SPECTRUM PHARMACEUTICALS INC
Form 10-K/A
December 06, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K/A

Amendment No. 1

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

For the fiscal year ended December 31, 2012

¨ **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 x

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2012 was $783,502,234 based on the closing sale price of such common equity on such date.

As of February 15, 2013 there were 60,157,023 shares of the registrant s common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s Proxy Statement for the registrant s 2013 Annual Meeting of Shareholders, to be filed on or before April 30, 2013, are incorporated by reference into Part III, Items 10-14 of this Annual Report on Form 10-K/A.

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Explanatory Note

We are filing this Amendment No. 1 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2012 to amend and revise portions of our original Annual Report for this period (the Original Report). This Amendment No. 1 amends and revises the following items from the Original Report: (A) Part I, Item I Business, (B) Part I, Item 1A Risk Factors, (C) Part II, Item 6 Selected Financial Data, (D) Part II, Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations, (E) Part II, Item 8 Financial Statements and Supplementary Data, and (F) Part II, Item 9A Controls and Procedures.

The disclosures set forth in these items in the Original Report, that are amended by this Amendment No. 1 include:

(A) Amendments to Part I, Item I Business, to restate presented research and development expense detail for the 2012, 2011, and 2010 annual periods, as described below in (C) (ii).

(B) Amendments to Part I, Item 1A Risk Factors, to add an additional risk factor regarding our internal controls over financial reporting as a result of the identification of a material weakness in our financial reporting.

(C) Amendments to Part II, Item 6 Selected Financial Data, to revise our 2008 through 2012 annual financial results, and as of each fiscal year-end date, to reflect: (i) $2.1 million of intangible asset amortization in the year ended December 31, 2012; (ii) a reduction in operating expenses related to certain accounts payable and other accrued obligations accounts which had the effect of overstating our consolidated operating expenses by $3.0 million, $1.4 million, $1.8 million, $0.7 million, and $0.2 million for the years ended 2012, 2011, 2010, 2009, and 2008, respectively; and (iii) the impact on our intangible assets, goodwill, and income tax accounts for the effects of above items (i) and/or (ii) within our balance sheet as of December 31, 2012, 2011, 2010, 2009, and 2008.

(D) Amendments to Part II, Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations, to reflect the revision of our financial results, described in (C) above.

(E) Amendments to Part II, Item 8 Financial Statements and Supplementary Data, to revise our 2010 through 2012 annual financial results, and as of December 31, 2012 and 2011, to reflect the revision of our financial results, described in (C) above, as well as revising our statements of comprehensive income (loss), stockholders equity, and cash flows for the years ended December 31, 2012, 2011, and 2010 for the items noted within (C) above, specifically for (i), (ii), and (iii).

(F) Amendments to Part II, Item 9A Controls and Procedures, to (i) describe changes in our disclosure controls and procedures and its internal controls over financial reporting to address a material weakness, (ii) a modification to management s opinion of the effectiveness of our internal controls over financial reporting as of December 31, 2012, and (iii) a modification of the Report of our Independent Registered Public Accounting Firm for its opinion of the effectiveness of our internal controls over

financial reporting as of December 31, 2012.

Our financial statement revisions result from errors related to our accounting for the acquisition of Allos Therapeutics, Inc. in September 2012. We designated an acquired intangible asset as in-process research & development (IPR&D), which should have been designated at the acquisition date as a definite-lived intangible asset, as described above within (C)(i), resulting in under-reported amortization expense of $2.1 million for the year ended December 31, 2012.

Also, during the financial statement close process for the quarter ended September 30, 2013, management identified an accounting error related to an overstatement of accounts payable and accrued obligations that accumulated between January 1, 2007 through June 30, 2013, as described above within (C)(ii). We assessed the impact of this error and concluded that it was not material to our financial statements for the each of the years ended December 31, 2012, 2011, and 2010, and reported fiscal quarters within each of these years. Although the error was not material to our issued quarterly and annual financial statements in these years, the correction of the cumulative error would have been material for the year ended December 31, 2013. Consequently, we have revised our financial results for the periods presented in this Annual Report on Form 10-K/A. Because these revisions are treated as corrections to our prior period financial results, the revisions are considered to be a restatement under U.S. generally accepted accounting principles. Accordingly, the revised financial information included in this Annual Report on Form 10-K/A has been identified as restated.

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The combined impact of the adjustments to the applicable line items in our consolidated financial statements for the periods subject to revision (collectively, the Restated Periods) is set forth in Note 1A, Revision of Previously Issued Consolidated Financial Statements, included in Part II, Item 8, of this Annual Report on Form 10-K/A.

Management has also concluded that as of December 31, 2012, our internal controls over financial reporting were not effective due to a material weakness in internal control over financial reporting related to the accurate and timely reporting of its accounting for accruals. Specifically, controls over the review of purchase order related accruals were not designed and operating effectively to timely review and accurately record purchase order accruals in the consolidated financial statements.

