SPECTRUM PHARMACEUTICALS INC
Form 10-K
March 02, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2011

¨ **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	**93-0979187**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

11500 South Eastern Avenue, Suite 240

Henderson, Nevada 89052

(Address of principal executive offices)

(702) 835-6300

(Registrant s telephone number, including area code)

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

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, $0.001 par value	The NASDAQ Stock Market, LLC
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 x

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 x

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 x 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 x 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 x

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 x

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2011 was $476,678,158 based on the closing sale price of such common equity on such date.

As of February 16, 2012 there were 59,271,035 shares of the registrant s common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s Proxy Statement for the registrant s 2012 Annual Meeting of Shareholders, to be filed on or before April 30, 2012, are incorporated by reference into Part III, Items 10-14 of this Annual Report on Form 10-K.

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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, our, Spectrum and Spe Pharmaceuticals refer to Spectrum Pharmaceuticals, Inc. and its subsidiaries and other consolidated entities, as a consolidated entity. We primarily conduct all our activities as Spectrum Pharmaceuticals.

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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 hematology and oncology. Our strategy is comprised of acquiring, developing and commercializing a broad and diverse pipeline of late-stage clinical and commercial products. In the United States, or the U.S., 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. In January 2012 we entered into an agreement to acquire licensing rights to market ZEVALIN outside of the U.S. ZEVALIN is currently approved for sale in more than 40 countries.

We have assembled an integrated in-house scientific team, including formulation development, clinical development, medical affairs, 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 after several years of declining sales and continue to work on growing the ZEVALIN brand, expand usage in Non-Hodgkins Lymphoma and expand indications through additional trials. We intend to increase our sales and marketing activities related to ZEVALIN as evidenced by the January 2012 agreement to acquire licensing rights to market ZEVALIN outside of the U.S. For FUSILEV, we are working to expand usage in colorectal cancer. We have initiated and continue to build appropriate infrastructure 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 M.D.s, Ph.D.s and other medical science liaison personnel.

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 beginning in the second half of 2010 due to a shortage of generic leucovorin. There has been a history of recurring and unreliable supply of generic leucovorin. In April 2011, we received two FDA approvals for FUSILEV. The first FDA approval was for the use of FUSILEV in combination with 5-fluorouracil in the palliative treatment of patients with advanced metastatic colorectal cancer. The second FDA approval was for a Ready-To-Use, or RTU, formulation of FUSILEV. We are now actively engaged in marketing FUSILEV for use in advanced metastatic colorectal cancer and have engaged a focused commercial sales organization to work with our commercial group to support efforts to grow FUSILEV sales.

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 safely and expeditiously to the point of regulatory approval. We plan to develop some of these drugs ourselves or with our subsidiaries and affiliates, or secure collaborations with third parties such that we are able to suitably monetize these assets.

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We have assembled a drug development infrastructure that is comprised of highly experienced and motivated M.D.s, Ph.D.s, clinical research associates and a complement of other support personnel to develop these drugs. During 2009, we achieved our goal of completing enrollment in the two Phase 3 apaziquone trials (with more than 1,600 patients enrolled) and finished the evaluation of the last patient in December 2011. We expect to file an NDA for apaziquone in 2012. We continue to work to maximize the value of apaziquone through further developmental efforts and additional trials.

With regard to our anti-cancer drug belinostat, a novel HDAC inhibitor, we have to date opened more than 100 clinical sites. We completed enrollment in September 2011, and expect to file an NDA in 2012. Belinostat has received Fast Track designation from the U. S. Food and Drug Administration, or the FDA, which means, if the FDA agrees, we can start filing a rolling new-drug application even before the clinical package is ready, beginning with the filing of pre-clinical data and Chemistry Manufacturing and Control.

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 development stage and commercial drugs through business development activities. 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 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. In January 2011, we entered into an 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. Under the agreement, we paid a nominal upfront payment and are required to make additional payments based on certain development, regulatory and sales milestones should we elect to continue development efforts. In late January 2012, we entered into a co-development and commercialization agreement with Hanmi Pharmaceutical Company for SPI-2012 (formerly known as LAPS-GCSF), a drug for the treatment of chemotherapy induced neutropenia. We believe our in-licensing of belinostat, a novel histone deacetylase, or HDAC, inhibitor, is also demonstrative of such 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 beginning in 2009 and continuing through 2011. 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 rely 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 realized from continued development.

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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 2011 and early 2012, we have continued to execute on our business strategy described above. We discuss below the key developments during that period.

In January 2011, we entered into an agreement with Viropro, Inc. for the development of a biosimilar version of the monoclonal antibody drug rituximab.

In April of 2011, we received two FDA approvals for FUSILEV. The first FDA approval was for the use of FUSILEV in combination with 5-fluorouracil in the palliative treatment of patients with advanced metastatic colorectal cancer. The second FDA approval was for an RTU formulation of FUSILEV. We recorded approximately $181 million in product sales for the year 2011 as compared to $61 million in 2010 of which FUSILEV sales were $153 million as compared to $32 million in 2010.

In November 2011, we received approval from the FDA to remove the pre-treatment biodistribution evaluation requirement, commonly referred to as the bioscan from the ZEVALIN administration procedures.

In December 2011, at the Annual Meeting of the American Society of Hematology in San Diego, California, a total of 19 scientific papers on ZEVALIN were presented. Of these, 5 papers were selected by the program committee of ASH for oral presentation. Encouraging data were seen in diverse patient groups, including those with newly diagnosed follicular lymphoma, relapsed/refractory follicular lymphoma, marginal zone lymphoma and patients who have received autologous or allogeneic transplantation. One oral presentation was recognized with special distinction as having the potential impact of changing the standard of care from current therapeutic approaches. Additionally, there were four abstracts related to using ZEVALIN for consolidation after response to chemotherapy. All studies presented at this meeting were investigator-sponsored studies.

In January 2012, we entered into an agreement to acquire licensing rights to market ZEVALIN, outside of the U.S., from Bayer Pharma AG. ZEVALIN is currently approved for sale in more than 40 countries for the treatment of B-cell non-Hodgkin lymphoma, including countries in Europe, Latin America and Asia. Under the agreement, Spectrum will have marketing rights, patents, and access to existing inventory of ZEVALIN from Bayer. Spectrum intends to utilize a combination of company resources and partnerships to support the product outside the U.S.

In late January 2012, we entered into a co-development and commercialization agreement with Hanmi Pharmaceutical Company for SPI-2012 (formerly known as LAPS-GCSF), a drug for the treatment of chemotherapy induced neutropenia based on Hanmi's proprietary LAPSCOVERY Technology. We expect to initiate Phase 2 trials in collaboration with Hanmi in 2012. If SPI-2012 is ultimately commercialized, we will have worldwide rights except for Korea, China and Japan.

We expect to receive top-line data in 2012 from two Phase 3 pivotal clinical trials for apaziquone. The two trials enrolled more than 1,600 patients with non-muscle invasive bladder cancer.

Through the above-referenced agreements and our continued efforts, we strive to continue to build a global pharmaceutical organization in 2012. For two of our non-U.S. 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 continue to grow and establish these entities in an effort to facilitate the opening of clinical trials sites in these countries to advance the clinical development of our products at a reduced cost.

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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 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:

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.

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Overview of Cancer

According to the American Cancer Society s publication *Cancer Facts & Figures 2011*, cancer is the second leading cause of death in the U.S., accounting for approximately 25% of all deaths. In the U.S., approximately 1.6 million new cancer cases were expected to be diagnosed in 2011 and over 572,000 persons were expected to die from the disease in 2011. 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 may 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 or a virus.

