the chairs of the Audit and Compensation Committees. Our directors are also reimbursed for certain out-of-pocket expenses incurred in connection with attendance at board meetings. Directors who are also our employees receive no

compensation for service as directors.

2. The amounts reflect the aggregate grant date fair value of the following option awards made to such non-employee director. On April 20, 2010, each Board member of record on that date received a stock option to purchase up to 30,000 shares of our common stock at \$5.05 per share; with 100% of the shares vesting on the last day of service as a Board member for the 2009-2010 period. On July 1, 2010, upon confirmation of election as a Board member for the 2010-2011 period, each elected non-employee director received an option to purchase up to 30,000 shares of our common stock at \$3.92 per share; 25% of the shares vested on the date of grant and the remaining shares vested equally in three annual increments from the date of grant; and on. For

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additional information, refer to note 12 of our financial statements that are included elsewhere in this annual report.

3. Includes \$30,000 related to Board, Committee and Committee Chair service from January 1, 2011 until June 30, 2011, or date of Annual Stockholder Meeting.
4. Includes \$25,000 related to Board and Committee service for the period from January 1, 2011 until June 30, 2011, or date of Annual Stockholder Meeting.
5. Excludes \$119,250 compensation as consultant prior to election as director. Such consulting arrangement terminated effective July 1, 2010.
6. Excludes \$127,399 compensation as consultant prior to election as director. While his consulting agreement expired December 31, 2010. Dr. Lenaz's consulting arrangements terminated effective July 1, 2010.
7. Excludes \$3,000 compensation as consultant prior to election as director. Such consulting arrangement terminated effective July 1, 2010.

**COMPENSATION COMMITTEE INTERLOCKS AND INSIDER PARTICIPATION**

The Compensation Committee is currently comprised of Drs. Krassner, Maida and Arora. None of the members of our Compensation Committee is or has been an officer or employee of Spectrum. None of our executive officers has served as a director or member of the compensation committee of any other entity, any of whose executive officers served on our Board of Directors or our Compensation Committee.

**REPORT OF THE COMPENSATION COMMITTEE**

*The following Compensation Committee Report does not constitute soliciting material and should not be deemed filed or incorporated by reference into any other company filing under the Securities Act of 1933 or the Exchange Act, except to the extent we specifically incorporate it by reference therein.*

The Compensation Committee has reviewed and discussed the CD&A with management. Based on its review and discussions with management, the Compensation Committee recommended to the Board of Directors that the CD&A be included in our 2010 Annual Report on Form 10-K.

*Stuart M. Krassner, Sc.D., Psy.D, Chair.  
Anthony E. Maida, III, M.A., M.B.A., Ph.D  
Krishan K. Arora, Ph.D.*

**Summary Compensation Table**

The following information sets forth summary information concerning the compensation we awarded or accrued during 2010, 2009 and 2008 to our Chief Executive Officer, Chief Scientific Officer, Senior Vice President Of Finance, Chief Commercial Officer and Acting Chief Financial Officer. In 2008 and 2009, we had no other named executive officers.

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Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)(1)	Option Awards (\$)(1)	All Other Compensation (\$)	Total (\$)
Rajesh Shrotriya	2010	650,000	950,000	930,000	2,530,000	454,195(2,4)	5,514,195
Chairman, Chief Executive Officer and President	2009	600,000	1,000,000		2,159,000	33,956(2)	3,792,956
	2008	600,000	1,000,000	388,000	839,500	34,694(2)	2,862,194
George Tidmarsh	2010	181,258	50,000	60,300	472,000	6,276	769,835
Chief Scientific Officer							
Shyam Kumaria	2010	290,000	100,000	46,500	394,000	97,524(3,4)	928,024
Senior Vice President, Finance	2009	275,000	60,000		429,900	21,449(3)	786,349
	2008	250,000	50,000	65,850	113,000	22,113(3)	500,963
James Shields	2010	138,433	86,975		288,234	17,566	531,208
Chief Commercial Officer							
Brett Scott	2010	49,959			247,000	2,374	299,333
Acting Chief Financial Officer							

- (1) The amounts reflect the aggregate grant date fair value of awards made to such named executive officers. For additional information, refer to note 12 of our financial statements that are included elsewhere in this annual report.
- (2) Amounts include: (a) annual 401(k) matching contribution made by us in shares of our common stock and healthcare premiums, which is a benefit offered to all our employees, (b) premiums paid on life insurance policies covering his life and having as beneficiary his estate or other beneficiaries, (c) amounts related to the personal use of a leased company car, gas and repairs, and (d) legal fees related to negotiations of his employment agreement. No individual component of this amount exceeds \$25,000.
- (3) Amounts include annual 401(k) matching contribution made by us in shares of our common stock, and premiums paid on healthcare and life insurance policies, which are benefits that are offered to all of our employees.

**Grants of Plan Based Awards in 2010**

The following table provides information about equity awards granted to the named executive officers in 2010. There can be no assurance that the grant date fair value of stock and option awards will be realized by the named executive officers.

Name	Grant Date	All Other Option Awards:	All Other Stock Awards:	Exercise or Base Price of Option Awards (\$)	Grant Date Fair Value of Stock and Option Awards (\$)(1)
		Number of Securities Underlying Options (#)	Number of Shares of Stock or Units (#)		



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Rajesh Shrotriya	1/8/2010	500,000		4.65	\$ 1,380,000
	7/1/2010	500,000		3.92	\$ 1,150,000
George Tidmarsh	1/8/2010		200,000		\$ 930,000
	7/15/2010	200,000		4.02	\$ 472,000
	7/15/2010		15,000		\$ 60,300
Shyam Kumaria	1/8/2010	50,000		4.65	\$ 138,000
	2/5/2010	10,000		4.39	\$ 26,000
	7/1/2010	100,000		3.92	\$ 230,000
	1/8/2010		10,000		\$ 46,500
James Shields	5/10/2010	100,000		4.65	\$ 275,000
	6/30/2010	1,080		3.9	\$ 2,473
	7/1/2010	1,000		3.92	\$ 2,300
	9/30/2010	3,570		4.09	\$ 8,461
Brett L. Scott	10/11/2010	100,000		4.28	\$ 247,000

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The exercise price of all the option awards listed above is equal to the fair market value on the dates of grant in accordance with the terms of our equity incentive plans. All the awards listed above vest annually in equal 25% increments with 25% immediately vested on the date of grant.

- (1) The amounts reflect the grant date fair value dollar amount for financial statement reporting purposes. Fair value assumptions can be found in Note 11 to our financial statements.

**Outstanding Equity Awards at Fiscal Year-End 2010**

Name	Option Awards				Stock Awards		
	Number of Securities	Number of Securities			Equity Incentive Plan Awards: Number of Shares of Stock Not Vested (#)	Equity Incentive Plan Awards: Market Value of Shares of Stock Not Vested (\$)(7)	
	Underlying Unexercised Options (#)	Underlying Unexercised Options (#)	Option Exercise Price	Option Expiration Date	Plan Awards: Number of Shares of Stock Not Vested (#)	of Shares of Stock Not Vested (\$)(7)	
Rajesh Shrotriya	12,000		4.75	06/17/12			
	75,000		1.06	09/25/12			
	225,000		1.99	09/05/13			
	215,000		4.90	09/12/13			
	200,000		4.23	01/01/16			
	150,000		5.08	09/26/16			
	350,000		5.53	01/01/17			
	100,000		3.15	12/06/17			
	500,000		2.55	03/25/18			
	112,500	37,500(1)	1.43	12/06/18			
					50,000(4)	343,500	
		175,000	175,000(1)	1.47	01/16/19		
		250,000	250,000(1)	6.09	06/26/19		
	125,000	375,000(1)	4.65	01/08/20			
	125,000	375,000(1)	3.92	07/01/20			
					150,000(5)	1,030,500	
George Tidmarsh		200,000(3)	4.02	07/15/20			
					15,000(6)	103,050	
Shyam Kumaria	40,000		4.26	12/06/15			
	20,000		3.15	12/06/17			
	50,000		2.55	03/25/18			
	37,500	12,500(1)	1.43	12/06/18			
					7,500(4)	51,525	
		25,000	25,000(1)	1.47	01/16/19		
	2,500	2,500(1)	4.89	05/21/19			
	50,000	50,000(1)	6.09	06/26/19			

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	12,500	37,500(1)	4.65	01/08/20		
	10,000	(2)	4.39	02/05/20		
	25,000	75,000(1)	3.92	07/01/20		
					7,500(5)	51,525
James Shields		100,000(3)	4.65	05/10/20		
	250	750(1)	3.92	07/01/20		
	1,080	(2)	3.90	06/30/20		
	3,570	(2)	4.09	09/30/20		
Brett Scott		100,000(3)	4.28	10/11/20		

(1) Option shares vest annually in equal 25% increments, with 25% immediately vested on the grant date.

(2) Option shares vest immediately.

(3) Option shares vest 25% on anniversary date, and in 36 equal monthly increments thereafter.

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- (4) Shares granted on December 6, 2008 with 25% vesting on the grant date, and continuing to vest in equal 25% increments every December 6th thereafter.
- (5) Shares granted on January 8, 2010 with 25% vesting on the grant date, and continuing to vest in equal 25% increments every January 8th thereafter.
- (6) Shares granted on July 15, 2010, and vesting in equal 25% increments every July 15th thereafter.
- (7) Calculation based on the closing price of the common stock on December 31, 2010 of \$6.87 per share.

**Stock Vested Table in Fiscal Year 2010**

The following table provides information regarding the number of shares acquired upon exercise and/or vesting in 2010 and the value realized by the named executive officers.

Name	Stock Awards	
	Number of Shares acquired on Vesting (#)	Value realized on Vesting (\$)(1)
Rajesh Shrotriya	125,000	602,250
Shyam Kumaria	15,000	71,975

- (1) The value realized on vesting in the above table was calculated based on the price of the common stock on the vesting date.

**Executive Employment Agreements, Termination of Employment and Change-in-Control Arrangements**

On June 20, 2008, we entered into an employment agreement with Dr. Shrotriya, our President and Chief Executive Officer, which became effective as of January 2, 2008 and replaced his previous employment agreement. The employment agreement expires on January 2, 2012, unless terminated earlier, and automatically renews for a one-year term unless either party gives written notice of such party's intent not to renew the agreement at least 90 days prior to the commencement of the next year. The employment agreement requires Dr. Shrotriya to devote his full working time and effort to our business and affairs of us 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.

**Compensation and Benefits**

Dr. Shrotriya shall receive an annual base salary of \$600,000, as adjusted annually based upon the performance of Dr. Shrotriya and Spectrum, as determined by the Compensation Committee.

Dr. Shrotriya shall also be paid an annual performance bonus in cash and/or equity based awards, no later than January 31 of the year following, in an amount to be determined by the Compensation Committee according to Dr. Shrotriya's achievement of annual performance objectives mutually agreed upon by Dr. Shrotriya and our Board of

Directors.

Under the agreement, Dr. Shrotriya is entitled to receive additional employment benefits, including the right to participate in any incentive plans and to receive life, medical, dental, paid vacation, estate planning services, a leased vehicle and reimbursements for automobile related expenses, and other benefits.

***Termination***

Dr. Shrotriya's employment may be terminated due to non-renewal of the agreement by us, by mutual agreement of the parties, by us for cause (as that term is defined in the agreement) or without cause, on grounds of disability or death of Dr. Shrotriya, by Dr. Shrotriya for no reason or for good reason (as those terms are defined in the agreement), or by Dr. Shrotriya's non-renewal of the agreement.

If (i) the agreement is not renewed by us, (ii) Dr. Shrotriya is terminated without cause, or (iii) Dr. Shrotriya resigns for good reason, then Dr. Shrotriya's guaranteed severance payments include the right to receive (a) a lump

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sum payment equivalent to the aggregate of two years' cash compensation; (b) company-paid continued coverage for Dr. Shrotriya and his eligible dependents under our existing health and benefit plans for two years; and (c) immediate vesting of all options, restricted stock and other equity based awards granted to Dr. Shrotriya. Dr. Shrotriya shall have three years to exercise all vested equity based awards. Since options issued to Dr. Shrotriya pursuant to our 1997 Stock Incentive Plan can only be exercised for ninety days after termination, a replacement option shall be granted to Dr. Shrotriya at termination to allow for three years' of exercisability.

In the event Dr. Shrotriya voluntarily resigns for good reason, or is terminated by us without cause, we will pay or reimburse Dr. Shrotriya for reasonable relocation expenses up to a certain amount.

If Dr. Shrotriya's employment is terminated without cause prior to the end of a calendar year, then our Board of Directors shall determine the amount of any bonus that would have been paid to Dr. Shrotriya had his employment continued through the end of the calendar year and we shall pay Dr. Shrotriya the pro rata amount of the bonus.

If the agreement is terminated due to death or disability of Dr. Shrotriya, a lump sum equal to three months of base salary, at the time of his termination, shall be paid to Dr. Shrotriya, his legal representative or estate, as applicable. All equity based awards, such as options and restricted stock, shall immediately vest and shall remain exercisable in accordance with the terms of the respective equity plan and individual agreement(s) governing such options and as otherwise set forth in the agreement.

If Dr. Shrotriya voluntarily resigns his employment for no reason, any stock options or other equity based awards (except for restricted stock) shall immediately become fully vested upon the effective date of Dr. Shrotriya's resignation, and he shall have three years to exercise all such vested equity based awards. Dr. Shrotriya shall receive the same benefits for any unexpired options issued pursuant to our 1997 Plan as if he had been terminated without cause by us.

If during the term of the agreement, Dr. Shrotriya resigns for good reason (as defined in the agreement) other than pursuant to the circumstances of a change in control and the board has not cured the condition(s) that constitute good reason, then Dr. Shrotriya shall receive all of the severance benefits he would receive if he had been terminated without cause by us. Upon a change of control of Spectrum, if (i) Dr. Shrotriya's employment is terminated (other than by Dr. Shrotriya) without cause within twelve months thereafter; or (ii) Dr. Shrotriya is adversely affected in certain terms outlined in the agreement, and Dr. Shrotriya, within twelve months after an event constituting a change of control, elects to resign his employment with us, then in either case, Dr. Shrotriya shall be provided with company-paid senior executive outplacement and shall receive the same severance benefits as he would receive if he was terminated by us without cause. However, instead of two years' cash compensation, Dr. Shrotriya shall receive three years cash compensation. In addition, upon a change of control, we shall pay Dr. Shrotriya a one-time payment of \$600,000.

If the agreement is terminated due to mutual agreement, Dr. Shrotriya's non-renewal of the agreement, or by us for cause, he shall not be entitled to any severance.

***Other***

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 IRC or any interest or penalties are incurred by the 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.

**Table of Contents*****Potential Payments Upon Termination or Following a Change in Control***

The tables below reflect the amount of compensation to each of our named executive officers in the event of termination of such executive's employment or following a change in control of our Company. The amount of compensation payable to each named executive officer upon voluntary termination without cause, retirement, involuntary termination without cause, involuntary termination for cause or termination following a change of control, in the event of disability or death of the executive, and following a change in control of our Company is shown below. Where applicable, the amounts shown assume that termination was effective as of December 31, 2010 and use the closing price of our common stock as of December 31, 2010 (\$6.87), and are estimates of the amounts which would be paid out to the executives upon their termination. In the case of payments upon termination, the actual amounts to be paid out can only be determined at the time of such executive's separation from our Company.