We believe that presenting the restated information regarding the Restated Periods in this Form 10-K/A allows investors to review all pertinent data in a single presentation. Accordingly, investors should rely only on the financial information and other disclosures regarding the Restated Periods in this Form 10-K/A or in future filings with the Securities and Exchange Commission, as applicable, and not on any previously issued or filed reports, earnings releases or similar communications relating to these periods. The restatement has no effect on our net cash used in operating activities or on our cash and cash equivalents or short-term investments for the Restated Periods.

Item 15 of Part IV of this Form 10-K/A has been amended to contain the currently-dated certifications from our principal executive officer and principal financial officer, as required by Section 302 and 906 of the Sarbanes-Oxley Act of 2002. Ernst & Young LLP has dual dated their reports on the consolidated financial statements and internal control over financial reporting to the board of directors and stockholders with regard to Note 1A. of the consolidated financial statements and the material weakness in internal controls over financial reporting noted above, and updated their consent to the date of this filing.

Because this Form 10-K/A sets forth the 2012 Form 10-K in its entirety, it includes items that have been changed as a result of the restatement and the items that are unchanged from the 2012 Form 10-K. Other than the amending of the disclosures relating to the restatement, this Form 10-K/A speaks as of the original filing date of the 2012 10-K and has not been updated to reflect other events occurring subsequent to the original filing date. This includes forward-looking statements and the portions of the Business section, Risk Factors and all other sections of this Form 10-K/A that were not directly impacted by the restatement, which should be read in their historical context. This Form 10-K/A should be read in conjunction with our Forms 10-Q/A for the quarters ended March 31, 2013 and June 30, 2013 and our Form 10-Q for the quarter ended September 30, 2013.

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

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 three oncology drugs, FUSILEV® , FOLOTYN® and ZEVALIN® and also market ZEVALIN outside of the U.S. We 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 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 has been studied in two large Phase 3 clinical trials for non-muscle invasive bladder cancer, or NMIBC, and is under strategic collaborations with 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. FOLOTYN is being further developed under a collaboration agreement with Mundipharma International Corporation Limited, or Mundipharma.

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Our business strategy is comprised of the following initiatives:

Maximizing the growth potential of our marketed drugs, *FUSILEV, FOLOTYN and ZEVALIN*. Our near-term outlook largely depends on sales and marketing successes for our three marketed drugs. For FUSILEV, we are working to expand usage in colorectal cancer. We launched FUSILEV in August 2008 and 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. While generic leucovorin supplies and utilization have been negatively impacted by this shortage, we cannot predict how long the shortage may continue or the extent of the impact the shortage may ultimately have on FUSILEV utilization. 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 a Ready-To-Use formulation, or RTU, of FUSILEV. We are now actively engaged in marketing FUSILEV for use in advanced metastatic colorectal cancer.

We added FOLOTYN to our commercial drug portfolio with the acquisition of Allos Therapeutics, Inc. or Allos in September 2012. FOLOTYN is a folate analogue metabolic inhibitor designed to accumulate preferentially in cancer cells. FOLOTYN targets the inhibition of dihydrofolate reductase, or DHFR, an enzyme critical in the folate pathway, thereby interfering with DNA and RNA synthesis and triggering cancer cell death. FOLOTYN can be delivered as a single agent, for which we currently have approval in the United States for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma, or PTCL, and has the potential to be used in combination therapy regimens. We believe that FOLOTYN s unique mechanism of action offers us the ability to target the drug for development in a variety of hematological malignancies and solid tumor indications and for autoimmune diseases as well. FOLOTYN has been available for commercial sale in the United States since October 2009.

For ZEVALIN, we continue to work on growing the ZEVALIN brand and are working to expand indications for use beyond follicular non-Hodgkin s lymphoma through additional trials. Effective April 2, 2012, with the acquisition of licensing rights from Bayer Pharma AG, we began the sales of ZEVALIN outside of the U.S. 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, to expand utilization. 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 our drugs. In addition our scientific department supports field activities through various MDs, PhDs and other medical science liaison personnel.

Optimizing our development portfolio and maximizing the asset values of its components. While over the recent few years, we have evolved from a development-stage to a commercial-stage pharmaceutical company, we have maintained a highly focused development portfolio. Our strategy with regard to our development portfolio is to focus on late-stage drugs and to develop them 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 MDs, PhDs, clinical research associates and a complement of other support personnel to develop these drugs. In April 2012, we announced that the single instillation Phase 3 clinical trials for apaziquone did not meet their primary endpoint however the pooled data from the studies did show a statistically significant treatment effect. A meeting with the FDA was held in December 2012 to discuss the results from these

clinical trials. Based on the discussions with the FDA, we understand that the FDA can accept the NDA filing with the current Phase III data and will likely convene an Advisory Committee meeting. Further, based on discussions with the FDA, we have agreed to conduct one additional Phase III study following consultation with the FDA on its design.

With regard to our anti-cancer drug belinostat, a novel HDAC inhibitor, we have to date opened more than 100 international sites in the study of relapsed refractory peripheral T Cell Lymphoma. We completed enrollment in this trial in September 2011, announced top line results in December 2012 and expect to file a NDA in 2013.