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 may 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.

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Development of Our Drug Products

ZEVALIN ([90Y]-ibritumomab tiuxetan): In December 2008, we acquired rights to commercialize and develop ZEVALIN in the U.S., as the result of a transaction with Cell Therapeutics, Inc., or CTI as further described below. In January 2012, we entered into an agreement with Bayer Pharma AG to acquire licensing rights to market ZEVALIN outside of the U.S.

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 for the treatment of follicular non-Hodgkin s lymphoma, or 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 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 and microscopy 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.

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 U. S. 66,360 people were expected to be newly diagnosed with NHL in 2011. Additionally, approximately 19,320 were expected to die from this disease in 2011.

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, or 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, or 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 Centers for Medicaid & Medicare Services or the CMS decided that ZEVALIN should be reimbursed under an Average Sales Price, or ASP, methodology in the Hospital Outpatient Prospective Payment System, or 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.

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In December 2011 at the Annual Meeting of the American Society of Hematology, or the ASH, in San Diego, California, a total of 19 scientific papers on ZEVALIN were presented. Of these, 5 papers were selected by the program committee of ASH for oral presentations. Encouraging data were seen in diverse patient groups, including those with newly diagnosed follicular lymphoma, relapsed/refractory follicular lymphoma, marginal zone lymphoma and patients who have received autologous or allogeneic transplantation. One oral presentation was selected for a special recognition as having the potential to change the standard of care for these patients. Additionally, there were four abstracts related to using ZEVALIN for consolidation after response to chemotherapy. All studies presented at this meeting were investigator-sponsored studies.

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

On December 15, 2008, we closed a transaction to form a 50/50 owned joint venture in an entity called RIT Oncology, LLC or 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, referred to as the 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, in 2009 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, referred to as the 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.

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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).

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.

In January 2012, we entered into an agreement to acquire licensing rights to market ZEVALIN outside of the U.S. from Bayer Pharma AG. ZEVALIN is currently approved for sale in more than 40 countries outside the U.S. for the treatment of B-cell non-Hodgkin lymphoma, including countries in Europe, Latin America and Asia. Under the agreement, Spectrum will have marketing rights, patents, and access to existing inventory of ZEVALIN from Bayer. Spectrum plans to utilize a combination of company resources and partnerships to support the product outside the U.S.

FUSILEV® (levoleucovorin) for injection: On March 7, 2008, our new drug application or 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 and psoriasis.

The American Cancer Society estimated that the 2011 incidence of colorectal cancer in the U. S. would be approximately 141,210 and is the third most common cancer in both men and women. 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 U.S. Additionally, in the fourth quarter of 2008, FUSILEV was listed and continues to be listed in the NCCN Drugs and Biologic Compendium for use in combination with high-dose methotrexate for the treatment of bone cancer (osteosarcoma and de-differentiated chrondrosarcoma). The NCCN Drugs and Biologics Compendium is an important reference that has been recognized by United HealthCare as a formal guidance for coverage policy. In addition, CMS announced in June 2008 that it would recognize the NCCN Drugs & Biologics Compendium as a source of information to determine which drugs may be covered under Medicare Part B.

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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. Pursuant to the agreement, as of the end of 2011, Targent has received all payments provided for under the agreement based on the achievement of certain regulatory and sales milestones. We made such payments in a combination of our common stock and cash.

In May 2006, we amended and restated a license agreement with Merck & Cie AG, a Swiss corporation, which 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, and 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. Merck & Cie is also eligible to receive a payment upon achievement of another regulatory milestone, in addition to royalties on net sales. The term of the license agreement is determined on a product-by-product and country-by-country basis until royalties are no longer owed under the license agreement. The license agreement expires in its entirety after the date that we no longer owe any royalties to 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 2011 incidence and prevalence of bladder cancer in the U.S. would be approximately 69,250 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 rarely 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.

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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. Apaziquone 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.

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 agreement 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_aG1-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, or the EMEA whereby the EMEA 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®, 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 October, 2008, we entered into a license, development, supply and distribution agreement with Allergan pursuant to which we and Allergan agreed to 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 U.S., whereby we and Allergan will share equally all profits and commercialization expenses.

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 $302.5 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 U.S.

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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 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 $18.6 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 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. 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 platinums 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 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 second half of 2012. There are currently no approved therapies or drugs for treatment of CUP, which is an indication with a large patient population. The National Cancer Institute 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

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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 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 we agreed to 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, benign prostatic hyperplasia, or 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. Currently, we are conducting a randomized 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.

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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 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.

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

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

In the first quarter of 2008, we initiated an open label, dose-escalation Phase 1 study assessing the safety, tolerability, pharmacokinetics and pharmacodynamics of SPI-1620 in patients with recurrent or progressive carcinoma. We completed the Phase 1 study in 2011 and expect to begin Phase 2 in the second half of 2012.

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, or SPI-014, 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 U.S. Renal Data System in 2010, there will be an estimated 600,000 patients with end-stage renal disease in the U.S. 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 filed an IND in 2011 and expect to begin a Phase 1 study in the first half of 2012.

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., collectively referred to as Altair, whereby we acquired an exclusive worldwide right to develop and commercialize RenaZorb for all human therapeutic and diagnostic uses in January 2005. Under the terms of the license agreement, we made up-front and milestone payments and are obligated to make additional payments upon achievement of certain clinical development and regulatory and sales milestones, in addition to royalties on potential net sales.

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In August 2009, we entered into an asset 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.

SPI-2012: SPI-2012 is a drug for the treatment of chemotherapy induced neutropenia. In January 2012 we entered into a co-development and commercialization agreement with Hanmi Pharmaceutical Company (Hanmi) for SPI-2012 based on Hanmi's proprietary LAPSCOVERY Technology.

Granulocyte colony-stimulating factor (GCSF) stimulates the production of white blood cells by the bone marrow. A recombinant form of GCSF is used in appropriate cancer patients to accelerate recovery from neutropenia after chemotherapy, allowing higher-intensity treatment regimens to be given at full-dose and on schedule. Chemotherapy can cause myelosuppression and unacceptably low levels of white blood cells, making patients prone to infections, hospitalizations, and interruption of additional chemotherapy treatments. We believe the worldwide market for GCSF-related drugs was over $5 billion in 2011.

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 have multiple 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 develop, 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 have contracted with an independent contract sales organization to supplement our sales force. 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.

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Customers

Our product sales are concentrated in a limited number of customers. Sales to Customer A for the years ended December 31, 2011, 2010 and 2009 were 57.0%, 45.7% and 27.1% respectively, of our total consolidated gross product sales. Sales to Customer B for the year ended December 31, 2011 were 19.1% of our total consolidated gross product sales. No other single customer generated over 10% of our consolidated gross product sales during the prior three fiscal years.

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 26.8% and 56.1% of net receivables as of December 31, 2011 and 2010, respectively. Customer B owed us 54.1% of net receivables as of December 31, 2011. No other single customer owed us more than 10% of net receivables during the prior two fiscal years and all sales were to customers in the U.S.

Competition

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

Competing in the branded product business requires us to identify and quickly bring to market new products embodying therapeutic innovations. Successful marketing of branded products depends primarily on the ability to communicate the effectiveness, safety and value of the products to healthcare professionals in private practice, group practices, hospitals and academic institutions, and managed care organizations. Competition for branded drugs is less driven by price and is more focused on innovation in treatment of disease, advanced drug delivery and 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.(Roche), Bristol-Myers Squibb Company, GlaxoSmithKline, Biogen-IDEC Pharmaceuticals, Inc., OSI Pharmaceuticals, Inc. (Astellas Pharma), Cephalon, Inc.(Teva Pharmaceuticals), 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.