	Voluntary Termination			Involuntary Termination		Change in	Change in Control (\$)
	Without Cause (\$)			Without Cause (\$)		Qualifying Termination (\$)	
	Retirement	Death (\$)	Disability (\$)	Cause (\$)	Cause (\$)	For Termination (\$)	
<b>Rajesh Shrotriya</b>							
Cash Severance payments		162,500	162,500	3,200,000		4,800,000	
Cash payments							600,000
Benefit payments				173,690		263,036	
Vesting Acceleration Options	3,282,750	3,282,750	3,282,750	3,282,750		3,282,750	
Vesting Acceleration Restricted stock		1,374,000	1,374,000	1,374,000		1,374,000	
280 G gross up						2,251,286	
<b>Total</b>	<b>3,282,750</b>	<b>0</b>	<b>4,819,250</b>	<b>4,819,250</b>	<b>8,030,440</b>	<b>11,971,072</b>	<b>600,000</b>
<b>George Tidmarsh</b>							
Cash Severance payments							
Benefits payments							
Vesting Acceleration Options						570,000	
Vesting Acceleration Restricted stock						103,050	
<b>Total</b>						<b>673,050</b>	
<b>Shyam Kumaria</b>							
Cash Severance payments							
Benefits payments							
Vesting Acceleration Options						551,450	
Vesting Acceleration Restricted stock						103,050	
<b>Total</b>						<b>654,500</b>	
<b>James Shields</b>							
Cash Severance payments							
Benefits payments							
Vesting Acceleration Options						224,213	
Vesting Acceleration Restricted stock							



Total	224,213
Brett Scott	
Cash Severance payments	
Benefits payments	
Vesting Acceleration Options	259,000
Vesting	
Acceleration Restricted stock	0
Total	259,000

*Cash severance payments:* Includes base salary, bonus and auto allowance payable, pursuant to terms of the employment agreement described above, for two years.

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*Cash payments:* Consists of a one-time payment upon a change in control of our Company pursuant to terms of the employment agreement described above.

*Benefit payments:* Includes COBRA insurance payments for healthcare insurance premiums payable, pursuant to terms of the employment agreements described above, for two years unless the lump-sum option is elected. Under the Change in Control scenario, an estimated cost for outplacement services is also included, pursuant to terms of the employment agreement described above.

*Vesting Acceleration Options:* Includes the aggregate intrinsic value of those stock options whose vesting is accelerated upon termination, either pursuant to terms of the employment agreements described above, or pursuant to terms of our equity incentive plans. The calculation of such fair value is based on the difference between the last closing price of our common stock, on or before December 31, 2010, and the exercise price of the options.

*Vesting Acceleration Restricted stock:* Includes the aggregate fair market value of restricted stock whose vesting is accelerated upon termination pursuant to terms of our equity incentive plans. The calculation of such fair value is based on the last closing price of our common stock, on or before December 31, 2010.

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

Based on information publicly filed and provided to us by certain holders, the following table shows the amount of our Series E Preferred Stock and common stock beneficially owned on February 25, 2011 (unless otherwise indicated) by holders of more than 5% of the outstanding shares of any class of our voting securities, other than with respect to Dr. Rajesh C. Shrotriya (our Chairman, Chief Executive Officer and President) whose ownership is included in the second table below. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting and/or investment power with respect to our voting securities, unless footnoted to the contrary. For purposes of the following tables, the percentage ownership is based upon 20 shares of our Series E Preferred Stock, and 52,003,514 shares of our common stock, outstanding as of February 25, 2011. Unless otherwise indicated, the business address of each stockholder is c/o Spectrum Pharmaceuticals, Inc., 11500 S. Eastern Avenue, Suite 240, Henderson, Nevada 89052.

Name and Address of Beneficial Owner	Preferred		Common		Percent of Shares Eligible to Vote on February 25, 2011(4)
	Shares Beneficially Owned(1)	Percent of Preferred Stock Outstanding(2)	Shares and Equivalent Beneficially Owned(3)	Percent of Common Shares Outstanding(3)	
BlackRock, Inc.(5) 40 East 52nd Street New York, NY 10022			3,161,135	6.08%	6.08%
Eastern Capital Limited(6) P.O. Box 31363/P.O. Box 31300 Grand Cayman, KY1-1206, Cayman Islands			4,737,307	9.11%	9.11%
Sands Brothers Venture Capital Funds 1-IV, LLC(7)	20	100.00%	40,000	*	*

90 Park Avenue, 31st Floor New York,  
NY 10016

\* Less than 1%

- (1) The amount relates to the shares of our Series E Preferred Stock owned by the entity as of February 25, 2011. There are no outstanding shares of any other series of our preferred stock.
- (2) Represents the percentage ownership of the total number of our outstanding shares of Series E Preferred Stock.
- (3) Shares of common stock owned as of February 25, 2011 and shares of common stock subject to preferred stock and warrants currently convertible or exercisable, or convertible or exercisable within 60 days of February 25, 2011, are deemed beneficially owned and outstanding for computing the percentage of the person holding such securities, but are not considered outstanding for computing the percentage of any other person.

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- (4) Reflects actual voting percentage. Each holder of Series E Preferred Stock shall be entitled to the number of votes equal to the number of shares of common stock into which such shares of Series E Preferred Stock could be converted on the record date at the then current conversion value as determined pursuant to the Certificates of Designations. At the current conversion value, each share of Series E Preferred Stock is entitled to 2,000 votes on each matter at the annual meeting. Consequently, the holders of our Series E Preferred Stock shall have a total of 40,000 votes on each matter at the annual meeting.
- (5) The information set forth herein is based solely on information contained in a Schedule 13G filed with the SEC on February 8, 2011 by BlackRock, Inc. ( BlackRock ). According to the Schedule 13G, BlackRock has sole voting and dispositive power over 3,161,135 shares of our common stock.
- (6) The information set forth herein is based solely on information contained in a Schedule 13G filed with the SEC on February 14, 2011 by Eastern Capital Limited. Eastern Capital Limited is a direct wholly-owned subsidiary of Portfolio Services Ltd. Kenneth B. Dart is the beneficial owner of all of the outstanding shares of Portfolio Services Ltd., which in turns owns all the outstanding shares of Eastern Capital Limited. As of the date of the Schedule 13G filing, Eastern Capital Limited and Mr. Dart beneficially own in the aggregate 4,737,307 shares of our common stock. Eastern Capital Limited and Mr. Dart have shared voting and dispositive powers with respect to 4,737,307 shares of our common stock.
- (7) Based upon the information provided to us by the holder, SB Venture Capital Management I-IV, LLCs are the Investment Advisors to Sands Brothers Venture Capital LLC ( SBV ), Sands Brothers Venture Capital II LLC ( SBV II ), Sands Brothers Venture Capital LLC III ( SBV III ) and Sands Brothers Venture Capital IV LLC ( SBV IV ) (collectively, the Funds ). The Funds beneficial ownership includes the effect of converting the 20 shares of Series E Preferred Stock into 40,000 shares of common stock. Martin S. Sands and Steven B. Sands are co-Member Managers of SB Venture Capital Management LLC, SB Venture Capital Management II LLC, SB Venture Capital Management III LLC, and SB Venture Capital Management IV LLC, each a New York limited liability company and each the member-manager of SBV, SBV-II, SBV-III and SBV-IV, respectively, and are the natural persons exercising voting and investment control over securities beneficially owned by the Funds.

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The following table sets forth certain information regarding the beneficial ownership of our common stock as of February 25, 2011 (unless otherwise noted) by: (i) each of our directors and director nominees, (ii) our named executive officers, and (iii) all of our directors, director nominees and executive officers as a group. Shares of common stock owned as of February 25, 2011 and shares of common stock subject to options or warrants currently exercisable or exercisable within 60 days of February 25, 2011, are deemed beneficially owned and outstanding for computing the percentage of the person holding such securities, but are not considered outstanding for computing the percentage of any other person. Unless otherwise noted, each person listed below has sole voting power and sole investment power with respect to shares shown as owned by him. Information as to beneficial ownership is based upon statements furnished to us or filed with the SEC by such persons. Unless otherwise indicated, the business address of each stockholder is c/o Spectrum Pharmaceuticals, Inc., 11500 S. Eastern Avenue, Suite 240, Henderson, Nevada 89052.

Name of Beneficial Owner	Options	Shares(1)	Total Owned	Percent of Shares Outstanding
<b>Named Executive Officers</b>				
Shrotriya, Rajesh(2)	3,077,000	1,423,466	4,500,466	8.2%
Kumaria, Shyam(3)	310,000	221,798	531,798	1.0%
Tidmarsh, George(4)	12,500	42,818	55,318	*
Shields, James(5)	17,400	26,269	43,669	*
Scott, Brett		4,000	4,000	*
<b>Directors/Directors Nominees</b>				
Krassner, Stuart	152,500	10,750	163,250	*
Maida, Anthony	174,500	2,250	176,750	*
Lenaz, Luigi	52,500	21,877	74,377	*
Arora, Krishan	7,500		7,500	*
Mehta, Dilip	7,500	32,000	39,500	*
All Executive Offices and Director/Director Nominees as a group (10 persons)(6)	3,811,400	1,785,228	5,596,628	10.0%

\* less than 1%

- (1) The holders of restricted stock are entitled to vote and receive dividends, if declared, on the shares of common stock covered by the restricted stock grant.
- (2) The number of shares includes 337,500 unvested restricted shares of our common stock subject to future vesting within 60 days of February 25, 2011.
- (3) The number of shares includes 27,500 unvested restricted shares of our common stock subject to future vesting within 60 days of February 25, 2011.
- (4) The number of shares includes 30,000 unvested restricted shares of our common stock subject to future vesting within 60 days of February 25, 2011.
- (5)

The number of shares includes 15,000 unvested restricted shares of our common stock subject to future vesting within 60 days of February 25, 2011.

- (6) The number of shares includes 410,000 unvested restricted shares of our common stock held as a group subject to future vesting within 60 days of February 25, 2011.

We are not aware of any arrangements that may at a subsequent date result in a change of control of the Company.

**Table of Contents****Equity Compensation Plan Information**

The following table summarizes all equity compensation plans including those approved by security holders and those not approved by security holders, as of December 31, 2010.

<b>Plan Category</b>	<b>Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants or Rights</b>	<b>Weighted-average Exercise Price of Warrants and Rights</b>	<b>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a))</b>
Equity compensation plans approved by security holders(1)	8,756,594	4.16	10,816,185
Equity compensation plans not approved by security holders(2)	445,000	5.04	
Employee Stock Purchase Plan approved by security holders	N/A	N/A	4,766,002
<b>Total</b>	<b>9,201,594</b>	<b>4.20</b>	<b>15,582,187</b>

- (1) We have three stock incentive plans: the 1997 Stock Incentive Plan, or the 1997 Plan, the 2003 Incentive Award Plan, or the 2003 Plan, and the 2009 Plan collectively as the Plans. We are not granting any more options pursuant to the 1997 Plan or the 2003 Plan. The 2009 Plan authorizes annual increases in the number of shares of our common stock available for issuance under the 2009 Plan by an amount equal to the greater of (i) 2,500,000 and (ii) a number of shares such that the total number of shares available for issuance equals 30% of the then number of shares of our common stock issued and outstanding. Thus, the authorized and available shares may fluctuate over time.
- (2) The number represents 445,000 shares of common stock issuable upon exercise of warrants issued to our non-employees under plans approved by our board of directors that we believe are not required to be approved by our stockholders pursuant to the rules of the NASDAQ Stock Market. We issued these warrants in circumstances that enable us to adequately compensate, without the payment in cash, for outside consultant services, in order to conserve our cash for operating activities. The number of securities remaining available for future issuance under these types of equity compensation plans is zero; however, our Board of Directors may approve additional issuances of warrants under circumstances that it decides are appropriate.

The above table does not include warrants issued to investors in connection with financing transactions. As of December 31, 2010, there were outstanding investor warrants to purchase up to an aggregate of 3,747,312 shares of our common stock, with a weighted average exercise price of \$6.62 per share, which are scheduled to expire on September 15, 2011, if not exercised.

Further details regarding warrants issued by us are included in note 11 to our audited consolidated financial statements included elsewhere in this annual report.

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

*Transactions with Related Parties*

***Dr. Lenaz Consulting Arrangement***

On April 28, 2008, we entered into a consulting agreement with Dr. Lenaz, our former Chief Scientific Officer, which provided for Dr. Lenaz to provide part-time consulting services from June 30, 2008, the date of his retirement as our Chief Scientific Officer, through December 31, 2010. On July 1, 2010, effective with his election as a director of the Company, Dr. Lenaz's consulting services were terminated. Under the terms of the consulting agreement, as amended from time to time, Dr. Lenaz was paid \$127,399 during 2010 for consulting services provided through June 30, 2010.



**Table of Contents*****Policy on the Review, Approval or Ratification of Transactions with Related Persons***

We have adopted a written policy for approval or ratification of all transactions with related parties that are required to be reported under Item 404(a) or Regulation S-K. The policy provides that the Audit Committee of the board of directors shall review the material facts of all transactions and either approve or disapprove of the entry into the transaction. If advance Audit Committee approval of a transaction is not feasible, then the transaction shall be considered by the Audit Committee chair and, if the Audit Committee determines it to be appropriate, ratified by the Audit Committee.

The Audit Committee may establish that certain transactions may be pre-approved by the Audit Committee. However the Audit Committee has not established any such transactions.

No director shall participate in any approval of a transaction for which he or she is a related party. The director shall provide all material information concerning the transaction to the Audit Committee.

***Director Independence***

In determining whether members of our Board of Directors are independent, the Board reviews a summary of the relationships of each director with the Company and other facts relevant to the analysis of whether the directors qualify as independent director under the NASDAQ Global Market listing standards.

All members of the Board, except for Dr. Rajesh C. Shrotriya, President and Chief Executive Officer of the Company, and Dr. Luigi Lenaz, Board Member, are independent pursuant to the listing standards of the NASDAQ Global Market. All members of the Audit, Compensation and Nominating and Corporate Governance Committees are independent pursuant to the listing standards of the NASDAQ Global Market and the rules promulgated by the SEC for the Audit Committee.

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

The following summarizes aggregate fees billed to us by our independent registered public accounting firms, E&Y and K&C, for the fiscal years ended December 31, 2010 and 2009:

	<b>Ernst &amp; Young LLP 2010(\$)</b>	<b>Ernst &amp; Young LLP 2009(\$)</b>	<b>Kelley &amp; Co. 2009(\$)(1)</b>
Audit Fees	416,000	210,000	85,280
Audit-related Fees	5,200		27,210
Tax Fees	253,825		24,800
 Total	 675,025	 210,000	 137,290

(1) Represents fees billed to us by K&C as our independent registered public accounting firm through December 3, 2009.

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The fees billed to us by E&Y and K&C during or related to our 2010 and 2009 fiscal years consist solely of audit fees, audit-related fees and tax fees, as follows:

*Audit Fees.* Represents the aggregate fees billed to us for professional services rendered for the audit of our annual consolidated financial statements and our internal controls over financial reporting, for the reviews of our consolidated financial statements included in our Form 10-Q filings for each fiscal quarter, and the preparation of comfort letters and consents with respect to registration statements.

*Audit-related Fees.* Represents the aggregate fees billed to us for assurance and related services that are reasonably related to the performance of the audit and review of our consolidated financial statements that are not already reported in Audit Fees. These services include accounting consultations and attestation services that are not required by statute.

*Tax Fees.* Represents the aggregate fees billed to us for professional services rendered for tax returns, compliance and tax advice.

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**Policy on Audit Committee Pre-approval of Audit and Permissible Non-audit Services of Independent Auditor**

All audit and permissible non-audit services by our independent registered public accounting firms were pre-approved by our Audit Committee. Pursuant to its charter, the Audit Committee may establish pre-approval policies and procedures, subject to SEC and NASDAQ rules and regulations, to approve audit and permissible non-audit services, however, it has not yet done so.

**PART IV**

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

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

	<b>Page</b>
<u>Reports of Independent Registered Public Accounting Firms</u>	F-2
<u>Consolidated Balance Sheets as of December 31, 2010 and 2009</u>	F-4
<u>Consolidated Statements of Operations for each of the years in the periods ended December 31, 2010, 2009 and 2008</u>	F-5
<u>Consolidated Statements of Stockholders' Equity for the years ended December 31, 2010, 2009 and 2008</u>	F-6
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2010, 2009 and 2008</u>	F-7
<u>Notes to Consolidated Financial Statements</u>	F-8

(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.*

**Table of Contents****Index to Exhibits**

<b>Exhibit No.</b>	<b>Description</b>
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.)
2.4#	Limited Liability Company Interest Assignment Agreement, dated as of March 15, 2009, by and between the Registrant and Cell Therapeutics, Inc. (Filed as Exhibit 2.1 to Form 10-Q, as filed with the Securities and Exchange Commission on May 15, 2009, and incorporated herein by reference.)
3.1+	Amended Certificate of Incorporation, as filed.
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, 2010, 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 Rights of Stockholder Rights Plan. (Filed as Exhibit 4.1 to Form 8-K, as filed with the Securities and Exchange Commission on December 13, 2010, and incorporated herein by reference.)
4.2	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.)
4.3	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.)
4.4	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.)
4.5	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.)
10.1+	Sublease Agreement, dated as of December 2, 2010, between the Registrant and Del Webb Corporation.
10.2	Industrial Lease Agreement, dated as of January 16, 1997, between the Registrant and the Irvine Company. (Filed as Exhibit 10.11 to Form 10-KSB, as filed with the Securities and Exchange Commission on March 31, 1997, and incorporated herein by reference.)
10.3	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.)
10.4	

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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.)

- 10.5 Common Stock and Warrant Purchase Agreement, dated as of April 20, 2004, 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 April 23, 2004, and incorporated herein by reference.)
- 10.6#+ Amended and Restated License and Collaboration Agreement by and between the Registrant and Aeterna Zentaris GmbH (formerly Zentaris GmbH), dated as of November 5, 2010.

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<b>Exhibit No.</b>	<b>Description</b>
10.7*	Form of Stock Option Agreement under the 2003 Amended and Restated Incentive Award Plan. (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.)
10.8#	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.)
10.9*	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, as filed with the Securities and Exchange Commission on May 10, 2005, and incorporated herein by reference.)
10.10*	Restricted Stock Award Grant Notice and Restricted Stock Award Agreement under the 2003 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.)
10.11#	License Agreement between the 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.)
10.12*	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.)
10.13#	Agreement by and between the 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.)
10.14*	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.)
10.15#	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, and incorporated herein by reference.)
10.16*	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.)
10.17*	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.)
10.18*+	Amendment Number One to Consulting Agreement by and between the Registrant and Luigi Lenaz, M.D., effective as of March 16, 2010.
10.19*+	Amendment Number Two to Consulting Agreement by and between the Registrant and Luigi Lenaz, M.D., effective as of July 2, 2010.
10.20*	Form of Indemnity Agreement of the Registrant. (Filed as Exhibit 10.32 to Form 10-K, as filed with the Securities and Exchange Commission on March 31, 2009, and incorporated herein by reference.)
10.21#	License, Development, Supply and Distribution Agreement, dated October 28, 2008, by and among the Registrant, Allergan Sales, LLC, Allergan USA, Inc. and Allergan, Inc. (Filed as Exhibit 10.33 to Form 10-K, as filed with the Securities and Exchange Commission on March 31, 2009, and incorporated herein by reference.)
10.22*	2009 Employee Stock Purchase Plan. (Filed as Exhibit 99.1 to Form S-8, as filed with the Securities and Exchange Commission on June 29, 2009, and incorporated herein by reference.)

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- 10.23\* 2009 Incentive Award Plan. (Filed as Exhibit 99.2 to Form S-8, as filed with the Securities and Exchange Commission on June 29, 2009, and incorporated herein by reference.)
- 10.24\* 2003 Amended and Restated Incentive Award Plan. (Filed as Exhibit 10.1 to Form 8-K, as filed with the Securities and Exchange Commission on July 2, 2009, and incorporated herein by reference.)
- 10.25 Fourth Amendment, dated July 29, 2009, to Industrial Lease Agreement dated as of January 16, 1997 by and between the Registrant and the Irvine Company. (Filed as Exhibit 10.29 to Form 10-K, as filed with the Securities and Exchange Commission on April 5, 2010, and incorporated herein by reference.)

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<b>Exhibit No.</b>	<b>Description</b>
10.26*	Term Sheet for 2009 Incentive Award Plan Stock Option Award. (Filed as Exhibit 10.8 to Form 10-Q, as filed with the Securities and Exchange Commission on August 13, 2009, and incorporated herein by reference.)
10.27*	Term Sheet for 2009 Incentive Award Plan, Nonqualified Stock Option Award Awarded to Non-Employee Directors. (Filed as Exhibit 10.9 to Form 10-Q, as filed with the Securities and Exchange Commission on August 13, 2009, and incorporated herein by reference.)
10.28*	Term Sheet for 2009 Incentive Award Plan, Restricted Stock Award. (Filed as Exhibit 10.10 to Form 10-Q, as filed with the Securities and Exchange Commission on August 13, 2009, and incorporated herein by reference.)
10.29#	License Agreement, dated November 6, 2009, by and between the Registrant and Nippon Kayaku Co., Ltd. (Filed as Exhibit 10.36 to Form 10-K, as filed with the Securities and Exchange Commission on April 5, 2010, and incorporated herein by reference.)
10.30#	License and Collaboration Agreement, dated February 2, 2010, by and between the Registrant and TopoTarget A/S. (Filed as Exhibit 10.37 to Form 10-K, as filed with the Securities and Exchange Commission on April 5, 2010, and incorporated herein by reference.)
10.31	Asset Purchase Agreement, dated August 15, 2007, by and between Cell Therapeutics, Inc. and Biogen Idec Inc. (Filed as Exhibit 10.1 to Cell Therapeutics, Inc.'s Form 8-K, No. 001-12465, as filed with the Securities and Exchange Commission on August 21, 2007, and incorporated herein by reference.)
10.32	First Amendment to Asset Purchase Agreement, dated December 9, 2008, by and between Cell Therapeutics, Inc. and Biogen Idec Inc. (Filed as Exhibit 10.48 to Cell Therapeutics, Inc.'s Form 10K, No. 001-12465, as filed with the Securities and Exchange Commission on March 16, 2009, and incorporated herein by reference.)
10.33	Supply Agreement, dated December 21, 2007, by and between Cell Therapeutics, Inc. and Biogen Idec Inc. (Filed as Exhibit 10.2 to Cell Therapeutics, Inc.'s Form 8-K, No. 001-12465, as filed with the Securities and Exchange Commission on December 31, 2007, and incorporated herein by reference.)
10.34#+	First Amendment to Supply Agreement, dated December 15, 2008, by and between Cell Therapeutics, Inc. and Biogen Idec Inc.
10.35+	Security Agreement, dated December 15, 2008, by and between RIT Oncology, LLC and Biogen Idec Inc.
16.1	Letter from Kelly and Company to the Securities and Exchange Commission, dated December 3, 2009. (Filed as Exhibit 16.1 to Form 8-K, as filed with the Securities and Exchange Commission on December 8, 2009, and incorporated herein by reference.)
21+	Subsidiaries of Registrant.
23.1+	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
23.2+	Consent of Kelly & Company, Independent Registered Public Accounting Firm.
24.1	Power of Attorney (included in the signature page.)
31.1+	Certification of Principal Executive Officer, pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.
31.2+	Certification of Principal Financial Officer, pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.
32.1+	Certification of Principal 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 Principal Financial Officer, 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 9, 2011

**POWER OF ATTORNEY**

Each person whose signature appears below constitutes and appoints each of Rajesh C. Shrotriya and Brett L. Scott 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:

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Rajesh C. Shrotriya, M.D. Rajesh C. Shrotriya, M.D.	Chairman of the Board, Chief Executive Officer, and President (Principal Executive Officer)	March 9, 2011
/s/ Brett L. Scott Brett L. Scott	Senior Vice President and Acting Chief Financial Officer (Principal Financial and Accounting Officer)	March 9, 2011
/s/ Krishan K. Arora, Ph.D. Krishan K. Arora, Ph.D.	Director	March 9, 2011
/s/ Luigi Lenaz, M.D. Luigi Lenaz, M.D.	Director	March 9, 2011
/s/ Stuart M. Krassner, Sc.D., Psy.D. Stuart M. Krassner, Sc.D., Psy.D.	Director	March 9, 2011

/s/ Anthony E. Maida, III, M.A., M.B.A., Ph.D	Director	March 9, 2011
Anthony E. Maida, III, M.A., M.B.A., Ph.D		
/s/ Dilip J. Mehta, M.D., Ph.D.	Director	March 9, 2011
Dilip J. Mehta, M.D., Ph.D.		

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

**Consolidated Financial Statements**

*As of December 31, 2010 and 2009 and*

*For Each of the Three Years Ended December 31, 2010*

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

**Consolidated Financial Statements**

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**Report of Ernst & Young LLP, Independent Registered Public Accounting Firm**

The Board of Directors and  
Stockholders of Spectrum Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Spectrum Pharmaceuticals, Inc. and Subsidiaries as of December 31, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2010. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements 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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Spectrum Pharmaceuticals, Inc. and Subsidiaries at December 31, 2010 and 2009, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2010, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Spectrum Pharmaceuticals, Inc. and Subsidiaries internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 9, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Irvine, California  
March 9, 2011

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders of  
Spectrum Pharmaceuticals, Inc. and Subsidiaries.

We have audited the accompanying consolidated statements of operations, stockholders' equity and cash flows for the year ended December 31, 2008 of Spectrum Pharmaceuticals, Inc. and Subsidiaries. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the results of operations and cash flows of Spectrum Pharmaceuticals, Inc. and Subsidiaries for the year ended December 31, 2008 in conformity with U.S. generally accepted accounting principles.

/s/ Kelly & Company

Kelly & Company  
Costa Mesa, California  
March 31, 2009

**Table of Contents****Spectrum Pharmaceuticals, Inc. and Subsidiaries****Consolidated Balance Sheets**  
**(In thousands, except share and per share data)**

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 53,557	\$ 82,336
Marketable securities	42,117	31,005
Accounts receivable, net of allowance for doubtful accounts of \$339, and \$150, respectively	21,051	8,658
Inventories	4,234	3,230
Prepaid expenses and other current assets	906	1,028
<b>Total current assets</b>	<b>121,865</b>	<b>126,257</b>
Bank certificates of deposit	8,569	11,438
Property and equipment, net	3,158	1,928
Zevalin related intangible assets, net of accumulated amortization of \$12,295 and \$8,575, respectively	29,605	33,325
Other assets	434	185
<b>Total assets</b>	<b>\$ 163,631</b>	<b>\$ 173,133</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current Liabilities:		
Accounts payable and other accrued obligations	\$ 38,704	\$ 16,606
Accrued compensation and related expenses	3,313	3,360
Deferred revenue	12,300	8,300
Common stock warrant liability	3,904	6,635
Accrued drug development costs	5,101	4,598
<b>Total current liabilities</b>	<b>63,322</b>	<b>39,499</b>
Capital lease obligations	40	69
Deferred revenue and other credits less current portion	25,495	24,943
Zevalin related contingent obligations	298	298
<b>Total liabilities</b>	<b>89,155</b>	<b>64,809</b>
Commitments and contingencies		
Stockholders Equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized of which 1,000,000 shares have been designated as Series B junior participating preferred stock, no shares issued and outstanding		
Series E convertible voting preferred stock \$10,000 par value; 2,000 shares authorized; 26 and 68 shares issued and outstanding at December 31, 2010 and 2009,	160	419



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respectively, (aggregate liquidation value of \$312)

Common stock, \$0.001 par value 100,000,000 shares authorized; 51,459,284 and 48,926,314 issued and outstanding at December 31, 2010 and 2009, respectively	51	49
Additional paid-in capital	384,757	369,482
Accumulated other comprehensive loss	(92)	(70)
Accumulated deficit	(310,400)	(261,556)
Total stockholders' equity	74,476	108,324
Total liabilities and stockholders' equity	\$ 163,631	\$ 173,133

See accompanying notes to consolidated financial statements.

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**Table of Contents****Spectrum Pharmaceuticals, Inc. and Subsidiaries****Consolidated Statements of Operations**  
**(In thousands, except share and per share data)**

	<b>Year Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
Revenues:			
Product sales, net	\$ 60,921	\$ 28,225	\$ 8,049
License and contract revenue	13,192	9,800	20,676
Total revenues	\$ 74,113	\$ 38,025	\$ 28,725
Operating costs and expenses:			
Cost of product sales (excludes amortization of purchased intangible assets)	17,439	8,148	1,193
Selling general and administrative	48,550	33,607	15,156
Research and development	57,301	21,058	26,683
Amortization of purchased intangible assets	3,720	3,720	158
Acquired in-process research and development			4,700
Total operating costs and expenses	127,010	66,533	47,890
Loss from operations	(52,897)	(28,508)	(19,165)
Non-operating income:			
Change in fair value of common stock warrant liability	2,731	8,075	1,271
Other income, net	1,279	662	1,165
Loss before provision for income taxes	(48,887)	(19,771)	(16,729)
Benefit (provision) for income taxes	43	(421)	(5)
Net loss	(48,844)	(20,192)	(16,734)
Net loss attributable to non-controlling interest		1,146	2,538
<b>Net loss attributable to Spectrum Pharmaceuticals, Inc. stockholders</b>	<b>\$ (48,844)</b>	<b>\$ (19,046)</b>	<b>\$ (14,196)</b>
Basic and diluted net loss per share:	\$ (0.99)	\$ (0.48)	\$ (0.45)
Basic and diluted weighted average shares outstanding:	49,502,854	39,273,905	31,551,152

See accompanying notes to consolidated financial statements.