Our proprietary product, 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 three generic companies currently approved by the FDA to sell the leucovorin product and therefore we are competing against a low cost alternative. Also, FUSILEV is 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.

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Regarding ZEVALIN, there are three competitive products for its currently approved indications.

Rituxan® (rituximab), marketed by Genentech and Biogen, is indicated for the treatment of patients with relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL as a single agent; previously untreated follicular, CD20-positive, B-cell NHL in combination with CVP (cyclophosphamide, vincristine and 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.

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

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

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

Research and Development

New drug development, which is the process whereby drug product candidates are tested for the purpose of filing an NDA or a Biologistics License Application, 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 U.S., 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 $27.7 million, $57.3 million and $21.1 million, respectively, in 2011, 2010 and 2009 broken out by product as follows:

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	September 30, 2011	September 30, 2010	September 30, 2009
	Year Ended December 31, ($ in 000 s)		
Apaziquone	$ 8,122	$ 6,165	$ 10,915
Belinostat	7,607	36,045	
FUSILEV	1,309	1,281	1,125
ZEVALIN	176	421	563
Ozarelix	781	1,916	1,168
Ortataxel	113	716	311
Other development drugs	1,998	3,469	1,535
Total Direct Costs	20,106	50,013	15,617
Indirect Costs (including non-cash share-based compensation of $1.6 million, $2.4 million and $3.2 million, respectively)	16,502	14,838	16,652
Partner Reimbursement	(8,888)	(7,550)	(11,211)
Total Research & Development	$ 27,720	$ 57,301	$ 21,058

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 other intellectual property rights related to these products.

The protection, preservation and infringement-free commercial exploitation of these patents and related intellectual property rights are 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, our patents and the patents we have licensed may not prevent other companies from developing similar or functionally equivalent products or from successfully challenging the validity of our patents. If our patent applications are not allowed or, even if allowed and issued as patents, if such patents or the patents we have in-licensed, are circumvented or not upheld by the courts, our ability to competitively exploit our patented products and technologies may be significantly reduced. Also, such patents may or may not provide competitive advantages for their respective products or they may be challenged or circumvented by competitors, in which case our ability to commercially exploit these products may be diminished.

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 U.S. 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 U.S. composition of matter patent that covers FUSILEV that expires in 2019. For ZEVALIN, we have sublicensed U.S. patents that cover the processes and tools for making monoclonal anti-bodies or MABs, in general, licensed U.S. patents that cover the CD-20 MAB in ZEVALIN as well as the use of ZEVALIN to treat NHL, and acquired patents covering the ZEVALIN compounding process (*i.e.*, process of linking

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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 U.S. patents covering the compounding process expiring in 2019, 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 U.S. and foreign patent applications pending that cover belinostat formulations, uses and manufacturing and synthesis processes. We plan to file additional U.S. and foreign patent applications covering new formulations, uses and manufacturing and synthesis processes, where appropriate. For apaziquone, there is a U.S. formulation patent that does not expire until 2022 and method of treatment of bladder cancer using a stabilized formulation that does not expire until 2024. We have filed and plan to file additional U.S. and foreign patent applications covering new formulations and/or uses for this product. For ozarelix, there is a U.S. composition patent that will expire in 2020, a formulation patent expiring in 2023, and method of use patent applications on file in the U.S. For ortataxel, there are two U.S. 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 U.S. patent covering satraplatin, a method of use patent expired in 2010. For lucanthone, there is a U.S. method of use patent that expires in 2019. For RenaZorb, there is one method of use patent that expires in 2024 and pending U.S. and foreign patent applications covering compositions of matter and methods directed to treating hyperphosphatemia. For SPI-1620, we have filed method of use patent applications in the U.S. and Europe. We also have multiple U.S. method of use patents that expire in 2024, and there is ongoing prosecution for their European counterparts. We have also filed another method of use patent application in the U.S. 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 U.S. 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 U.S. and Europe. Limitations on patent protection in these countries, and the differences in what constitutes patentable subject matter in countries outside the U.S., may limit the protection we have on patents issued or licensed to us outside of the U.S. In addition, laws of foreign countries may not protect our intellectual property to the same extent as would laws in the U.S. To minimize our costs and expenses and to maintain effective protection, we usually focus our patent and licensing activities within the U.S., the European Union, Canada and Japan. In determining whether or not to seek a patent or to license any patent in a certain foreign country, we weigh the relevant costs and benefits, and consider, among other things, the market potential and profitability, the scope of patent protection afforded by the law of the jurisdiction and its enforceability, and the nature of terms with any potential licensees. Failure to obtain adequate patent protection for our proprietary drugs and technology would impair our ability to be commercially competitive in these markets.

In addition to the specific intellectual property subjects discussed above, we have trademark protection in the U.S. for Spectrum Pharmaceuticals, Inc®, FUSILEV®, Spectrum Therapy Access Resources, STAR, ZEVALIN® and RenaZorb®. Additionally, for some other of these and other works related to our business, we have pending U.S. and ex-U.S. trademark applications. EOquin® 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.

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The Patent Process

The U.S. Constitution provides Congress with the authority to provide inventors the exclusive right to their discoveries. Congress codified this right in U.S. 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 U.S. 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 U.S. 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 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

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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 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 U.S., 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 U.S., 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 U.S. 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.

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Under European Union medicines laws, the criteria for designating an orphan medicinal product are similar in principle to those in the U.S. 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.

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 and biologic products are subject to regulation for safety, efficacy and quality by numerous governmental authorities in the U.S. and other countries. In the U.S., drugs and biologics 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 quality, 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 GMP, regulations and are subject to inspections by the FDA. To supply drug ingredients or products for use in the U.S., foreign manufacturing establishments must also comply with GMP and are subject to inspections by the FDA or by other regulatory authorities in certain countries under reciprocal agreements with the FDA.

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

The U.S. system of new drug and biologics approval is a rigorous process. 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 products.

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

Investigational New Drug Application: After certain pre-clinical studies are completed, an Investigational New Drug, or IND, Application is submitted to the FDA to request the ability to begin human testing of the drug or biologic. 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 or biologic 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 product s overall benefit-risk profile, and to provide information for physician labeling.

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

New Drug Application or Biologic License Application: After completion of all three clinical trial phases, if the data indicates that the drug is safe and effective, a NDA or BLA 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 an abbreviated new drug application 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 process generally takes less time than the NDA drug development process since the ANDA process usually does not require new clinical trials establishing the safety and efficacy of the drug product.

NDA/BLA and ANDA Approval: The FDA approves drugs and biologics that are subject to NDA and BLA review based on data in the application demonstrating the product is safe and effective in its proposed use(s) and that the product s benefits outweigh its risks. FDA will also review the NDA or BLA applicant s manufacturing process and controls to ensure they are adequate to preserve the drug s identity, strength, quality, and purity. Finally, the FDA will review and approve the product 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.

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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 or BLA.

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.

FDA Enforcement

The development of drug and biologic products, as well as the marketing of approved drugs and biologics, is subject to substantial continuing regulation by the FDA, including regulation of adverse event reporting, manufacturing practices and the advertising and promotion of the product. 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, BLAs, 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.

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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 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 European 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 U.S. 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.