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

**Consolidated Statements of Stockholders Equity**

(In thousands, except share data)

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders Equity	Non- Controlling Interest	Total
	Shares	Amount	Shares	Amount						
Balance at December 31, 2017	170	\$ 1,048	31,233,798	\$ 31	\$ 273,455	\$ 493	\$ (228,313)	\$ 46,713	\$ (2,538)	\$ 46,713
Loss							(14,196)	(14,196)	(2,538)	(16,835)
Realized gains						(493)		(493)		(493)
Investments						(146)		(146)		(146)
Realized loss										
Investments										
Comprehensive net contributions						(639)	(14,196)	(14,835)	(2,538)	(17,473)
Non-controlling interest									16,800	16,800
Conversion of Series E Preferred Stock to Common Stock	(102)	(629)	204,000		629					
Value of common stock issued to Spectrum, Inc. for Approval			125,000		305			305		
Value of common stock issued to Spectrum, LLC, University of Texas at Austin et al			75,000		74			74		
Share-based compensation			362,088	1	6,322			6,323		6,323
Share and common stock issued (net of										

itures)																	
nce of																	
non stock																	
1(k) plan		166,430			274				274								
<b>nce at</b>																	
<b>ber 31,</b>																	
68	\$	419	32,166,316	\$	32	\$	281,059	\$	(146)	\$	(242,510)	\$	38,854	\$	14,262	\$	53,
Loss											(19,046)		(19,046)		(1,146)		(20,
ized gains																	
vestments									101				101				
alized loss																	
vestments									(25)				(25)				
prehensive																	
net									76		(19,046)		(18,970)		(1,146)		(20,
nce of																	
non stock																	
warrants for																	
net of																	
nce costs			15,187,715		15		81,779						81,794				81,
ributions																	
controlling																	
est															2,067		2,
nase of non																	
olling																	
est											(1,798)		(1,798)		(15,183)		(16,
nce of																	
non stock																	
mployees																	
takedown			432,200		1		1,166						1,167				1,
Options																	
er offer											(2,520)		(2,520)				(2,
nce of																	
non stock																	
1(k) plan			139,795				448						448				4
nce of																	
non stock																	
SPP			65,715				292						292				2
nce of																	
non stock																	
exercise																	
ock options			488,750		1		1,261						1,262				1,
e-based																	
ensation																	
nse and																	
non stock																	
d (net of																	
itures)			207,014				6,860						6,860				6,

value of common stock issued to Spectra Pharmaceuticals, Inc. for the approval of the value of common stock issued to Altair for the exercise of the subscription rights			125,000		185			185		
value of common stock issued to Altair for the exercise of the subscription rights			113,809		750			750		
<b>Balance at December 31,</b>	68	\$ 419	48,926,314	\$ 49	\$ 369,482	\$ (70)	\$ (261,556)	\$ 108,324	\$ (48,844)	\$ 108,324
Loss on sale of investments						(22)		(22)		(48,844)
Comprehensive income (loss)						(22)	(48,844)	(48,866)		48,866
Conversion of preferred stock to common stock	(42)	(259)	84,000		259					
Change in fair value of common stock under the 2011(k) plan			136,121		598			598		
Change in fair value of common stock under the SPP			168,283		554			554		
Change in fair value of common stock under the exercise of stock options			1,135,340	1	3,073			3,074		3,073
Change in fair value of common stock under the performance-based compensation plan and the restricted stock plan (net of forfeitures)			257,270		7,687			7,687		7,687
Change in fair value of common stock under the license			751,956	1	3,104			3,105		3,104
<b>Balance at December 31,</b>	26	\$ 160	51,459,284	\$ 51	\$ 384,757	\$ (92)	\$ (310,400)	\$ 74,476	\$ (48,844)	\$ 74,476

See accompanying notes to consolidated financial statements.

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**Table of Contents****Spectrum Pharmaceuticals, Inc. and Subsidiaries****Consolidated Statements of Cash Flows**  
(In thousands)

	<b>Year Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
<b>Cash Flows From Operating Activities:</b>			
Net loss	\$ (48,844)	\$ (20,192)	\$ (16,734)
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization of deferred revenue	(12,300)	(9,186)	
Depreciation and amortization	4,506	4,244	610
Stock-based compensation	8,285	7,423	6,537
Acquired in-process research and development			4,700
Fair value of common stock issued for drug license	3,105	935	379
Change in fair value of common stock warrants	(2,731)	(8,075)	(1,271)
Provision for bad debt	359		
Provision for expiring inventory	50		
Loss on disposal of fixed assets	11		
Changes in operating assets and liabilities:			
Accounts receivable	(12,752)	1,118	(4,811)
Inventories	(1,054)	(1,389)	(1,841)
Prepaid expenses and other assets	(134)	(250)	101
Accounts payable and other accrued obligations	21,546	7,097	2,387
Accrued compensation and related expenses	(47)	404	1,845
Accrued drug development costs	503	1,149	
Landlord contributions to tenant improvements	995		
Deferred revenue and other credits	15,958	(912)	93
Net cash used in operating activities	(22,544)	(17,634)	(8,005)
<b>Cash Flows From Investing Activities:</b>			
Maturities of marketable securities	32,391	25,783	
Purchases of marketable securities	(40,649)		(13,056)
Investment in Zevalin acquisition		(30,940)	(10,202)
Purchases of property and equipment	(1,576)	(673)	(1,518)
Net cash used in investing activities	(9,834)	(5,830)	(24,776)
<b>Cash Flows From Financing Activities:</b>			
Proceeds from issuance of common stock and warrants, net of related offering costs and expenses		95,810	
Proceeds from issuance of common stock option exercises	3,074	1,262	
Proceeds from issuance of common stock to employees shelf takedown		1,167	
Proceeds from issuance of common stock under the ESPP plan	554	292	
Proceeds from Allergan, Inc. collaboration			41,500
Repurchase of warrants		(71)	

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Repurchase of stock options pursuant to tender offer		(2,520)	
Repayment of capital leases	(29)		
Net cash provided by financing activities	3,599	95,940	41,500
Net (decrease) increase in cash and cash equivalents	(28,779)	72,476	8,719
Cash and cash equivalents beginning of year	82,336	9,860	1,141
Cash and cash equivalents end of year	\$ 53,557	\$ 82,336	\$ 9,860
<b>Supplemental Disclosure of Cash Flow Information:</b>			
Cash paid for income taxes	\$ 27	\$ 45	\$ 5
Cash paid for interest	\$ 17	\$ 28	\$ 36
Financed portion of leasehold improvements	\$ 451	\$	\$
Conversion of preferred stock to common stock	\$ 259	\$	\$

See accompanying notes to consolidated financial statements.

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

**Notes to Consolidated Financial Statements**

**1. Nature of Business**

Spectrum Pharmaceuticals, Inc. is a biotechnology company with fully integrated commercial and drug development operations, with a primary focus in oncology. We are 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.

Our strategy is comprised of acquiring, developing and commercializing a broad and diverse pipeline of late-stage clinical and commercial products. We market two oncology drugs, ZEVALIN® and FUSILEV® and have two drugs, apaziquone and belinostat, in late stage development along with a diversified pipeline of novel drug candidates. We have assembled an integrated in-house scientific team, including formulation development, clinical development, medical research, regulatory affairs, biostatistics and data management, and have established a commercial infrastructure for the marketing of our drug products. We also leverage the expertise of our worldwide partners to assist in the execution of our strategy. Apaziquone is presently being studied in two large Phase 3 clinical trials for non-muscle invasive bladder cancer, or NMIBC, under strategic collaborations with Allergan, Inc., ( Allergan ), Nippon Kayaku Co. Ltd., ( Nippon Kayaku ), and Handok Pharmaceuticals Co. Ltd., ( Handok ). Belinostat, is being studied in multiple indications including a Phase 2 registrational trial for relapsed or refractory peripheral T-cell lymphoma, ( PTCL ), under a strategic collaboration with TopoTarget A/S ( TopoTarget ).

**2. Summary of Significant Accounting Policies**

***Basis of Presentation***

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America.

***Principles of Consolidation***

The consolidated financial statements include the accounts of Spectrum Pharmaceuticals, Inc., our wholly-owned subsidiaries, and joint ventures the Company controls, or of which it is determined to be the primary beneficiary. We evaluate the need to consolidate joint ventures in accordance with authoritative guidance. Investments by outside parties in our consolidated entities are recorded as non-controlling interest in our consolidated financial statements, and stated net after allocation of income and losses in the entity.

As of December 31, 2010, we had three consolidated subsidiaries: OncoRx Pharma Private Limited ( OncoRx ), 100% owned, organized in Mumbai, India in 2008; Spectrum Pharmaceuticals GmbH, wholly-owned inactive subsidiary, incorporated in Switzerland in April 1997; RIT Oncology, LLC ( RIT ), 100% owned since March 15, 2009, organized in Delaware in October 2008; and a consolidated joint venture, Spectrum Pharma Canada, organized in Quebec, Canada in January 2008. We have eliminated all significant intercompany balances and transactions among the consolidated entities from the consolidated financial statements.

***Use of Estimates***

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities,

revenues and expenses and disclosure of contingent obligations in the consolidated financial statements and accompanying notes. The estimation process requires assumptions to be made by management about future events and conditions, and as such, is inherently subjective and uncertain. Actual results could differ materially from those estimates.

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

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

***Segment and Geographic Information***

We operate in one reportable segment: acquiring, developing and commercializing prescription drug products. Accordingly, we report the accompanying consolidated financial statements in the aggregate, including all of our activities in one reportable segment. Foreign operations were not significant for any of the periods presented herein.

***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. 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. All of our available for sale securities are classified as current assets based on our intent and ability to use any and all of these securities as necessary to satisfy our cash needs as they arise, by redeeming them at par with short notice and without penalty.

As of December 31, 2010, we held substantially all of our cash, cash equivalents and marketable securities at major financial institutions, which must invest our funds in accordance with our investment policy with the principal objectives of such policy 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 securities, with limitations on investing in securities of any single issuer. We maintain cash balances in excess of federally insured limits in reputable financial institutions. To a limited degree, the Federal Deposit Insurance Corporation and third parties insure these investments. 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. We manage such risks on our portfolio by investing in highly liquid, highly rated instruments and limit investing in long-term maturity instruments.

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. We have classified \$8.6 million of our investments with maturity dates over 1 year from December 31, 2010 as long term based on our intention to hold to maturity.

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

The carrying values of our cash and cash equivalents, marketable securities, other securities and common stock warrants, carried at fair value as of December 31, 2010 and 2009, are classified in the table below in one of the three categories described below:

	<b>Fair Value Measurements</b>			<b>Total</b>
	(\$ in 000 s)			
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	
<b><u>2010</u></b>				
Assets:				
Cash and cash equivalents	\$ 53,557	\$	\$	\$ 53,557
FDIC insured bank CDs		29,985		29,985
Money market currency funds		15,488		15,488
U.S. Government securities		2,909		2,909
Corporate debt securities		2,304		2,304
Cash and cash equivalents and marketable securities	53,557	50,686		104,243
Other securities	26			26
	\$ 53,583	\$ 50,686	\$	\$ 104,269
Liabilities:				
Common stock warrant liability			3,904	3,904
	\$	\$	\$ 3,904	\$ 3,904
<b><u>2009</u></b>				
Assets:				
Cash and cash equivalents	\$ 82,336	\$	\$	\$ 82,336
FDIC insured bank CDs		20,948		20,948
Money market currency funds		4,800		4,800
U.S. Government securities		16,542		16,542
Corporate debt securities		153		153
Cash and cash equivalents and marketable securities	82,336	42,443		124,779
Other securities	35			35
	\$ 82,371	\$ 42,443	\$	\$ 124,814
Liabilities:				
Common stock warrant liability			6,635	6,635

\$	\$	\$ 6,635	\$ 6,635
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We measure fair value based on the prices that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value measurements are based on a three-tier hierarchy that prioritizes the inputs used to measure fair value. These tiers include the following:

*Level 1:* Quoted prices (unadjusted) in active markets for identical assets or liabilities that are accessible at the measurement date. 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. These inputs include quoted prices for similar assets or liabilities; quoted market prices in markets that are not

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

active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

*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 the assessment of fair value. Cash equivalents consist of certificates of deposit and are valued at cost, which approximates fair value due to the short-term maturities of these instruments. Marketable securities consist of certificates of deposit, US Government Treasury bills, US treasury-backed securities and corporate deposits, which are stated at fair market value, based on values provided us by the financial institutions where we invest our funds.

We had classified all of our marketable securities as Level 1 measurements as of December 31, 2009. Based on the recent guidance on disclosures for fair value measurements and in order to be consistent with industry practice, as of December 31, 2010 and 2009, we have reclassified all of our marketable securities under Level 2 measurements. There were no other transfers in and out of Level 2 during the year ended December 31, 2010.

The following summarizes the activity of Level 3 inputs measured on a recurring basis for the years ended December 31, 2010 and 2009:

	<b>Fair Value Measurements of Common Stock Warrants Using Significant Unobservable Inputs (Level 3) (\$ in 000 s)</b>	
Balance at December 31, 2008	\$	765
Transfers in / (out) of Level 3		
Issuance of common stock warrants		14,016
Repurchases or forfeitures		(394)
Gain on repurchase recognized in earnings		323
Adjustments resulting from change in value of warrants recognized in earnings		(8,075)
Balance at December 31, 2009		6,635
Transfers in / (out) of Level 3		
Forfeitures		(788)
Adjustments resulting from change in value of warrants recognized in earnings		(1,943)
Balance at December 31, 2010	\$	3,904

The fair value of common stock warrants are measured on their respective origination dates and at the end of each reporting period using Level 3 inputs. The significant assumptions we use in the calculations under the Black-Scholes

Option Pricing Model as of December 31, 2010 and 2009, included an expected term based on the remaining contractual life of the warrants, a risk-free interest rate based upon observed interest rates appropriate for the expected term of the instruments, volatility based on the historical volatility of our common stock, and a zero dividend rate based on our past, current and expected practices of granting dividends on common stock. These warrants will expire on September 14, 2011 if not exercised.

We did not elect the fair value option, as allowed, for our financial assets and liabilities that were not previously carried at fair value. Therefore, material financial assets and liabilities that are not carried at fair value, such as trade accounts receivable and payable, are still reported at their historical carrying values, which approximates fair value due to their short term nature.

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

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

***Concentration of credit risk***

Our cash investments are subject to concentration of credit risk, which is managed by diversification of the investment portfolio and by the purchase of investment-grade securities.

Our product sales are concentrated in a limited number of customers. Sales to Customer A for the years ended December 31, 2010, 2009 and 2008 were 45.7%, 27.1%, and 35.7% respectively, of our total consolidated gross product sales. No other single customer generated over 10% of our consolidated gross product sales.

We are exposed to risks associated with extending credit to our customers related to the sale of products. We do not require collateral or other security to support credit sales, however, we maintain reserves for potential bad debt and to date, credit losses have been within management's expectations. Customer A owed us 56.1% of net receivables as of December 31, 2010 and no single customer owed us more than 10% at December 31, 2009. All sales were to customers in the United States.

We have single source suppliers for raw materials and the manufacturing of finished product of Zevalin and Fusilev and have begun the process of qualifying additional contract manufacturers for Fusilev. We are exposed to loss of revenue from the sale of these products if the supplier cannot fulfill demand. We also have single source suppliers for raw materials, and manufactured finished product for our development drug candidates. If we are unable to obtain sufficient quantities of such product, our research and development activities may be adversely affected.

***Inventories***

Inventories are valued 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.

We continually review product inventories on hand, evaluating inventory levels relative to product demand, remaining shelf life, future marketing plans and other factors. We adjust our inventory to reflect situations in which the cost of inventory is not expected to be recovered. We record a reserve to adjust inventory to its net realizable value if (i) a product is close to expiration and not expected to be sold, (ii) when a project has reached its expiration date or (iii) when a product is not expected to be saleable. In determining reserves for these products, we consider factors such as the amount of inventory on hand and its remaining shelf life, and current and expected market conditions, including management forecasts and levels of competition. We have evaluated the current level of inventory considering historical trends and other factors, and based on our evaluation, we have recorded adjustments to reflect inventory at its net realizable value. These adjustments are estimates, which could vary significantly from actual results if future economic conditions, customer demand, competition or other relevant factors differ from expectations. These estimates require us to make assessments about the future demand for our products in order to categorize the status of such inventory items as slow-moving, obsolete or in excess-of-need. These future estimates are subject to the ongoing accuracy of our forecasts of market conditions, industry trends, competition and other factors. Differences between our estimated reserves and actual inventory adjustments have not been significant, and are accounted for in the current period as a change in estimate. During 2010, expiring inventory reserves of \$50,000 were recorded against cost of goods sold and the total reserve was \$50,000 and \$89,000 at December 31, 2010 and 2009, respectively.

***Property and Equipment***



Property and equipment are recorded at cost less accumulated depreciation. Maintenance and repairs are expensed as incurred. Upon sale or disposition of assets, any gain or loss is included in the statements of operations.

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

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

The cost of property, plant and equipment is depreciated using the straight-line method over the following estimated useful lives of the respective assets. Leasehold improvements are amortized over the lesser of the estimated useful lives of the respective assets or the related lease terms.

Computers and software	3 to 5 years
Office furniture and equipment	5 to 7 years
Lab and media equipment	2 to 7 years

All long-lived assets, including property and equipment, are reviewed 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. Fair value would be determined by the use of appraisals, discounted cash flow analyses or comparable fair values of similar assets.

***Patents and Licenses***

We expense all licensing and patent application costs as they are incurred.

***Intangible Assets***

As described in note 3 below, we acquired 50% of the rights in RIT in December 2008 and the remaining 50% in March 2009.

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. 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.

Identifiable intangible assets with definite lives are amortized on a straight-line basis over their estimated useful lives, ranging from 1 to 10 years.

We evaluate the recoverability of indefinite and definite intangible assets whenever events or changes in circumstances indicate that an intangible asset's carrying amount may not be recoverable. Such circumstances could include, but are not limited to the following:

- (i) a significant decrease in the market value of an asset;
- (ii) a significant adverse change in the extent or manner in which an asset is used; or
- (iii) an accumulation of costs significantly in excess of the amount originally expected for the acquisition of an asset.

We measure the carrying amount of the asset against the estimated undiscounted future cash flows associated with it. Should the sum of the expected future net cash flows be less than the carrying value of the asset being evaluated, an

impairment loss would be recognized. The impairment loss would be calculated as the amount by which the carrying value of the asset exceeds its fair value. No impairment loss was recorded during the years 2010, 2009, or 2008.

***Revenue Recognition***

Revenue from product sales is recognized upon shipment of product when title and risk of loss have transferred to the customer. We sell our products to wholesalers and distributors of oncology products and directly to the end user, directly or through GPOs (e.g., certain hospitals or hospital systems and clinics with whom we have entered into a direct purchase agreement). Our wholesalers and distributors purchase our products and sell the products

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

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

directly to end users, which include, but are not limited to, hospitals, clinics, medical facilities, managed care facilities and private oncology based practices. Revenue from product sales is recognized upon shipment of product when title and risk of loss have transferred to the customer, and the following additional criteria are met:

- (i) the price is substantially fixed and determinable;
- (ii) our customer has economic substance apart from that provided by us;
- (iii) our customer's obligation to pay us is not contingent on resale of the product;
- (iv) we do not have significant obligations for future performance to directly bring about the resale of our product; and
- (v) we have a reasonable basis to estimate future returns.

Generally, revenue is recognized when all four of the following criteria are met:

- (i) persuasive evidence that an arrangement exists;
- (ii) delivery of the products has occurred, or services have been rendered;
- (iii) the selling price is both fixed and determinable; and
- (iv) collectibility is reasonably assured.

Provision for estimated product returns, sales discounts, rebates, chargebacks and distribution and data fees are established as a reduction of gross product sales at the time such revenues are recognized. Thus, revenue is recorded, net of such estimated provisions.

Shipments of Fusilev for the year ended December 31, 2008 were approximately \$10.8 million (net of estimates for promotional, price and other adjustments). We deferred the recognition of approximately \$3.1 million of such revenue to allow for potential sales returns. In 2010 and 2009, based on our evaluation of return history to date combined with inventory held by distributors, sell through data of distributor sales to end users, customer and end-user ordering and re-ordering patterns, aging of accounts receivables, rates of returns for directly substitutable products and other pharmaceutical products for the treatment of therapeutic areas similar to indications served by our products, shelf life of our products and the extensive experience of our management with selling the same and similar oncology products, we reserved approximately \$2.0 million and \$1.2 million as of December 31, 2010 and 2009, respectively. No returns reserve is recorded for Zevalin since we invoice our end user customers and recognize revenues only when a patient is treated with Zevalin.

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.

We utilize a third-party logistics company to store and distribute Fusilev. The same third party logistics company also stores and ships Zevalin kits containing the CD20 MAB.

During 2009, we changed the supply and distribution model for Zevalin. Previously, we sold Zevalin kits containing the CD20 MAB to radiopharmacies, who in turn ordered the radioactive isotope (Y-90 or In-111) separately and radiolabeled (or attached) the radioactive isotope to the CD20 MAB. The radiopharmacy then sold the end user product to the consumer. Under the current model we do not sell the Zevalin kits containing the CD20 MAB to the radiopharmacies, but instead contract with them, as a fee-for-service, to radiolabel the individual components of the CD20 MAB to the radioactive isotope, and then, also under a fee-for-service arrangement, have them distribute the end use product to the end user; the clinics, hospitals or other medical settings. In this regard, we now sell the CD20 MAB together with the radioactive isotope as the end user product.

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

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

Consistent with industry practice, our product return policy permits our customers to return products within 30 days after shipment, if incorrectly shipped or not ordered, and within a window of time 6 months before and 12 months after the expiration of product dating, subject to certain restocking fees and preauthorization requirements, as applicable. The returned product is destroyed if it is damaged, its quality is compromised or it is past its expiration date. Based on our returns policy, we refund the sales price to the customer as a credit and record the credit against receivables. In general, returned product is not resold. We generally reserve the right to decline granting a return and to decide on product destruction. As of each balance sheet date, we estimate potential returns, based on several factors, including: inventory held by distributors, sell through data of distributor sales to end users, customer and end-user ordering and re-ordering patterns, aging of accounts receivables, rates of returns for directly substitutable products and other pharmaceutical products for the treatment of therapeutic areas similar to indications served by our products, shelf life of our products and the extensive experience of our management with selling the same and similar oncology products. We record an allowance for future returns by reducing gross revenues and increasing the allowance for returns based upon the Company's historical patterns of product returns matched against sales, and management's evaluation of specific factors that may influence the risk of product returns. If allowances exceed the related accounts receivables, we reclassify such allowances to accrued obligations. Historical allowances for product returns have been within estimated amounts reserved or accrued.

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.

***Research and Development***

Research and development expenses include 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 collaborative research and development and include activities such as product registries and investigator-sponsored trials. Research and development costs are expensed as incurred. In certain instances, we enter into agreements with third parties for research and development activities, where we may prepay fees for services at the initiation of the contract. We record such prepayment as a prepaid asset and charge research and development expense over the period of time the contracted research and development services are performed. 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.

As of each balance sheet date, we review purchase commitments 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.

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

We calculate basic and diluted net income (loss) per share using the weighted average number of common shares outstanding during the periods presented, and adjust the amount of net income (loss) used in this calculation for preferred stock dividends (if any) declared during the period. In periods of a net loss position, basic and diluted weighted average shares are the same. For the diluted earnings per share calculation, we adjust the weighted average

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

number of common shares outstanding to include dilutive stock options, warrants and other common stock equivalents outstanding during the period.

The following shows the amounts used in computing basic and diluted loss per share for each of the three years in the period ended December 31, 2010:

	<b>Year Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
	(\$ in 000 s except per share data)		
Net loss attributable to Spectrum Pharmaceuticals, Inc. stockholders	\$ (48,844)	\$ (19,046)	\$ (14,196)
Less:			
Preferred dividends paid in cash or stock			
Loss attributable to Spectrum stockholders	\$ (48,844)	\$ (19,046)	\$ (14,196)
<b>Weighted average shares issued and outstanding</b>	49,502,854	39,273,905	31,551,152
Basic and diluted net loss per share	\$ (0.99)	(0.48)	(0.45)

The following table sets forth the number of shares excluded from the computation of diluted earnings per share, as their inclusion would have been anti-dilutive:

	<b>Year Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
Series E Preferred Shares	52,000	136,000	136,000
Stock Options	5,157,935	4,451,733	5,097,835
Warrants	4,142,312	8,379,912	5,444,555
	9,352,247	12,967,645	10,678,390

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

We measure compensation cost for all share-based awards at fair value on the date of grant and recognize compensation expense in our consolidated statements of operations over the service period that the awards are expected to vest. We have elected to recognize compensation expense for all options with graded vesting on a straight-line basis over the vesting period of the entire option.



The fair value of share-based compensation is estimated based on the closing market price of our common stock on the day prior to the award grants for stock awards, and the Black-Scholes Option Pricing Model for stock options and warrants. We estimate volatility based on historical volatility of our common stock, and estimate the expected term based on several criteria, including the vesting period of the grant and the term of the award.

We recorded share-based employee compensation as follows:

	<b>Year Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
	(\$ in 000 s)		
Research and development expense	\$ 2,484	\$ 3,192	\$ 3,925
Selling, general and administrative expense	5,801	4,231	2,612
	<b>\$ 8,285</b>	<b>\$ 7,423</b>	<b>\$ 6,537</b>

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

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

***Warrant accounting***

We account for common stock warrants pursuant to the applicable guidance on accounting for derivative financial instruments indexed to, and potentially settled in, a company's own stock, on the understanding that in compliance with applicable securities laws, registered warrants require the issuance of registered securities upon exercise and do not sufficiently preclude an implied right to net cash settlement. We classify registered warrants on the consolidated balance sheet as a current liability, which is revalued at each balance sheet date subsequent to the initial issuance. Determining the appropriate fair-value model and calculating the fair value of registered warrants requires considerable judgment, including estimating stock price volatility and expected warrant life. We develop our estimates based on historical data. A small change in the estimates used may have a relatively large change in the estimated valuation. We use the Black-Scholes pricing model to value the registered warrants. Changes in the fair market value of the warrants are reflected in the consolidated statement of operations as Change in the fair value of common stock warrant liability.

***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 net deferred tax asset does not meet the more likely than not to be realized criteria and, accordingly, a valuation allowance has been recorded to reduce the net deferred tax asset to zero.

***Acquisitions and Collaborations***

For all in-licensed products, pursuant authoritative guidance, we perform an analysis to determine whether we hold a variable interest or interests that give us a controlling financial interest in a variable interest entity. On the basis of our interpretations and conclusions, we determine whether the acquisition falls under the purview of variable interest entity accounting and if so, consider the necessity to consolidate the acquisition.

We also perform an analysis to determine if the inputs and/or processes acquired in an acquisition qualify as a business. On the basis of our interpretations and conclusions, we determine if the in-licensed products qualify as a business and whether to account for such products as a business combination or an asset acquisition.

***Comprehensive Income (loss)***

Comprehensive income (loss) is calculated in accordance with authoritative guidance which requires the disclosure of all components of comprehensive income, including net income (loss) and changes in equity during a period from transactions and other events and circumstances generated from non-owner sources. Our accumulated other comprehensive loss at December 31, 2010 and 2009, respectively consisted primarily of net unrealized gains/losses on investments in marketable securities as of that date.

***Recent Accounting Pronouncements***

In June 2009, the FASB issued authoritative guidance that requires companies to perform an analysis to determine whether such companies' variable interest or interests give it a controlling financial interest in a variable interest entity. This analysis identifies the primary beneficiary of a variable interest entity as the enterprise that has both the power to direct the activities of a variable interest entity that most significantly impact the entity's economic performance, and the obligation to absorb losses or the right to receive benefits of the entity that could potentially be significant to the variable interest entity. This guidance also requires ongoing reassessments of

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

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

whether an enterprise is the primary beneficiary of a variable interest entity and eliminates the quantitative approach previously required for determining the primary beneficiary. We adopted the provisions of this guidance in the first quarter of 2010, and determined that none of the unconsolidated entities with which we currently conduct business or collaborations are variable interest entities to be consolidated.

***New Accounting Standards Not Yet Adopted***

In December 2010, the FASB issued an accounting standards update that provides guidance on the recognition and classification of the annual fee imposed by the Patient Act and Affordable Care Act as amended by the Health Care and Education Reconciliation Act on pharmaceutical companies that manufacture or import branded prescription drugs. Under this guidance, the annual fee should be estimated and recognized in full as a liability upon the first qualifying sale with a corresponding deferred cost that is amortized to operating expense using a straight-line method of allocation unless another method better allocates the fee over the calendar year in which it is payable. The annual fee ranges from \$2.5 billion to \$4.1 billion for all affected entities in total, a portion of which will be allocated to us on the basis of the amount of our branded prescription drug sales for the preceding year as a percentage of the industry's branded prescription drug sales for the same period. The annual fee is not deductible for federal income tax purposes. This guidance will be effective for calendar years beginning after December 31, 2010, which will be the Company's fiscal year 2011. We are currently evaluating the potential impact of adopting this guidance on our consolidated financial statements.

In April 2010, the FASB issued an accounting standards update that provides guidance on the milestone method of revenue recognition for research and development arrangements. This guidance allows an entity to make an accounting policy election to recognize revenue that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. This guidance is effective for fiscal years beginning on or after June 15, 2010, which will be our 2011 fiscal year, and may be applied prospectively to milestones achieved after the adoption date or retrospectively for all periods presented, with earlier application permitted. The Company does not expect that the adoption of the guidance will have a material impact on the Company's consolidated financial statements.

In October 2009, the FASB issued an accounting standards update that requires an entity to allocate arrangement consideration at the inception of an arrangement to all of its deliverables based on their relative selling prices, eliminates the use of the residual method of allocation, and requires the relative-selling-price method in all circumstances in which an entity recognizes revenue of an arrangement with multiple deliverables. This guidance is effective for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, which will be our 2011 fiscal year, with earlier application permitted. We are currently evaluating the potential impact of adopting this guidance on our consolidated financial statements.

**3. Commercial and Drug Development Drug Products**

We currently market two oncology products in the United States, Zevalin and Fusilev. In addition, we have several products in clinical development, primarily including apaziquone which has completed patient enrollment for two Phase 3 clinical trials for bladder cancer and belinostat is being studied under a Special Protocol Assessment, or SPA, in a Phase 2 trial for relapsed or refractory PTCL. The following is a brief description of our key products as of December 31, 2010.

Zevalin: Zevalin is a prescribed form of cancer therapy called radioimmunotherapy which combines a source of radiation, called a radioisotope, with an antibody.

During the year ended December 31, 2010, 2009 and 2008, we recorded net revenues of \$29.0 million, \$15.7 million and \$0.3 million, respectively from sales of Zevalin.

In December 2008, we partnered with Cell Therapeutics, Inc., or CTI, to form a 50-50 owned joint venture, RIT Oncology, LLC, or RIT, to commercialize and develop Zevalin, a CD20-directed radiotherapeutic antibody, in

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

the United States. We paid \$15 million for our 50% interest in RIT. Pursuant to provisions of the 2008 joint-venture agreement, in March 2009, we acquired the remaining 50% ownership of RIT for \$16.5 million, resulting in RIT becoming our wholly-owned subsidiary. In April 2009, we disputed payment of an installment of \$3.5 million of the \$16.5 million, on the grounds that CTI's unpaid liabilities pertaining to Zevalin, and CTI's share of joint venture expenses equaled or exceeded the installment amount. In May 2009, we received an arbitration award of approximately \$4.3 million. The entire \$3.5 million was released to us and CTI additionally paid us approximately \$0.8 million. The award was final, binding and non-appealable by either party.