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Third Party Reimbursement and Pricing Controls

In the U.S. 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 U.S. 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 U.S., 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, 2011, we had 176 employees, of which 11 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.

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.

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Risks Related to Our Business

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 for which our product is approved. 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 is offered as part of a treatment regimen, and that regimen may change to exclude FUSILEV. Accordingly, it may not gain sustained acceptance by the medical field or become commercially successful.

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

There is no assurance that FUSILEV sales will be sustainable at its current levels. Our customer concentration of FUSILEV is high. Sales to Customer A for the years ended December 31, 2011, 2010 and 2009 were 57.0%, 45.7% and 27.1%, respectively, of our total consolidated gross product sales. Sales to Customer B for the year ended December 31, 2011 were 19.1% of our total consolidated gross product sales. If our relationship with our top distributors is impaired our sales of FUSILEV would be negatively impacted.

The marketing and sale of FUSILEV 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. 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.

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 U.S. and other countries, that each of the products is both safe and effective. For each drug product, we will need to demonstrate its efficacy and monitor its safety throughout the process. If such development is unsuccessful, our business and reputation would be harmed and our stock price would be adversely affected.

All of our drug products are prone to the risks of failure inherent in drug development. Clinical trials of new drug products sufficient to obtain regulatory marketing approval are expensive and take years to complete. We may not be able to successfully complete clinical testing within the time frame we have planned, or at all. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent us from receiving regulatory approval or commercializing our drug products. In addition, the results of pre-clinical studies and early-stage clinical trials of our drug products do not necessarily predict the results of later-stage clinical trials. Later-stage clinical trials may fail to demonstrate that a drug product is safe and effective despite having progressed through initial clinical testing. Even if we

believe the data collected from clinical trials of our drug products is promising, such data may not be sufficient to support approval by the FDA or any other U.S. or foreign regulatory approval. Pre-clinical and clinical data can be interpreted in different ways.

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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.

Our repositioning campaign for ZEVALIN and the removal of the bioscan requirement may not yield increased sales for some time if ever.

In December 2011, at the American Society for Hematology conference in San Diego, we announced the repositioning campaign for ZEVALIN based on the FDA s approval of the previously required bioscan. We believe that the removal of the bioscan requirement and the repositioning campaign could result in increased sales. However, there can be no assurance that sales of ZEVALIN will increase as a result of these developments.

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®, Treanda® and other developmental products, 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.

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 U.S. 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

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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, our supplier for ZEVALIN cold kits is a sole-source supplier, and currently no qualified alternative suppliers exist. Furthermore, we have multiple but a limited number of suppliers of FUSILEV. If problems arise during the 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 promotion agreement and a license, development, supply and distribution agreement with Allergan, Inc., or Allergan, for the worldwide development and commercialization of our drug product, apaziquone. Pursuant to the terms of the agreements, as amended in 2011, 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.

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

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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 most 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.

We entered in to an agreement on January 23, 2012 with Bayer Pharma AG to acquire rights to market ZEVALIN outside the U.S. which is subject to customary closing conditions. The closing may not occur as quickly as we anticipate or at all. The transition of the business from Bayer to us may experience unforeseen delays, which could negatively impact our sales efforts and results.

We are subject to risks associated with doing business internationally.

As we expand internationally and 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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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
- 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

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mistakes as well as difficulties in coordinating activities. Outside parties may have staffing difficulties, may undergo changes in priorities or may become financially distressed, adversely affecting their willingness or ability to conduct our trials. We may experience unexpected cost increases that are beyond our control. Problems with the timeliness or quality of the work of a contract research organization may lead us to seek to terminate the relationship and use an alternative service provider. However, making this change may be costly and may delay our trials, and contractual restrictions may make such a change difficult or impossible. Additionally, it may be impossible to find a replacement organization that can conduct our trials in an acceptable manner and at an acceptable cost.

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

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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 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,

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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.

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 potential size of the market for our drug 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 chargeback s. 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). We do not have significant historical data on returns and allowances given our limited commercial distribution history. 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 chargeback s exceed the estimates we made at the time of the sale of our products.

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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.

Risks Related to Our Industry

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 U.S. and foreign patents issued and pending, however, we primarily rely on patent rights licensed from others. Our license agreements generally give us the right and/or obligation to maintain and enforce the subject patents. We may not receive patents for any of our pending patent applications or any patent applications we may file in the future. If our pending and future patent applications are not allowed or, if allowed and issued into patents, if such patents and 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 U.S. The laws of many countries may not protect intellectual property rights to the same extent as U.S. 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 U.S. 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;

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

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

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

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

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.

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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.

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 U.S. 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.

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If third-party payers 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 payers, both in the U.S. 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 payers may depend upon a number of factors, including a governmental or other third-party payer 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 payer 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 payer. We may not be able to provide data sufficient to obtain reimbursement.

In the U.S., 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 U.S. 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 U.S.

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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 U.S. 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.

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, some of 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.

Failure to obtain regulatory approval outside the U.S. 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 U.S. 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.

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.

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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 payers and the medical community. The degree of market acceptance of any approved drug products will depend on a number of factors, including:

- the effectiveness of the drug product;
- the prevalence and severity of any side effects;
- potential advantages or disadvantages over alternative treatments;
- relative convenience and ease of administration;
- the strength of marketing and distribution support;
- the price of the drug product, both in absolute terms and relative to alternative treatments; and
- sufficient third-party coverage or reimbursement.

If our drug products receive regulatory approval but do not achieve an adequate level of acceptance by physicians, healthcare payers 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.

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If we obtain regulatory approval for our drug products, we, our partners, our manufacturers, and other contract entities will continue to be subject to extensive requirements by a number of national, foreign, state and local agencies. These regulations will impact many aspects of our operations, including testing, research and development, manufacturing, safety, effectiveness, labeling, storage, quality control, adverse event reporting, record keeping, approval, advertising and promotion of our future products. Failure to comply with applicable regulatory requirements could, among other things, result in:

- warning letters;
- fines;
- changes in advertising;
- revocation or suspension of regulatory approvals of products;
- product recalls or seizures;
- delays, interruption, or suspension of product distribution, marketing and sales;
- 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).

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

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

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

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

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

In both the U.S. 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 payers such as government health administration authorities, private health insurers, health maintenance organizations including pharmacy benefit managers and other health care-related organizations. Both the federal and state governments in the U.S. and foreign governments continue to propose and pass new legislation and regulations designed to contain or reduce the cost of health care. Such legislation and regulations may result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce the prices charged for prescription drugs. This could harm our ability to market our products and generate revenues.

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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 payers are increasingly challenging the price and cost-effectiveness of medical products and services. Significant uncertainty exists as to the reimbursement status of newly-approved pharmaceutical products.

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.

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 payers. 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.

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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 payer. 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 designed to comply with applicable federal, state and local requirements wherever we operate, including but not limited to the laws of the states of California and Nevada.

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 increase 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.

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 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.

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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.

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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, 2011, there were 59,247,483 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 10.7 million additional shares of common stock. However, we would receive approximately $57.9 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. 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. 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.

The market price and trading volume of our common stock fluctuate significantly and could result in substantial losses for individual investors.

The stock market from time to time experiences significant price and trading volume fluctuations that are unrelated to the operating performance of particular companies. These broad market fluctuations may cause the market price and trading volume of our common stock to decrease. In addition, the market price and trading volume of our common stock is often highly volatile.

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

- 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;

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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 U.S. 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 3, 2011 through February 16, 2012, the closing price of our common stock ranged between $5.97 and $15.87, and the daily trading volume was as high as 7,426,200 shares and as low as 270,100 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.