The assets contributed by CTI to RIT were all of its interests in the Zevalin business, which included the U.S. development, sales and marketing rights to Zevalin as well as other assets acquired in the December 2007 agreement with Biogen. 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. The assets contributed by CTI to RIT also included the assets acquired in the June 2008 Access Agreement with Bayer Schering Pharma AG, which holds the rights to Zevalin outside of the United States. Under the Access Agreement, Bayer gave CTI access to data from Bayer's Phase 3 first-line indolent trial of Zevalin. Finally, the assets contributed by CTI to RIT included CTI's September 30, 2008 submission of the Zevalin supplemental Biologics License Application, or sBLA, for use in first-line consolidation therapy for patients with B-cell follicular NHL. 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.

**(In thousands)**

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)
Maximum amount available	\$ 10,602	
Contingent obligations, restricted out of \$10,602 as recorded		(8,798)
Total initial capitalization of joint venture		\$ 30,000

The total fair value of developed and core assets equals \$37.2 million. 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 are amortized over the term of the patents related to such technologies. 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. In addition, during 2008 an amount of \$4.7 million of in process research and development, or IPR&D, for a medical indication still awaiting approval by the FDA was recorded to operating expenses. Such amount was completely written off during the year ended December 31, 2008. Amortization expense expected to be recorded over the next five years is approximately \$18.5 million. 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

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

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 was charged to operations for the year ended December 31, 2008 as of the formation date of RIT. The March 2009 50% acquisition of the non-controlling interest in RIT included a premium of \$1.8 million, including certain acquisition related costs, and was charged to additional paid in capital.

The RIT transaction involved contingent consideration, therefore 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. Certain contingencies were resolved during 2009 and \$8.5 million of the contingent consideration payable was charged to the recorded amount, which reduced contingent liabilities to approximately \$298,000 at December 31, 2010 and 2009.

In December 2008, the FDA had accepted for filing and review, and granted priority review status for a sBLA for the use of Zevalin as part of a first-line therapy for patients with previously untreated follicular non-Hodgkin's lymphoma, or NHL. The sBLA application was approved by the FDA on September 3, 2009, which now allows the use of Zevalin for a substantially larger patient population. Zevalin is now FDA approved and marketed by Spectrum for treatment of patients with previously untreated follicular NHL who achieve a partial or complete response to chemotherapy and with relapsed or refractory, low-grade or follicular B-cell NHL, including patients who have rituximab-refractory follicular NHL. In connection with the FDA approval, we paid \$8.5 million in milestone payments. In November 2009, the Centers for Medicare & Medicaid Services, or CMS finalized a policy to allow reimbursement for Zevalin®, in the Hospital Outpatient Prospective Payment System, based on the Average Sales Price methodology applicable to other injectable drugs and biologicals. This reimbursement methodology went into effect on January 1, 2010.

***Fusilev for Injection:*** Fusilev is the only commercially available drug containing only the pure active L-isomer of racemic (L and R forms) leucovorin. Fusilev is currently 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.

We commercially launched Fusilev in August 2008 and recorded net revenues of approximately \$32.0 million, \$12.5 million and \$7.7 million from Fusilev sales for the years ended December 31, 2010, 2009 and 2008 respectively.

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 2009 and 2008, we recorded stock-based research and development charges of \$185,000 and \$305,000, respectively, which represents the fair market value of 125,000 shares of our common stock issued at each of March 2008 and 2009 as milestone payments to Targent, LLC.

***Apaziquone:*** 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 up-front 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.

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

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

In the United States, we will co-promote apaziquone with Allergan 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 two Phase 3 registrational trials, and will be jointly responsible for obtaining regulatory approval for the product. Both parties share development expenses with Allergan bearing 65% of the cost. Pursuant to our revenue recognition policy, 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, 2010, and 2009, we have classified \$8.3 million of such amount recorded on the consolidated balance sheet as current portion of deferred revenue.

In December 2009, we completed enrollment of our two Phase 3 pivotal clinical trials enrolling more than 1,600 patients with non-muscle invasive bladder cancer. As per the collaboration agreement with Allergan, Spectrum recorded a \$1.5 million milestone payment from Allergan. Such amount was received in January 2010.

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<sup>®</sup>, formerly NDDO Research Foundation, or INC, 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 nominal amount of cash and issued them a nominal 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 November 2009, we entered into a collaboration agreement with Nippon Kayaku Co., LTD. for the development and commercialization of apaziquone in Asia, except North and South Korea (the Nippon Kayaku Territory ). In exchange, Nippon Kayaku paid Spectrum an up-front payment of \$15.0 million, which was received in January 2010, and agreed to make additional payments of up to \$136.0 million based on the achievement of certain regulatory and commercialization milestones. Nippon Kayaku received exclusive rights to apaziquone for the treatment of non-muscle invasive bladder cancer in Asia (other than North and South Korea), including Japan and China. Under the terms of the Nippon Kayaku collaboration agreement, Nippon Kayaku will conduct the apaziquone clinical trials pursuant to a development plan. In addition, Nippon Kayaku will be responsible for all expenses relating to the development and commercialization of apaziquone in the Nippon Kayaku Territory.

Also in November 2009, we entered into collaboration agreement with Handok Pharmaceuticals of Korea for the development and commercialization of apaziquone for the treatment of non-muscle invasive bladder cancer in North and South Korea. Under the terms of the Handok collaboration agreement, Handok paid us an up-front payment of \$1.0 million, which was received in January 2010, and potential milestone payments totaling approximately \$19 million. The potential milestones will be based on the achievement of certain regulatory and commercialization milestones. Additionally, Handok will conduct the apaziquone clinical trials pursuant to a development plan and will

be responsible for all expenses relating to the development and commercialization of apaziquone in North and South Korea.

*Belinostat*: Belinostat is a histone deacytelase, or HDAC, inhibitor that is being studied in multiple clinical trials, both as a single drug and in combination with chemotherapeutic drugs for the treatment of various hematological and solid tumors.

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

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

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

In February 2010, we entered into a licensing and collaboration agreement with TopoTarget, for the development and commercialization of belinostat, pursuant to which TopoTarget and the Company agreed to a collaboration for the development and commercialization of belinostat. The agreement provides that we have the exclusive right to make, develop and commercialize belinostat in North America and India, with an option for China. The agreement also grants TopoTarget a co-promote option if and only if we do not maintain a minimum number (subject to adjustment for certain events outside of our control) of field personnel (as defined in the agreement) for a certain number of years post-approval of the PTCL indication.

In consideration for the rights granted to us under the license and collaboration agreement with TopoTarget, we paid TopoTarget an up-front fee of \$30.0 million which is recorded as research and development expense in the accompanying consolidated financial statements. In addition, we will pay up to \$313 million and one million shares of Spectrum common stock based on the achievement of certain development, regulatory and sales milestones, as well as certain royalties on net sales of belinostat.

Under the terms of the agreement, all development, including studies, will be conducted under a joint development plan and in accordance with a mutually agreed upon target product profile provided that we have final decision-making authority for all developmental activities in North America and India (and China upon exercise of the option for China) and TopoTarget has final decision-making authority for all developmental activities in all other jurisdictions. We will assume all responsibility for and future costs of the ongoing registrational PTCL trial while TopoTarget will assume all responsibility for and future costs of the ongoing Phase 2 CUP trial. We and TopoTarget will conduct future planned clinical trials pursuant to the joint development plan, of which we will fund 70% of the development costs and TopoTarget will fund 30% of the development costs.

The Company and TopoTarget will each pay 50% of the costs for chemical, pharmaceutical and other process development related to the manufacturing of the product that are incurred with a mutually agreed upon budget in the joint development plan. TopoTarget is responsible for supplying us with both clinical and commercial product.

**4. Cash, Cash Equivalents and Investments**

Cash, cash equivalents and investments in marketable securities, including long term bank certificates of deposits, totaled \$104.2 million and \$124.8 million as of December 31, 2010 and 2009, respectively. Long term bank certificates of deposit include a \$500,000 restricted certificate of deposit that collateralizes tenant

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

improvement obligations to the lessor of our principal offices. The following is a summary of such investments (in thousands):

	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Estimated Fair Value</b>	<b>Cash</b>	<b>Marketable Current</b>	<b>Security Long Term</b>
<b>December 31, 2010</b>							
Cash and cash equivalents	\$ 53,557	\$	\$	\$ 53,557	\$ 53,557	\$	\$
Bank CDs (including restricted certificate of deposit of \$500)	29,985			29,985		21,416	8,569
Money market currency funds	15,488			15,488		15,488	
U.S. Government securities	2,909			2,909		2,909	
Corporate debt securities	2,304			2,304		2,304	
Other securities (included in other assets)	35		9	26			26
Total investments	\$ 104,278	\$	\$ 9	\$ 104,269	\$ 53,557	\$ 42,117	\$ 8,595
<b>December 31, 2009</b>							
Cash and cash equivalents	\$ 82,336	\$	\$	\$ 82,336	\$ 82,336	\$	\$
Bank CDs	20,948			20,948		12,260	8,688
Money market currency funds	4,800			4,800		4,800	
U.S. Government securities	16,542			16,542		13,792	2,750
Corporate debt securities	153			153		153	
Other securities (included in other assets)	47		12	35			35
Total investments	\$ 124,826	\$	\$ 12	\$ 124,814	\$ 82,336	\$ 31,005	\$ 11,473

**5. Inventories**

Inventories consist of the following:

**December 31,  
2010      2009**

	(\$ in 000 s)	
Raw materials	\$ 962	\$ 280
Finished goods	3,272	2,950
	\$ 4,234	\$ 3,230

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Property and equipment consist of the following:

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
	<b>(\$ in 000 s)</b>	
Computers and software	\$ 1,299	\$ 1,195
Lab and media equipment	892	724
Office furniture and equipment	889	697
Leasehold improvements	2,742	1,255
Assets held under capital lease obligations	146	146
	5,968	4,017
Less accumulated depreciation and amortization	(2,810)	(2,089)
	\$ 3,158	\$ 1,928

Included in accumulated depreciation and amortization is \$88,000 and \$29,000 of amortization related to assets held under capital lease obligations at December 31, 2010 and 2009, respectively.

**7. Accounts Payable and Other Accrued Obligations**

Accounts payable and other accrued obligations consisted of the following:

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
	<b>(\$ in 000 s)</b>	
Trade payables	\$ 8,734	\$ 5,611
Allowance for rebates	14,474	388
Accrued product royalty	4,026	1,911
Allowance for returns	2,000	1,176
Accrued data and distribution fees	1,874	213
Allowance for chargebacks	350	851
Other accrued obligations	7,246	6,456
	\$ 38,704	\$ 16,606





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

For the periods ended December 31, 2010 and 2009, the following is a roll forward of the provisions for product returns, rebates, data and distribution fees and chargeback allowances (in thousands):

	<b>Chargebacks</b>	<b>Rebates</b>	<b>Returns</b>	<b>Data and Distribution Fees</b>
<b>Period ended December 31, 2010:</b>				
Balances at beginning of the period	\$ 851	388	\$ 1,176	\$ 213
Add provisions:	862	14,721	3,540	3,029
Less: Credits or actual allowances:	(1,363)	(635)	(2,716)	(1,368)
Balances at the close of the period	\$ 350	\$ 14,474	\$ 2,000	\$ 1,874
<b>Period ended December 31, 2009:</b>				
Balances at beginning of period	\$ 1,439	\$	\$ 3,144	\$
Add provisions:	3,454	469	95	1,212
Less: Credits or actual allowances:	(4,042)	(81)	(2,063)	(999)
Balances at the close of the period	\$ 851	\$ 388	\$ 1,176	\$ 213

**8. Income Taxes**

Significant components of the provision for income taxes consist of the following:

	<b>For the Years Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
	<b>(\$ in 000 s)</b>		
Current:			
Federal	\$ (128)	\$ 78	
State	82	343	\$ 5
Foreign	3		
	\$ (43)	\$ 421	\$ 5
Deferred:			
Federal			
State			
Foreign			
Total	\$ (43)	\$ 421	\$ 5



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

The income tax provision differs from that computed using the federal statutory rate applied to income before taxes as follows:

	2010	2009	2008
		(\$ in 000 s)	
Tax benefit computed at the federal statutory rate	\$ (16,658)	\$ (6,697)	\$ (6,086)
State tax, net of federal benefit	(2,082)	(981)	(1,039)
Expired tax attributes	32,236	8,097	
Credits	(406)	(1,644)	
Common stock warrant liability	(928)	(2,745)	(432)
Stock based compensation	1,397	1,533	
Permanent items and other	1,548	(737)	
Valuation allowance	(15,150)	3,595	7,562
Income tax provision	\$ (43)	\$ 421	\$ 5

Significant components of the Company's deferred tax assets as of December 31, 2010 and 2009 are shown below. A valuation allowance has been recognized to offset the net deferred tax assets as realization of such deferred tax assets has not met the more likely than not threshold.

	2010	2009
	(\$ in 000 s)	
Deferred tax assets:		
Net operating loss carry forwards	\$ 36,279	\$ 58,597
Research credits	7,044	10,230
Stock based compensation	2,535	2,641
Deferred revenue	9,611	12,839
Depreciation and amortization differences	14,451	1,466
Other, net	1,914	1,211
Valuation allowance	(71,834)	(86,984)
	\$	\$

At December 31, 2010, the Company has federal and state net operating loss carry forwards of approximately \$92 million and \$81 million, respectively. The Company has approximately \$1.9 million of foreign loss carry forwards that begin to expire in 2011. The federal and state loss carry forwards begin to expire in 2018 and 2016, respectively, unless previously utilized. At December 31, 2010, the Company has federal and state research and development tax credits of approximately \$6.7 million and \$1.5 million, respectively. The federal research tax credit begins to expire in 2023 unless previously utilized. The state research and development credits have an indefinite

carryover period.

The utilization of the net operating loss and research and development tax credit carry forwards is subject to an annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, and similar state tax provisions due to the amount of the net operating loss and research and development tax credits carry forwards and other deferred tax assets that can be utilized to offset future taxable income and tax, respectively.

The Company completed its most recent Section 382 study in December of 2010. As a result of the ownership changes from that study, we removed approximately \$27.9 million of deferred tax assets relating to net operating losses and approximately \$4.4 million of deferred tax assets related to research and development credits from the table of deferred taxes presented above as these deferred tax assets are expected to expire unutilized. The Company

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

will continue to monitor for additional ownership changes as another change could result in additional net operating losses and credits expiring unutilized in the future.

In July 2006, the Financial Accounting Standards Board, or FASB, issued authoritative guidance for the accounting for uncertainty in income taxes, which prescribes a recognition threshold and measurement process for recording in the financial statements uncertain tax positions taken or expected to be taken in a tax return. Additionally, the authoritative guidance addresses the derecognition, classification, accounting in interim periods and disclosure requirements for uncertain tax positions. Only tax positions that meet the more likely than not recognition threshold at the effective date may be recognized.

The following table summarizes activity related to our gross unrecognized tax benefits:

	<b>2010</b> <b>(\$ in 000 s)</b>
Balance at Beginning of year	
Adjustments related to prior year tax positions	1,310
Increases related to current year tax positions	387
Decreases due to settlements	
Decreases due to IRC Section 382 limitation	
Balance at end of year	1,697

There were no unrecognized tax benefits as of December 31, 2009 and 2008.

During 2010, the Company continues to believe that its tax positions meet the more likely than not standard required under the recognition phase of the authoritative guidance. However, it considers the amounts and probabilities of the outcomes that can be realized upon ultimate settlement with the tax authorities and determined unrecognized tax benefits primarily related to credits should be established as noted in the summary rollforward above.

Approximately \$42,000 of the total unrecognized tax benefits as of December 31, 2010, would reduce our annual effective tax rate if recognized. Additional amounts in the summary rollforward could impact our effective tax rate if we did not maintain a full valuation allowance on our net deferred tax assets.

We do not expect our unrecognized tax benefits to change significantly over the next 12 months. With a few exceptions, the Company is no longer subject to U.S. federal, state and local income tax examinations for years before 2006. The Company's policy is to recognize interest and/or penalties related to unrecognized tax benefits in income tax expense in the consolidated statements of operations.

On November 1, 2010 we received notice that we were awarded grants totaling \$978,000 under the Qualifying Therapeutic Discovery Project, or QTDP, Program administered under section 48D of the Internal Revenue Code, of which we recorded \$978,000 in December 2010 as other income in the consolidated financial statements. The QTDP tax credit is provided under new section 48D of the Internal Revenue Code, enacted as part of the Patient Protection

and Affordable Care Act of 2010 (P.L. 111-148).

## **9. Commitments and Contingencies**

### ***Facility and Equipment Leases***

We sublease our principal executive office in Henderson, Nevada under a non cancelable operating lease expiring April 30, 2014. We also lease our research and development facility in Irvine, California under a non cancelable operating lease expiring June 30, 2016. The lease agreement contains certain scheduled rent increases which are accounted for on a straight-line basis.

As part of our Irvine facility lease renewal in 2009, the landlord agreed to contribute up to approximately \$1.5 million toward the cost of tenant improvements. The tenant improvements were completed in the second

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

quarter of 2010 at an aggregate cost of approximately \$1.4 million, of which, \$451,000 is being financed. This landlord contribution is being amortized on a straight-line basis over the term of the lease as a reduction to rent expense.

The Company has acquired certain furniture, fixtures and equipment under capital leases that are payable in various scheduled monthly installments through December 2012.

Future minimum lease payments are as follows:

	<b>Operating Leases</b>	<b>Capital Leases</b>
	(\$ in	000 s)
Year ending December 31,		
2011	\$ 568	\$ 45
2012	601	45
2013	632	
2014	582	
2015	570	
Thereafter	292	
	\$ 3,245	\$ 90

Rent expense for the years ended December 31, 2010, 2009 and 2008 was approximately \$640,000, \$593,000, and \$583,000, respectively.

***Licensing Agreements***

Almost all of our drug candidates are being developed pursuant to license agreements that provide us with rights to certain territories to, among other things, develop, sublicense, and sell the drugs. We 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 represents typical milestone events for the Company: conclusion of Phase 2 or commencement of Phase 3 clinical trials; filing of new drug applications in each of the United States, Europe and Asia; and approvals from each of the regulatory agencies in those jurisdictions.

Given the uncertainty of the drug development and regulatory approval process, we are unable to predict with any certainty when any of the milestones will occur, if at all. Accordingly, the milestone payments represent contingent obligations that will be recorded as expense when the milestone is achieved. While it is difficult to predict when milestones will be achieved, we estimate that if all of our contingent milestones are successfully achieved within our anticipated timelines, our potential contingent cash development and regulatory milestone obligations, are \$204 million as of December 31, 2010. In connection with the development of certain in-licensed drug products, we anticipate the occurrence of certain of these milestones during 2011. Upon successful achievement of these milestones, we will likely become obligated to pay up to approximately \$6.1 million during 2011, payable in cash or stock at our discretion.

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

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

***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 radio-pharmacies, distributors, 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. 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 be 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.

***Supply Agreements***

In connection with our acquisition of Zevalin, RIT assumed a supply agreement with Biogen Idec Inc., or 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.

In 2010, we have a single source API supplier as well as a single source finished product manufacturer for Fusilev. In 2011, we began qualifying additional contract manufacturers.

***Employment Agreement***

We have entered into an employment agreement with Dr. Rajesh C. Shrotriya, our President and Chief Executive Officer, which expires January 2, 2012. The employment agreement automatically renews for subsequent 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 new term. The employment agreement requires Dr. Shrotriya to devote his full working time and effort to our business and affairs 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 our Board of Directors.

***Litigation***

We are involved with various legal matters arising in the ordinary course of our 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 consolidated results of operations, cash flows or financial condition.

**10. Stockholder's 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 50,000,000 shares to 100,000,000 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

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

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

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***

**Stockholder Rights Agreement**

In December 2000, we adopted a stockholder rights agreement pursuant to which we distributed rights to purchase units of our Series B Junior Participating Preferred Stock ( Series B Preferred Stock ). On November 29, 2010 our Board of Directors approved a replacement rights agreement, effective December 13, 2010, that replaced the stockholder rights agreement which was originally adopted in 2000 and expired on December 13, 2010. The new replacement rights agreement will extend until December 13, 2020 the framework of the expired rights plan. A stockholder rights agreement is designed to deter coercive, unfair, or inadequate takeovers and other abusive tactics that might be used in an attempt to gain control of Spectrum Pharmaceuticals without paying all stockholders a fair price for their shares. A stockholder rights agreement will not prevent takeovers at a full and fair price, but rather is designed to deter coercive takeover tactics and to encourage anyone attempting to acquire Spectrum Pharmaceuticals to first negotiate with the Board of Directors.

Under the terms of the new stockholder rights plan, 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.

**Series E Preferred Stock**

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, or the Series E Preferred Stock, convertible into 4,000,000 shares of common stock, and 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. As of December 31, 2010 and 2009, 26 and 68 shares of Series E Preferred Stock, convertible into 52,000 and 136,000 shares of common stock, respectively, were outstanding. No dividends are payable on the Series E Preferred Stock. Pursuant to certain provisions of the Certificate of Designation, Rights and Preferences of the Series E Preferred Stock, we have the option to redeem all of the unconverted Series E Preferred Stock outstanding at the end of a 20-day trading period if, among other things, in that period the common stock of the Company trades above \$12.00 per share.

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation, before any distribution of assets of the Corporation shall be made to the common stockholders, the holders of the Series 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.

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

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

***Common Stock Issuances for Cash***

On May 6, 2009, we sold an aggregate of 432,200 shares of common stock to certain of our employees at a purchase price of \$2.70 per share, which was the closing price of our common stock on May 6, 2009. This offering resulted in gross proceeds to us of approximately \$1.2 million. The investors in this offering included Dr. Rajesh Shrotriya, M.D., our Chairman, President and Chief Executive Officer, and Shyam Kumaria, our Vice President of Finance.

Dr. Shrotriya purchased 290,000 shares of common stock and Mr. Kumaria purchased 85,000 shares of common stock. We decided to conduct this offering with certain of our employees to allow such employees to invest their personal cash directly into the Company at the current fair market value of our stock. The purchase agreements include provisions prohibiting the investors from disposing of the shares of common stock purchased in the offering for ninety days. The offering was approved by the Placement Committee of the Board of Directors. In addition, the Audit Committee of the Board of Directors approved the offering pursuant to our Related Party Transaction Policies and Procedures.

On May 26, 2009, we sold 3,913,895 shares of our common stock at a purchase price of \$5.11 per share for net cash proceeds of approximately \$19 million, after placement agent fees and other offering costs of approximately \$1 million. In connection with this offering, 1,956,947 common stock warrants exercisable at \$5.11 between November 27, 2009 and February 25, 2010, were issued to the investors. All warrants expired unexercised as of February 25, 2010.

On June 15, 2009, we sold 1,715,266 shares of our common stock at a purchase price of \$5.83 per share for net cash proceeds of approximately \$9.5 million, after placement agent fees and other offering costs of approximately \$0.5 million. In connection with this offering, 857,633 common stock warrants exercisable at \$5.83 between December 15, 2009 and March 15, 2010, were issued to the investors. All warrants expired unexercised as of March 15, 2010.

On June 30, 2009, we sold 2,936,037 shares of our common stock at a purchase price of \$7.15 per share for net cash proceeds of approximately \$20 million, after placement agent fees and other offering costs of approximately \$1 million. In connection with this offering, 1,468,020 common stock warrants exercisable at \$7.10 between December 30, 2009 and March 30, 2010, were issued to the investors. All warrants expired unexercised as of March 30, 2010.

On September 18, 2009, we sold 6,622,517 shares of our common stock at a purchase price of \$7.55 per share for net cash proceeds of approximately \$47.5 million, after placement agent fees and other offering costs of approximately \$2.5 million. In connection with this offering, 2,649,007 common stock warrants exercisable at \$7.55 between March 22, 2010 and June 21, 2010, were issued to the investors. All warrants expired unexercised as of June 21, 2010.

**Other Equity Transactions**

Pursuant to the terms of the April 2006 asset purchase agreement with Targent, LLC, upon achievement of certain regulatory and sales milestones Targent is eligible to receive payments in the form of shares of the Company's common stock and/or cash. 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. During the three years ended December 31, 2010, we issued shares of common stock, for achievement of certain regulatory milestones, as follows. The fair value of the issued stock was recorded as

stock-based research and development expense for the period in which the milestone was achieved:

March 2008: 125,000 shares with a fair value of \$305,000.

March 2009: 125,000 shares with a fair value of \$185,000.

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

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 apaziqone. The fair value of the stock, \$74,000, was recorded as a stock-based research and development expense for the year ended December 31, 2008.

In August 2009, we acquired 100% of the rights to RenaZorb<sup>®</sup> and Renalin<sup>®</sup>, lanthanum-based nanotechnology compounds with potent and selective phosphate binding properties, for all uses pursuant to an amended and restated agreement that we entered into with Altair Nanomaterials, Inc. and Altair Nanotechnologies. In 2005, the Company had acquired the worldwide license from Altair to develop and commercialize Altair's lanthanum-based nanotechnology compounds and related technology for all human therapeutic uses. The August 2009 acquisition expanded the worldwide, exclusive license to include all uses. In conjunction with the expanded license, Altair assigned all intellectual property associated with RenaZorb<sup>®</sup> (associated with human uses), Renalin<sup>®</sup> (associated with animal or veterinarian use), its lanthanum-based nanotechnology and all of its other life sciences research and development to us. In consideration, we issued 113,809 shares of our common stock, with a then fair value of approximately \$750,000.

In July 2010, we issued 425,000 shares of our common stock in exchange for certain intellectual property and drug assets. The fair market value of the stock, approximately \$1.7 million, was charged to research and development during the third quarter of 2010. In December 2010, we issued 326,956 shares of our common stock in exchange for intellectual property and drug assets. The fair market value of the stock, approximately \$1.4 million, was charged to research and development during the fourth quarter of 2010.

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

As of December 31, 2010, approximately 12.6 million shares of common stock were issuable upon conversion or exercise of rights granted under prior financing arrangements, stock options and warrants, as follows:

Conversion of Series E preferred shares	52,000
Exercise of stock options	8,397,094
Exercise of warrants	4,192,312
<b>Total shares of common stock reserved for future issuances</b>	<b>12,641,406</b>

Of the warrants outstanding at December 31, 2010, 3,747,312 warrants relate to 2005 issuances which expire in September 2011 if not exercised.

**Table of Contents****Spectrum Pharmaceuticals, Inc. and Subsidiaries****Notes to Consolidated Financial Statements (Continued)****Warrant 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 December 2015. A summary of warrant activity is as follows:

		<b>Number of Shares</b>	<b>Weighted Average Exercise Price</b>
Outstanding	December 31, 2007	9,652,051	\$ 6.51
Issued		50,000	1.79
Forfeited		(157,450)	6.62
Expired		(4,100,046)	5.43
Outstanding	December 31, 2008	5,444,555	7.28
Issued		6,931,607	6.55
Repurchased		(95,238)	6.62
Expired		(1,252,005)	10.03
Outstanding	December 31, 2009	11,028,919	6.52
Issued		275,000	5.59
Forfeited		(180,000)	5.16
Expired		(6,931,607)	6.55
Outstanding	December 31, 2010	4,192,312	\$ 6.45
Exercisable	December 31, 2010	4,142,312	\$ 6.48

The following table summarizes information with respect to warrants outstanding and exercisable at December 31, 2010:

<b>Exercise Price</b>	<b>Number Outstanding</b>	<b>Weighted- Average Remaining Contractual Life (Years)</b>	<b>Weighted- Average Exercise Price</b>	<b>Number Exercisable</b>	<b>Weighted- Average Exercise Price</b>
\$1.00 - 2.50	50,000	2.3	\$ 1.79	50,000	\$ 1.79
\$2.51 - 5.00	75,000	4.5	\$ 3.82	25,000	\$ 3.82
\$5.01 - 6.00	120,000	2.7	\$ 5.13	120,000	\$ 5.13



\$6.01 - 7.00	3,947,312	0.9	\$	6.60	3,947,312	\$	6.60
	4,192,312				4,142,312		

Of the warrants outstanding at December 31, 2010, 3,747,312 warrants relate to 2005 issuances which expire in September 2011 if not exercised.

## 11. Share-Based Compensation

### *Stock Options*

We have three stock incentive plans: the 1997 Stock Incentive Plan, or the 1997 Plan, the 2003 Amended and Restated Incentive Award Plan, or the 2003 Plan and the 2009 Incentive Award Plan, or the 2009 Plan which was approved by our stockholders in June 2009 (collectively, the Plans). The 2003 Plan authorizes the grant of incentive awards, including stock options, for the purchase of up to a total of 10,000,000 shares. Subsequent to the adoption of the 2009 Plan, no new options have been granted pursuant the 2003 Plan or 1997 Plan. The Board and

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

the stockholders approved 10,000,000 shares of common stock available for issuance under the 2009 Plan. Beginning on January 1, 2010, and each January 1st thereafter, the number of shares of common stock available for issuance under the 2009 Plan shall increase by the greater of (i) 2,500,000 and (ii) a number of shares such that the total number of shares of common stock available for issuance under the Plan shall equal 30% of the then number of shares of common stock issued and outstanding. As of December 31, 2010, approximately 10.8 million incentive awards were available for grant under the 2009 Plan.

During each of the three years in the period ended December 31, 2010, we granted stock options at exercise prices equal to or greater than the quoted market price of our common stock on the grant date. The fair value of each option grant was estimated on the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions:

	<b>Year Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
Expected life (years)	4.93	5.0	5.0
Risk-free interest rate	1.04% - 2.75%	2.27%	2.66%
Volatility	70.7%	72.4%	65.9%
Dividend yield	0%	0%	0%

The expected option life assumption is estimated based on actual historical exercise activity and assumptions regarding future exercise activity of unexercised, outstanding options. 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 Company recognizes shared-based compensation cost over the vesting period using the straight-line single option method. Share-based compensation expense is recognized only for those awards that are ultimately expected to vest. An estimated forfeiture rate has been applied to unvested awards for the purpose of calculating compensation cost. Forfeitures were estimated based on historical experience. These estimates are revised, if necessary, in future periods if actual forfeitures differ from the estimates. Changes in forfeiture estimates impact compensation cost in the period in which the change in estimate occurs.