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.

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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, 2011, no new or existing material weaknesses were identified and we determined that our internal control over financial reporting was effective as of December 31, 2011.

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.

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.

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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 U.S. 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.

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.

On January 20, 2012 and February 17, 2012, respectively, we filed suit against Sandoz Inc. and Innopharma Inc, respectively following Paragraph IV certifications in connection with their filing separate Abbreviated New Drug Applications or ANDAs, to manufacture a generic version of FUSILEV. We filed the lawsuits in the U.S. District Court, District of Nevada and seek to enjoin the ANDAs plus recovery of our fees and costs incurred in such matters. While we believe our patent rights are strong, the ultimate outcome of these cases is uncertain.

Item 4. ***[Reserved]***

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PART II

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

Common Stock

As of February 16, 2012 there were 59,271,035 shares of common stock outstanding and 367 stockholders of record. On February 16, 2012, the closing sale price of our common stock was $13.91 per share.

Market for Securities

Our common stock is traded on the NASDAQ Global Market under the symbol SPPI. The high and low closing sale prices of our common stock reported by NASDAQ during each quarter ended in 2011 and 2010 were as follows:

	September 30, High	September 30, Low
Year 2011:		
First Quarter	$ 8.89	$ 5.97
Second Quarter	$ 10.36	$ 7.44
Third Quarter	$ 11.23	$ 7.53
Fourth Quarter	$ 14.97	$ 7.07
Year 2010		
First Quarter	$ 5.48	$ 4.28
Second Quarter	$ 5.24	$ 3.79
Third Quarter	$ 4.66	$ 3.67
Fourth Quarter	$ 7.08	$ 4.05

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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, 2006, the last trading day before our 2007 fiscal year, through the end of fiscal 2011 with the cumulative total return on $100 invested for the same period in the Russell 2000 index and two different peer indices, the Old Peer Group and the New Peer Group. We have elected to change our peer group to the New Peer Group because we believe the revised group is more representative of the companies perceived by investors as comparable to Spectrum based on the New Peer Group's similar stage of development and scale of operations, as opposed to being defined primarily by market capitalization, and therefore provides a more meaningful comparison of stock performance.

The New Peer Group consist of the following publicly-traded companies:

Alkermes, Inc.

Amarin Corporation plc

BioMarin Pharmaceutical Inc.

Celgene Corporation

Dendreon Corporation

Human Genome Sciences Inc

Jazz Pharmaceuticals Public Limited Company

Onyx Pharmaceuticals, Inc

Regeneron Pharmaceuticals, Inc.

Vertex Pharmaceuticals Incorporated

	September 30, 12/31/06	September 30, 12/31/07	September 30, 12/31/08	September 30, 12/31/09	September 30, 12/31/10	September 30, 12/31/11
Spectrum Pharmaceuticals, Inc.	100.00	49.19	26.94	80.29	124.23	264.56
Russell 2000	100.00	98.43	65.18	82.89	105.14	100.75
Old Peer Group	100.00	102.13	74.27	104.00	108.42	86.05

New Peer Group	100.00	93.91	91.29	112.03	118.34	119.90

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(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, 2011 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

During the three months ended December 31, 2011, we purchased 10,000 shares of our common stock under our previously approved repurchase plan for an aggregate purchase price of $85,449. The following table provides information regarding our repurchases for each month comprising the fourth quarter of fiscal year 2011.

Period	September 30, Total Number of Shares Purchased	September 30, Average Price Paid Per Share	September 30, Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (1)	September 30, Maximum Number of Shares (or Approximate Dollar Value) that May Yet Be Purchased Under the Plans or Programs (1)
October 1, 2011 October 31, 2011		$		$ 22,159,576
November 1, 2011 November 30, 2011		$		$ 22,159,576
December 1, 2011 December 31, 2011	10,000	$ 8.52	10,000	$ 22,074,127
Total	10,000	$ 8.52	10,000	

(1) On June 13, 2011, we announced that our board of directors had authorized the repurchase of up to $25 million of our outstanding common stock through the end of 2012. The repurchase plan was announced by press release and Form 8-K filed June 15, 2011.

Repurchased shares have been recorded as treasury shares and will be held until our Board of Directors designates that these shares be retired or used for other purposes.

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, 2011, 2010 and 2009 and balance sheet data as of December 31, 2011 and 2010 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, 2008 and 2007 and the balance sheet data as of December 31, 2009, 2008 and 2007 from our audited consolidated financial statements that do not appear in this annual report.

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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.

Statement of Operations Data:	September 30, 2011	September 30, 2010	September 30, 2009	September 30, 2008	September 30, 2007
	Years ended December 31, (In thousands, except per share data)				
Total revenues	$ 192,963	$ 74,113	$ 38,025	$ 28,725	$ 7,672
Operating expenses:					
Cost of product sales (excludes amortization of purchased intangible assets)	33,838	17,439	8,148	1,193	
Selling, general and administrative	72,553	48,550	33,607	15,156	11,577
Research and development	27,720	57,301	21,058	26,683	33,285
Amortization of purchased intangibles	3,720	3,720	3,720	158	
Acquired in-process research and development				4,700	
Income (loss) from operations	55,132	(52,897)	(28,508)	(19,165)	(37,190)
Change in fair value of common stock warrant liability	(3,488)	2,731	8,075	1,271	12,055
Other income, net	577	1,279	662	1,165	3,139
Income (loss) before provision for income taxes	52,221	(48,887)	(19,771)	(16,729)	(21,996)
(Provision) benefit for income taxes	(3,704)	43	(421)	(5)	(5)
Net loss attributable to non-controlling interest			1,146	2,538	20
Net income (loss) attributable to Spectrum Pharmaceuticals, Inc. stockholders	$ 48,517	$ (48,844)	$ (19,046)	$ (14,196)	$ (21,981)
Net income (loss) per share basic	$ 0.91	$ (0.99)	$ (0.48)	$ (0.45)	$ (0.76)
Net income (loss) per share diluted	$ 0.84	$ (0.99)	$ (0.48)	$ (0.45)	$ (0.76)

Balance Sheet Data:	2011	2010	As of December 31, 2009	2008	2007
			(In thousands)		
Cash, equivalents and investments	$ 170,545	$ 104,243	$ 113,341	$ 75,938	$ 55,659
Working capital	147,264	58,543	86,758	54,677	48,813
Total assets	280,780	163,631	173,133	129,509	57,540
Common stock warrant liability (at fair value)		3,904	6,635	765	2,035
Long term obligations, less current portion	14,336	25,833	25,310	42,822	992
Total stockholders equity (including non-controlling interest)	187,907	74,476	108,324	53,116	46,714

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

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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 after several years of declining sales and continue to work on growing the ZEVALIN brand, expand usage in Non-Hodgkins Lymphoma and expand indications through additional trials. We intend to increase our sales and marketing activities related to ZEVALIN as evidenced by the January 2012 agreement to acquire licensing rights to market ZEVALIN outside of the U.S. For FUSILEV, we are working to expand usage in colorectal cancer. We have initiated and continue to build appropriate infrastructure 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 M.D.s, Ph.D.s and other medical science liaison personnel.

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 beginning in the second half of 2010 due to a shortage of generic leucovorin. There has been a history of recurring and unreliable supply of generic leucovorin. In April 2011, we received two FDA approvals for FUSILEV. The first FDA approval was for the use of FUSILEV in combination with 5-fluorouracil in the palliative treatment of patients with advanced metastatic colorectal cancer. The second FDA approval was for a Ready-To-Use, or RTU, formulation of FUSILEV. We are now actively engaged in marketing FUSILEV for use in advanced metastatic colorectal cancer and have engaged a focused commercial sales organization to work with our commercial group to support efforts to grow FUSILEV sales.