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

A summary of stock option activity is as follows:

	Number of Shares	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding December 31, 2007	6,482,260	\$ 5.91		
Granted (weighted-average fair value of \$1.19 per share)	2,148,000	2.10		
Forfeited	(294,521)	4.38		
Expired	(1,219,967)	6.08		
Outstanding December 31, 2008	7,115,772	4.80		
Granted (weighted-average fair value of \$2.87 per share)	4,141,000	4.70		
Exercised	(488,750)	2.58		
Forfeited	(551,130)	5.35		
Cancelled	(2,165,372)	7.75		
Expired	(106,275)	4.62		
Outstanding December 31, 2009	7,945,245	4.04		
Granted (weighted-average fair value of \$2.65 per share)	3,350,070	4.26		
Exercised	(1,135,340)	3.21		
Forfeited	(1,347,786)	4.04		
Expired	(415,095)	5.45		
Outstanding December 31, 2010	8,397,094	\$ 4.17	7.4	\$ 22,747,151
Vested (exercisable) December 31, 2010	5,157,935	\$ 4.12	6.6	\$ 14,250,135
Unvested (unexercisable) December 31, 2010	3,239,159	\$ 4.26	8.7	\$ 8,492,016

The following table summarizes information with respect to stock options outstanding and exercisable at December 31, 2010:

Weighted- Average Remaining	Weighted- Average	Weighted- Average
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<b>Exercise Price</b>	<b>Number Outstanding</b>	<b>Contractual Life (Years)</b>	<b>Exercise Price</b>	<b>Number Exercisable</b>	<b>Exercise Price</b>
\$0.92 - 1.40	110,000	2.6	\$ 1.09	104,176	\$ 1.08
\$1.43 - 2.47	1,180,665	6.7	\$ 1.61	810,750	\$ 1.64
\$2.49 - 3.77	1,019,542	7.2	\$ 2.70	929,224	\$ 2.65
\$3.82 - 5.79	4,353,942	7.8	\$ 4.45	2,206,612	\$ 4.67
\$5.80 - 8.33	1,732,945	7.4	\$ 6.28	1,107,173	\$ 6.35
	8,397,094			5,157,935	

Due to our rapid growth over the past few years and personnel turnover rate, in early 2009, we had a limited number of shares available for future grant under the 2003 Plan. Primarily in order to increase the pool of shares available for future grant under such plan, we conducted a tender offer to eligible employees to acquire options

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

granted to certain employees of the Company pursuant to the 1997 Plan and 2003 Plan, and which were outstanding at March 23, 2009. Eligible employees were employees of Spectrum or its subsidiaries who held options with exercise prices in excess of \$5.00. The cash amount offered to those employees was \$0.01 for options with an exercise price over \$10.00 and \$1.15 for the options with an exercise price between \$5.00 and \$9.99.

On April 23, 2009, a total of 2,165,372 shares underlying eligible options were tendered by eligible employees and were accepted by us, representing 73% of the shares underlying eligible options that were eligible to be tendered in the offer. We made a cash payment in the aggregate of approximately \$2.5 million to the eligible employees participating in the offer.

As of December 31, 2010, there was unrecognized compensation expense of \$6.9 million related to unvested stock options, which we expect to recognize over a weighted average period of 2.4 years. The aggregate intrinsic value of the options outstanding and options exercisable as of December 31, 2010 was \$22.7 million and \$14.3 million, respectively. The weighted average grant date fair value of stock options granted during the year ended December 31, 2010 was \$2.65.

**Restricted Stock**

A summary of restricted stock activity is as follows:

		<b>Number of Restricted Shares</b>		<b>Weighted Average Grant Date Fair Value</b>
Non-vested	December 31, 2007	277,500	\$	5.03
Granted		372,500		1.65
Vested		(272,500)		3.17
Forfeited				
Non-vested	December 31, 2008	377,500		3.04
Granted		262,500		1.86
Vested		(284,375)		2.82
Forfeited		(2,500)		5.45
Non-vested	December 31, 2009	353,125		2.32
Granted		390,000		4.48
Vested		(261,500)		3.58
Forfeited		(122,125)		1.87
Non-vested	December 31, 2010	359,500	\$	3.96

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, 2010, 2009 and 2008, the stock-based charge in connection with the expensing of restricted stock awards was approximately \$974,000, \$665,000 and \$862,000, respectively. As of December 31, 2010, there was approximately \$1.1 million of unrecognized stock-based compensation cost related to non-vested restricted stock awards, which is expected to be recognized over a weighted average period of 2.0 years.

**Table of Contents****Spectrum Pharmaceuticals, Inc. and Subsidiaries****Notes to Consolidated Financial Statements (Continued)*****401(k) Plan Matching Contribution***

During the years ended December 31, 2010, 2009 and 2008 we issued 136,121, 139,795, and 166,430 shares of common stock as the Company's match of approximately \$598,000, \$448,000, and \$274,000 on the 401(k) contributions of our employees during those periods.

***Employee Stock Purchase Plan***

Effective July 2009, we adopted the 2009 Employee Stock Purchase Plan, or Purchase Plan. The Purchase Plan provides our eligible employees with an incentive by providing a method whereby they may voluntarily purchase shares of our common stock upon terms described in the Purchase Plan. The Purchase Plan is designed to be operated on the basis of six consecutive month offering periods commencing January 1 and July 1 of each year. The Purchase Plan provides that eligible employees may authorize payroll deductions to purchase shares of our common stock at 85% of the fair market value of common stock on the first or last day of the applicable purchase period. A participant may purchase a maximum of 50,000 shares of common stock during a 6-month offering period, not to exceed \$25,000 worth of stock on the offering date during each plan year. The Purchase Plan terminates in 2019.

A total of 5,000,000 shares of common stock are authorized for issuance under the Purchase Plan, and as of December 31, 2010, 233,998 shares have been issued under the Purchase Plan. Beginning on January 1, 2010, and each January 1st thereafter, the number of shares of common stock available for issuance under the Purchase Plan shall increase by an amount equal to the lesser of (i) 1,000,000 shares or (ii) an amount determined by the Purchase Plan Administrator. However, in no event shall the number of shares of common stock available for future sale under the Purchase Plan exceed 10,000,000 shares, subject to capitalization adjustments occurring due to dividends, splits, dissolution, liquidation, mergers, or changes in control.

The Purchase Plan replaces our 2001 Employee Stock Purchase Program, which was terminated by the Board effective June 26, 2009. Total Purchase Plan stock based compensation expense for the years ended December 31, 2010 and 2009 was \$230,000 and \$44,000, respectively.

**12. Quarterly Financial Data (Unaudited)**

A summary of quarterly financial data (unaudited) is as follows:

	<b>Quarter Ended</b>			
	<b>March 31</b>	<b>June 30</b>	<b>September 30</b>	<b>December 31</b>
<b>Year ended December 31, 2010</b>				
Total revenues	\$ 11,089	\$ 12,343	\$ 16,735	\$ 33,946
Operating (loss) income	\$ (40,492)	\$ (12,266)	\$ (6,880)	\$ 6,742
Net (loss) income	\$ (39,014)	\$ (9,676)	\$ (4,594)	\$ 4,440
Net (loss) income per share, basic	\$ (0.80)	\$ (0.20)	\$ (0.09)	\$ 0.09
Net (loss) income, diluted	\$ (0.80)	\$ (0.20)	\$ (0.09)	\$ 0.08
<b>Year ended December 31, 2009</b>				
Total revenues	\$ 14,163	\$ 8,141	\$ 7,101	\$ 8,620

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Operating (loss)	\$ (626)	\$ (9,831)	\$ (8,761)	\$ (9,290)
Net loss attributable to non-controlling interest	\$ 1,146	\$	\$	\$
Net income (loss)	\$ 115	\$ (29,819)	\$ 474	\$ 10,184
Net income (loss) per share basic	\$ 0.00	\$ (0.87)	\$ 0.01	\$ 0.21
Net income (loss) per share diluted	\$ 0.00	\$ (0.87)	\$ (0.07)	\$ 0.20

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**Spectrum Pharmaceuticals, Inc. and Subsidiaries**

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

Earnings per basic and diluted shares are computed independently for each of the quarters presented based on basic and diluted shares outstanding per quarter and, therefore, may not sum to the totals for the year.

**13. Subsequent Events**

In January 2011, we signed a letter of agreement with Viropro, Inc., for the development of a biosimilar version of the monoclonal antibody drug rituximab. Biosimilars, or follow-on biologics, are terms used to describe officially-approved subsequent versions of innovator biopharmaceutical products made by a different sponsor following patent and exclusivity expiry. Terms of the agreement call for a nominal upfront payment and additional payments based on certain development and regulatory milestones should the Company elect to continue development efforts.

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**Table of Contents****Index to Exhibits**

<b>Exhibit No.</b>	<b>Description</b>
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.)
2.4#	Limited Liability Company Interest Assignment Agreement, dated as of March 15, 2009, by and between the Registrant and Cell Therapeutics, Inc. (Filed as Exhibit 2.1 to Form 10-Q, as filed with the Securities and Exchange Commission on May 15, 2009, and incorporated herein by reference.)
3.1+	Amended Certificate of Incorporation, as filed.
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, 2010, 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 Rights of Stockholder Rights Plan. (Filed as Exhibit 4.1 to Form 8-K, as filed with the Securities and Exchange Commission on December 13, 2010, and incorporated herein by reference.)
4.2	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.)
4.3	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.)
4.4	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.)
4.5	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.)
10.1+	Sublease Agreement, dated as of December 2, 2010, between the Registrant and Del Webb Corporation.
10.2	Industrial Lease Agreement, dated as of January 16, 1997, between the Registrant and the Irvine Company. (Filed as Exhibit 10.11 to Form 10-KSB, as filed with the Securities and Exchange Commission on March 31, 1997, and incorporated herein by reference.)
10.3	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.)
10.4	

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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.)

- 10.5 Common Stock and Warrant Purchase Agreement, dated as of April 20, 2004, 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 April 23, 2004, and incorporated herein by reference.)
- 10.6#+ Amended and Restated License and Collaboration Agreement by and between the Registrant and Aeterna Zentaris GmbH (formerly Zentaris GmbH), dated as of November 5, 2010.
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<b>Exhibit No.</b>	<b>Description</b>
10.7*	Form of Stock Option Agreement under the 2003 Amended and Restated Incentive Award Plan. (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.)
10.8#	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.)
10.9*	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, as filed with the Securities and Exchange Commission on May 10, 2005, and incorporated herein by reference.)
10.10*	Restricted Stock Award Grant Notice and Restricted Stock Award Agreement under the 2003 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.)
10.11#	License Agreement between the 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.)
10.12*	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.)
10.13#	Agreement by and between the 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.)
10.14*	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.)
10.15#	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, and incorporated herein by reference.)
10.16*	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.)
10.17*	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.)
10.18*+	Amendment Number One to Consulting Agreement by and between the Registrant and Luigi Lenaz, M.D., effective as of March 16, 2010.
10.19*+	Amendment Number Two to Consulting Agreement by and between the Registrant and Luigi Lenaz, M.D., effective as of July 2, 2010.
10.20*	Form of Indemnity Agreement of the Registrant. (Filed as Exhibit 10.32 to Form 10-K, as filed with the Securities and Exchange Commission on March 31, 2009, and incorporated herein by reference.)
10.21#	License, Development, Supply and Distribution Agreement, dated October 28, 2008, by and among the Registrant, Allergan Sales, LLC, Allergan USA, Inc. and Allergan, Inc. (Filed as Exhibit 10.33 to Form 10-K, as filed with the Securities and Exchange Commission on March 31, 2009, and incorporated herein by reference.)
10.22*	2009 Employee Stock Purchase Plan. (Filed as Exhibit 99.1 to Form S-8, as filed with the Securities and Exchange Commission on June 29, 2009, and incorporated herein by reference.)

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- 10.23\* 2009 Incentive Award Plan. (Filed as Exhibit 99.2 to Form S-8, as filed with the Securities and Exchange Commission on June 29, 2009, and incorporated herein by reference.)
  - 10.24\* 2003 Amended and Restated Incentive Award Plan. (Filed as Exhibit 10.1 to Form 8-K, as filed with the Securities and Exchange Commission on July 2, 2009, and incorporated herein by reference.)
  - 10.25 Fourth Amendment, dated July 29, 2009, to Industrial Lease Agreement dated as of January 16, 1997 by and between the Registrant and the Irvine Company. (Filed as Exhibit 10.29 to Form 10-K, as filed with the Securities and Exchange Commission on April 5, 2010, and incorporated herein by reference.)
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<b>Exhibit No.</b>	<b>Description</b>
10.26*	Term Sheet for 2009 Incentive Award Plan Stock Option Award. (Filed as Exhibit 10.8 to Form 10-Q, as filed with the Securities and Exchange Commission on August 13, 2009, and incorporated herein by reference.)
10.27*	Term Sheet for 2009 Incentive Award Plan, Nonqualified Stock Option Award Awarded to Non-Employee Directors. (Filed as Exhibit 10.9 to Form 10-Q, as filed with the Securities and Exchange Commission on August 13, 2009, and incorporated herein by reference.)
10.28*	Term Sheet for 2009 Incentive Award Plan, Restricted Stock Award. (Filed as Exhibit 10.10 to Form 10-Q, as filed with the Securities and Exchange Commission on August 13, 2009, and incorporated herein by reference.)
10.29#	License Agreement, dated November 6, 2009, by and between the Registrant and Nippon Kayaku Co., Ltd. (Filed as Exhibit 10.36 to Form 10-K, as filed with the Securities and Exchange Commission on April 5, 2010, and incorporated herein by reference.)
10.30#	License and Collaboration Agreement, dated February 2, 2010, by and between the Registrant and TopoTarget A/S. (Filed as Exhibit 10.37 to Form 10-K, as filed with the Securities and Exchange Commission on April 5, 2010, and incorporated herein by reference.)
10.31	Asset Purchase Agreement, dated August 15, 2007, by and between Cell Therapeutics, Inc. and Biogen Idec Inc. (Filed as Exhibit 10.1 to Cell Therapeutics, Inc.'s Form 8-K, No. 001-12465, as filed with the Securities and Exchange Commission on August 21, 2007, and incorporated herein by reference.)
10.32	First Amendment to Asset Purchase Agreement, dated December 9, 2008, by and between Cell Therapeutics, Inc. and Biogen Idec Inc. (Filed as Exhibit 10.48 to Cell Therapeutics, Inc.'s Form 10K, No. 001-12465, as filed with the Securities and Exchange Commission on March 16, 2009, and incorporated herein by reference.)
10.33	Supply Agreement, dated December 21, 2007, by and between Cell Therapeutics, Inc. and Biogen Idec Inc. (Filed as Exhibit 10.2 to Cell Therapeutics, Inc.'s Form 8-K, No. 001-12465, as filed with the Securities and Exchange Commission on December 31, 2007, and incorporated herein by reference.)
10.34#+	First Amendment to Supply Agreement, dated December 15, 2008, by and between Cell Therapeutics, Inc. and Biogen Idec Inc.
10.35+	Security Agreement, dated December 15, 2008, by and between RIT Oncology, LLC and Biogen Idec Inc.
16.1	Letter from Kelly and Company to the Securities and Exchange Commission, dated December 3, 2009. (Filed as Exhibit 16.1 to Form 8-K, as filed with the Securities and Exchange Commission on December 8, 2009, and incorporated herein by reference.)
21+	Subsidiaries of Registrant.
23.1+	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
23.2+	Consent of Kelly & Company, Independent Registered Public Accounting Firm.
24.1	Power of Attorney (included in the signature page.)
31.1+	Certification of Principal Executive Officer, pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.
31.2+	Certification of Principal Financial Officer, pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.
32.1+	Certification of Principal 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 Principal Financial Officer, 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.