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 safely and expeditiously to the point of regulatory approval. We plan to develop some of these drugs ourselves or with our subsidiaries and affiliates, or secure collaborations with third parties 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 M.D.s, Ph.D.s, clinical research associates and a complement of other support personnel to develop these drugs. During 2009, we achieved our goal of completing enrollment in the two Phase 3 apaziquone trials (with more than 1,600 patients enrolled) and finished the evaluation of the last patient in December 2011. We expect to file an NDA for apaziquone in 2012. We continue to work to maximize the value of apaziquone through further developmental efforts and additional trials.

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With regard to our anti-cancer drug belinostat, a novel HDAC inhibitor, we have to date opened more than 100 clinical sites. We completed enrollment in September 2011, and expect to file an NDA in 2012. Belinostat has received Fast Track designation from the U. S. Food and Drug Administration, or the FDA, which means, if the FDA agrees, we can start filing a rolling new-drug application even before the clinical package is ready, beginning with the filing of pre-clinical data and Chemistry Manufacturing and Control.

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 development stage and commercial drugs through business development activities. 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 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. In January 2011, we entered into an 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. Under the agreement, we paid a nominal upfront payment and are required to make additional payments based on certain development, regulatory and sales milestones should we elect to continue development efforts. In late January 2012, we entered into a co-development and commercialization agreement with Hanmi Pharmaceutical Company for SPI-2012 (formerly known as "LAPS-GCSF"), a drug for the treatment of chemotherapy induced neutropenia. We believe our in-licensing of belinostat, a novel histone deacetylase, or HDAC, inhibitor, is also demonstrative of such 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 beginning in 2009 and continuing through 2011. 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 rely 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 realized from continued development.

Further enhancing the organizational structure to meet our corporate objectives. We have highly experienced staff in pharmaceutical operations, clinical development, regulatory and commercial functions who 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, 2011, are approximately $261.9 million. The year ended 2011 was the first year in which we generated a profit from operations. We remain dependent upon revenues from our two commercial drugs, specifically FUSILEV and ZEVALIN revenues. 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 of our other drug products.

While we believe that the approximately $171 million in cash, equivalents and investments, which includes long term marketable securities, we had available on December 31, 2011 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 licenses 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.

In November 2011, we received approval from the FDA to remove the pre-treatment biodistribution evaluation requirement, commonly referred to as the bioscan. ZEVALIN sales growth is largely dependent on the success of our repositioning campaign for ZEVALIN, which we announced in December 2011, at the American Society for Hematology conference in San Diego. We believe that the removal of the bioscan requirement and the repositioning campaign could result in increased sales. In April 2011 FUSILEV was approved for the use in combination with 5-fluorouracil in the palliative treatment of patients with advanced metastatic colorectal cancer. We are now actively engaged in marketing FUSILEV for use in advanced metastatic colorectal cancer and have engaged a focused commercial sales organization to work with our commercial group to support efforts to grow FUSILEV sales.

Our expenditures for research and development or 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.

	September 30, 2011	September 30, 2010	September 30, 2009
	Year Ended December 31,		
	($ in 000 s)		
Apaziquone	$ 8,122	$ 6,165	$ 10,915
Belinostat	7,607	36,045	
FUSILEV	1,309	1,281	1,125
ZEVALIN	176	421	563
Ozarelix	781	1,916	1,168
Ortataxel	113	716	311
Other development drugs	1,998	3,469	1,535
Total Direct Costs	20,106	50,013	15,617
Indirect Costs (including non-cash share-based compensation of $1.6 million, $2.4 million and $3.2 million, respectively)	16,502	14,838	16,652
Partner Reimbursement	(8,888)	(7,550)	(11,211)
Total Research & Development	$ 27,720	$ 57,301	$ 21,058

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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, 2012, excluding the cost of stock compensation expenses and in-licensing or acquisitions of additional drugs, if any, is expected to range between approximately $38 and $42 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 2012. Upon successful achievement of these milestones, we will likely become obligated to pay during 2012 up to approximately $5.6 million, payable in cash or shares of common stock.

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 Provided By Operating Activities

Net cash provided by operating activities was $43.3 million for 2011 which includes net income in the period of $48.5 million adjusted for net non-cash credits of $20.7 million, offset primarily by a $30.9 million increase in accounts receivable as a result of increased product sales.

Net Cash Provided By Investing Activities

Net cash provided by investing activities of $746,000 in 2011 was primarily due to the $1.2 million net maturities of marketable securities which were partially offset by a $475,000 increase in property and equipment acquisitions.

Net Cash Provided By Financing Activities

Net cash provided by financing activities of $23.6 million in 2011, primarily relates to the $24.8 million in proceeds from the issuance of common stock as a result of the exercise of approximately 3.7 million warrants and $5.8 million related to the exercise of stock options under our stock incentive plan and purchases of shares under our employee stock purchase plan. These provisions were partially offset by the $2.9 million purchase of treasury stock and $4.0 million repurchase of shares to satisfy minimum tax withholding for restricted stock vestings.

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Results of Operations

Results of Operations for Fiscal 2011 Compared to Fiscal 2010

Total Revenues. Total revenues increased $118.9 million, or 160.4%, to $193.0 million in 2011 from $74.1 million in 2010. We recognized approximately $180.7 million of revenue from net product sales, of which $153.1 million related to sales of FUSILEV and $27.6 million related to sales of ZEVALIN (each net of estimates for promotional, price and other adjustments, including adjustment of the allowance for product returns). Product revenues recorded for the year ended December 31, 2010 were $60.9 million, of which $32.0 million related to sales of FUSILEV and $28.9 million related to sales of ZEVALIN, a decrease of $1.3 million. Revenues from the sales of FUSILEV have increased due to FDA approval of FUSILEV for use in the treatment of advanced metastatic colorectal cancer received on April 29, 2011 and a supply disruption of generic leucovorin. Sales of FUSILEV initially grew significantly in the third and fourth quarter of 2010 and have continued through December 31, 2011.

We also recognized $12.3 million in 2011 and $13.2 million in 2010 of licensing revenues from the amortization of the $41.5 million upfront payment we received from Allergan in 2008 and a $16.0 million upfront payment we received from Nippon Kayaku and Handok in the first quarter of 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. Cost of product sales increased $16.4 million, or 94.0% to $33.8 million in 2011. The increase in total cost of product sales relates to an increase in product revenues achieved during the year, start up costs incurred for new suppliers in 2011, an increase of $1.0 million for the amortization of Targent milestones and an increase in inventory reserves of $1.3 million.

Selling, General and Administrative. Selling, general and administrative expenses increased $24.0 million, or 49.4%, to $72.5 million in 2011, from $48.6 million in 2010. The increase is primarily due to:

- $6.2 million increase in compensation and associated benefits, of which $3.5 million of the increase is attributable to sales and marketing expenses as a result of the expansion of our sales force. We expect sales and marketing activities will increase as we invest in additional commercial resources to increase market expansion of FUSILEV for its recently approved indication of colorectal cancer.

- $14.5 million increase in non-cash compensation expenses of which $7.5 million related to the long-term retention and management incentive plan adopted during the second quarter of 2011.

- $1.1 million increase in regulatory fees as a result of additional regulatory approvals in 2011.

Research and Development. Total research and development expenses decreased $29.6 million, or 51.6%, to $27.7 million in 2011, from $57.3 million in 2010. The decrease is primarily due to the $30.0 million upfront payment 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 in 2010. These decreases were partially offset by an increase in on-going clinical trials expense incurred in 2011. We anticipate research and development expenses in 2012 to be higher than 2011, excluding the cost of stock compensation expenses and in-licensing or acquisition for additional drugs, if any.

Amortization of Purchased Intangibles. We incurred a non-cash charge of $3.7 million for both 2011 and 2010 due to the amortization of intangibles from the acquisition of ZEVALIN.

Change in Fair Value of Common Stock Warrant Liability. We recorded a loss of $3.5 million for the change in the fair value of the warrant obligations during 2011 compared to income of $2.7 million in 2010. The change in fair value of the common stock warrant liability was primarily the result of the change in our stock price over the same period of time. Approximately 3.7 million of the outstanding warrants were exercised on or before September 15, 2011. No warrants recorded as a liability remain outstanding at December 31, 2011.

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Other Income, net. The principal components of other income of $577,000 and $1.3 million during 2011 and 2010, respectively, consisted of currency gains and losses and net interest income. In addition, in 2010 we received $977,000 related to grants under the Qualifying Therapeutic Discovery Project Program administered under Section 48D of the Internal Revenue Code. In the current economic environment, our principal investment objective is preservation of capital. Accordingly, for the foreseeable future we expect to earn minimal interest yields on our investments, until such time as the credit markets recover.

Provision/Benefit for Income Taxes. We recorded a provision for income taxes of $3.7 million in 2011 as compared to a $43,000 benefit in 2010 due to our profitability in 2011.

Results of Operations for Fiscal 2010 Compared to Fiscal 2009

Total Revenues. Total 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 chargeback s, 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.

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.

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.

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Other Income, Net. 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 U.S. 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 chargeback s 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, are 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, 2011 and 2010, 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:

	September 30, Chargeback s and Discounts	September 30, Rebates	September 30, Returns	September 30, Data and Distribution Fees	September 30, Doubtful accounts	September 30, Total
			($ in 000 s)			
Period ended December 31, 2011:						
Balances at beginning of the period	$ 675	$ 14,474	$ 2,000	$ 1,874	$ 339	$ 19,362
Add provisions:	7,548	17,658	2,094	8,484	139	35,923
Less: Credits or actual allowances:	(6,281)	(24,018)	(94)	(4,492)	(7)	(34,892)
Balances at the close of the period	$ 1,942	$ 8,114	$ 4,000	$ 5,866	$ 471	$ 20,393
Period ended December 31, 2010:						
Balances at beginning of the period	$ 860	388	$ 1,176	$ 213	$ 150	$ 2,787
Add provisions:	1,750	14,721	3,540	1,650	359	22,020
Less: Credits or actual allowances:	(1,935)	(635)	(2,716)	(982)	(170)	(6,438)
Balances at the close of the period	$ 675	$ 14,474	$ 2,000	$ 881	$ 339	$ 18,369

Amounts recorded as allowances on our consolidated balance sheets for 2011 and 2010 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 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 chargeback s already billed back) in the calculation and validation of our chargeback estimates and reserves.

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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 between us and our customers, specifically price and discount structures, and other payment terms 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 and Medicare 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 product revenues and crediting a reserve for returns to other accrued liabilities.

Data and Distribution 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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Off-Balance Sheet Arrangements

We do not have any off balance sheet arrangements within the meaning of Item 303(a)(4) of Regulation S-K.

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, 2011, approximately:

($ in 000 s)	September 30, Total	September 30, Less than 1 Year	September 30, 2-3 Years	September 30, 4-5 Years	September 30, After 5 Years
Contractual Obligations(1)					
Capital Lease Obligations(2)	$ 45	$ 45	$	$	$
Operating Lease Obligations(3)	2,809	654	1,293	862	
Purchase Obligations(4)	23,525	14,356	9,169		
Contingent Milestone Obligations(5)	210,469	5,591	61,547	21,492	121,839
Total	$ 236,848	$ 20,646	$ 72,009	$ 22,354	$ 121,839

(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, 2011. Approximately 90% of the purchase obligations consist of expenses associated with clinical trials and related costs for apaziquone, belinostat 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, 2011, 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 U.S., 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, 2013. 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 Spectrum s 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 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.

Subject to limited exceptions, 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 U.S., 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.

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;

(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) collectability 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.

Milestone payments under collaborative arrangements are triggered either by the results of our research and development efforts or by specified sales results by a third-party collaborator. Milestones related to our development-based activities may include initiation of various phases of clinical trials, successful completion of a phase of development or results from a clinical trial, acceptance of a New Drug Application by the FDA or an equivalent filing with an equivalent regulatory agency in another territory, or regulatory approval by the FDA or by an equivalent regulatory agency in another territory. Due to the uncertainty involved in meeting these development-based milestones, the development-based milestones are considered to be substantial (i.e. not just achieved through passage of time) at the inception of the collaboration agreement. In addition, the amounts of the payments assigned thereto are considered to be commensurate with the enhancement of the value of the delivered intellectual property as a result of our performance. Our involvement is necessary to the achievement of development-based milestones. We would account for development-based milestones as revenue upon achievement of the substantive milestone events. Milestones related to sales-based activities may be triggered upon events such as the first commercial sale of a product or when sales first achieve a defined level. These sales-based milestones would be achieved after the completion of our development activities. We would account for the sales-based milestones in the same manner as royalties, with revenue recognized upon achievement of the milestone. In addition, upon the achievement of either development-based or sales-based milestone events, we have no future performance obligations related to any milestone payments.

Fair Value of Acquired Assets

The fair value of acquired tangible and identifiable intangible assets and liabilities assumed, including in process research and development , based on their estimated fair values at the acquisition date requires extensive use of accounting estimates and judgments. For each acquisition, we engage 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 years ended December 31, 2011, 2010 and 2009, approximately $8.8 million, $7.5 million $11.2 million, respectively, of development costs were reimbursed by Allergan, and credited against total related research and development expense. In addition, $85,000 of development costs in 2011 were reimbursed by TopoTarget in connection with the development of belinostat, and credited against total related research and development.

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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.

Fair Value Measurements

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 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 U.S. Government Treasury bills, U.S. treasury-backed securities and corporate deposits, which are stated at carrying value as it approximates fair market value due to the short term maturities of these instruments.

A majority of our financial assets have been classified as Level 2. These assets have been initially valued at the transaction price and subsequently valued utilizing third party pricing services. The pricing services use many observable market inputs to determine value, including reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates and other industry and economic events. The disclosed fair value related to our investments is based primarily on the reported fair values in our period-end brokerage statements. We independently validate the prices provided by our third party pricing services by understanding the models used, obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming those securities trade in active markets.

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.

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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 expense for all share-based awards made to employees and directors. The fair value of share based awards is estimated at the grant date using the Black-Scholes option-pricing model and the portion that is ultimately expected to vest is recognized as compensation cost over the requisite service period. 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 the management incentive plan awards are estimated using a lattice or Monte Carlo valuation model. The determination of fair value using the Black-Scholes and lattice option-pricing models is affected by our stock price as well as assumptions regarding a number of complex and subjective variables, including expected stock price volatility, risk free interest rate, expected dividends and projected employee stock option exercise behaviors. 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 estimate employee stock option exercise behavior based on actual historical exercise activity and assumptions regarding future exercise activity of unexercised, outstanding options.

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.

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.

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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, 2011 and December 31, 2010, 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, 2011 or December 31, 2010, 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 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, 2011, the end of the period covered by this report, referred to as 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.

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(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, 2011, 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 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, 2011, 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, 2011 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, 2011 and 2010 and the related consolidated statements of operations, stockholders equity and cash flows for each of the three years in the period ended December 31, 2011 of Spectrum Pharmaceuticals, Inc. and Subsidiaries and our report dated March 2, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Irvine, California

March 2, 2012

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

None.

PART III

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

The information required under this item is incorporated by reference from our definitive proxy statement related to our 2012 Annual Meeting of Stockholders, or the Proxy Statement, to be filed pursuant to Regulation 14A, on or before April 30, 2012.

Item 11. ***Executive Compensation***

The information required under this item is incorporated herein by reference from the Proxy Statement.

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

The information required under this item is incorporated herein by reference from the Proxy Statement.

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

The information required under this item is incorporated herein by reference from the Proxy Statement.

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

The information required under this item is incorporated herein by reference from the Proxy Statement.

PART IV

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

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

(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.*

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Index to Exhibits

Exhibit No.	Description
2.1	Asset Purchase Agreement by and between the Registrant, Targent Inc. and Certain Stockholders of Targent, Inc., dated March 17 2006. (Filed as Exhibit 2.1 to Form 10-K/A, Amendment No. 1, as filed with the Securities and Exchange Commission on May 1, 2006, and incorporated herein by reference.)
2.2#	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.)
2.3#	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+	Certificate of Incorporation, as amended through June 24, 2011.
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	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. (Filed as Exhibit 10.1 to Form 10-K, as filed with the Securities and Exchange Commission on March 10, 2011, and incorporated herein by reference.)
10.2+	First Amendment to Sublease Agreement, dated November 16, 2011, between the Registrant and Del Webb Corporation.
10.3	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.)
10.4	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.)
10.5	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.)

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Exhibit No.	Description
10.6	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.)
10.7*	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*	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.)
10.9*	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.)
10.10#	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.)
10.11*	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.)
10.12*	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.)
10.13*	Long-Term Retention and Management Incentive Plan. (Filed as Exhibit 10.36 to Form 10-Q, as filed with the Securities and Exchange Commission on August 4, 2011, and incorporated herein by reference.)
10.14*	Deferred Compensation Plan (Filed as Exhibit 4.1 to Form S-8, as filed with the Securities and Exchange Commission on September 6, 2011, and incorporated herein by reference).
10.15*	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.)
10.16*	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.)
10.17#	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.)
10.18#	Amendment to License, Development, Supply and Distribution Agreement, dated June 13, 2011, by and among the Registrant, Allergan Sales, LLC, Allergan USA, Inc. and Allergan, Inc. (Filed as Exhibit 10.37 to Form 10-Q, as filed with the Securities and Exchange Commission on August 4, 2011, and incorporated herein by reference.)

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Exhibit No.	Description
10.19*	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.)
10.20*	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.)
10.21	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.)
10.22*	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.)
10.23*	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.)
10.24*	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.)
10.25#	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.)
10.26#	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.)
10.27	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.)
10.28	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.)
10.29	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.)
10.30#	First Amendment to Supply Agreement, dated December 15, 2008, by and between Cell Therapeutics, Inc. and Biogen Idec Inc. (Filed as Exhibit 10.34 to Form 10-K, as filed with the Securities and Exchange Commission on March 10, 2011, and incorporated herein by reference.)
10.31	Security Agreement, dated December 15, 2008, by and between RIT Oncology, LLC and Biogen Idec Inc. (Filed as Exhibit 10.35 to Form 10-K, as filed with the Securities and Exchange Commission on March 10, 2011, and incorporated herein by reference.)
21+	Subsidiaries of Registrant.
23.1+	Consent of 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.

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Exhibit No.	Description
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 2, 2012

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:

Signature	Title	Date
/s/ Rajesh C. Shrotriya, M.D.	Chairman of the Board, Chief Executive	March 2, 2012
Rajesh C. Shrotriya, M.D.	Officer, and President	
	(Principal Executive Officer)	
/s/ Brett L. Scott	Senior Vice President and Acting Chief	March 2, 2012
Brett L. Scott	Financial Officer	
	(Principal Financial and Accounting Officer)	
/s/ Krishan K. Arora, Ph.D.	Director	March 2, 2012
Krishan K. Arora, Ph.D.		
/s/ Luigi Lenaz, M.D.	Director	March 2, 2012
Luigi Lenaz, M.D.		
/s/ Stuart M. Krassner, Sc.D., Psy.D.	Director	March 2, 2012
Stuart M. Krassner, Sc.D., Psy.D.		
/s/ Anthony E. Maida, III, M.A., M.B.A., Ph.D	Director	March 2, 2012

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

/s/ Dilip J. Mehta, M.D., Ph.D. Director March 2, 2012

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

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Spectrum Pharmaceuticals, Inc. and Subsidiaries

Consolidated Financial Statements

As of December 31, 2011 and 2010 and

For Each of the Three Years Ended December 31, 2011

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Spectrum Pharmaceuticals, Inc. and Subsidiaries

Consolidated Financial Statements

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Report of 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, 2011 and 2010, and the related consolidated statements of operations, stockholders equity and cash flows for each of the three years in the period ended December 31, 2011. 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, 2011 and 2010, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, 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, 2011, 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 2, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Irvine, California

March 2, 2012

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Spectrum Pharmaceuticals, Inc. and Subsidiaries

Consolidated Balance Sheets

(In thousands, except share and per share data)

	September 30, 2011	December 31, 2010
ASSETS		
Current Assets:		
Cash and equivalents	$ 121,202	$ 53,557
Marketable securities	40,060	42,117
Accounts receivable, net of allowance for doubtful accounts of $471 and $339, respectively	51,703	21,051
Inventories, net	10,762	4,234
Prepaid expenses and other current assets	2,074	906
Total current assets	225,801	121,865
Investments	9,283	8,569
Property and equipment, net	2,681	3,158
Intangible assets, net	41,654	29,605
Other assets	1,361	434
Total assets	$ 280,780	$ 163,631
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable and other accrued obligations	$ 54,771	$ 38,704
Accrued compensation and related expenses	1,788	3,313
Deferred revenue	12,300	12,300
Common stock warrant liability		3,904
Accrued drug development costs	9,678	5,101
Total current liabilities	78,537	63,322
Capital lease obligations	9	40
Deferred revenue and other credits less current portion	14,029	25,495
Other long-term obligations	298	298
Total liabilities	92,873	89,155
Commitments and contingencies		
Stockholders Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized:		
Series B Junior participating preferred stock 1,500,000 shares authorized: no shares issued and outstanding		
Series E convertible voting preferred stock $10,000 par value; 2,000 shares authorized; 20 and 26 shares issued and outstanding at December 31, 2011 and 2010, respectively, (aggregate liquidation value of $240)	123	160
Common stock, $0.001 par value 175,000,000 shares authorized; 59,247,483 and 51,459,284 issued and outstanding at December 31, 2011 and 2010, respectively	59	51
Additional paid-in capital	452,761	384,757
Accumulated other comprehensive loss	(227)	(92)
Accumulated deficit	(261,883)	(310,400)
Less: Treasury stock at cost: 363,055 shares at December 31, 2011	(2,926)	

Total stockholders equity		187,907	74,476
Total liabilities and stockholders equity	$	280,780	