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

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Expanding our pipeline of 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.

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 2012. This policy includes the pursuit of dilutive and 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 three 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 dilutive and 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 to be 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.

Recent Developments

In 2012 and early 2013, we have continued to execute on our business strategy described above. We discuss below the key developments during that period.

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 2013. If SPI-2012 is ultimately commercialized, we will have worldwide rights except for Korea, China and Japan.

On April 1, 2012, through a subsidiary, Spectrum Pharmaceuticals Cayman, L.P., we completed the acquisition of the 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 acquired 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 July 2012, we initiated an international, randomized, placebo-controlled Phase 2 study evaluating lucanthone in primary therapy for Glioblastoma Multiforme. An orally administered small molecule, lucanthone inhibits topoisomerase II and AP endonuclease and has been shown to sensitize tumor cells to radiation and chemotherapy by inhibiting DNA repair.

In August 2012, we initiated patient enrollment in the second part of our randomized Phase 2 clinical program of ozarelix, a luteinizing hormone-releasing hormone antagonist, in men with prostate cancer for whom hormonal treatment is indicated.

On September 5, 2012 we successfully completed the acquisition of Allos Therapeutics, Inc. As a result of the acquisition, we acquired an assembled sales force and FOLOTYN (pralatrexate injection) a folate analogue metabolic inhibitor which enhanced our existing product base.

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In September 2012, we initiated patient enrollment in our randomized Phase 3 ZEVALIN Evaluation as Sequential Therapy trial of ZEVALIN injection for intravenous use for first-line consolidation in patients with diffuse large B-cell lymphoma who achieved remission following R-CHOP chemotherapy (rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone).

In December 2012, we announced surpassing the primary endpoint in the pivotal, registrational Phase 2 BELIEF trial for belinostat, a pan-histone deacetylase, or HDAC, inhibitor. We expect to file an NDA by the middle of 2013.

In early January 2013 we announced positive, statistically significant data from our Phase 1 clinical trial evaluating the safety and tolerability of RenaZorb (also referred to as SPI-014) in healthy volunteers. RenaZorb is an orally available, lanthanum-based nanotechnology compound with potent phosphate-binding properties that is being developed for the potential treatment of hyperphospaternia (high phosphate levels in the blood) in patients with stage 5 chronic kidney desease, or CKD.

In late January 2013, we announced that we had reacquired development and commercialization rights for apaziquone in the U.S., Europe and other territories pursuant to an agreed-upon restructuring of our collaboration with Allergan, Inc. Apaziquone is an anticancer agent being developed for the treatment of non-muscle invasive bladder cancer as a single instillation following transurethral resection of bladder tumor.

Through the above-referenced agreements and our continued efforts, we continue to build a global pharmaceutical organization in 2013. 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 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. In connection with our acquisition of the ZEVALIN rights outside of the U.S. we have formed entities in the Cayman Islands, Netherlands and Japan.

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.

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

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

Overview of Cancer

According to the American Cancer Society s publication *Cancer Facts & Figures 2012*, cancer is the second leading cause of death in the U.S., accounting for approximately 25% of all deaths. In the U.S., approximately 1.64 million new cancer cases were expected to be diagnosed in 2012 and over 577,000 persons were expected to die from the disease in 2012. 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, or travel of these cells to sites outside of their normal environment. 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 in their typical environment or migrate to other sites in the body.

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.

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Cancer usually forms as a tumor. Some cancers, like leukemia, do not typically form tumor masses. 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. In the more recent era, certain similar or identical molecular abnormalities may be found in histologically different kinds of cancers, with treatment designed to resolve the molecular abnormality. 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.

Development of Our Drug Products

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 2012 incidence of colorectal cancer in the U. S. would be approximately 143,460 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, Centers for Medicare & Medicaid Services, or 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. or Targent. 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 $200,000 payment upon achievement of FDA approval of an oral form of FUSILEV, in addition to royalties in the mid-single digits based on a percentage of 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.

FOLOTYN (pralatrexate injection): In September 2012, through the completion of our acquisition of Allos, we acquired FOLOTYN. FOLOTYN is a folate analogue metabolic inhibitor designed to accumulate preferentially in cancer cells. Based on preclinical studies, we believe that FOLOTYN selectively enters cells expressing RFC, a protein that is frequently over expressed on cancer cells compared to normal cells. Once inside cancer cells, FOLOTYN is efficiently polyglutamylated, which makes it less susceptible to efflux-based drug resistance and leads to high intracellular drug retention compared to other antifolates. Inside the cell, FOLOTYN targets the inhibition of DHFR, an enzyme critical in the folate pathway, thereby interfering with DNA and RNA synthesis and triggering cancer cell death.

The antimetabolites, including antifolates such as FOLOTYN, are a group of low-molecular weight compounds that exert their effect by virtue of their structural or functional similarity to naturally occurring molecules involved in DNA synthesis. Because the cell mistakes them for a normal metabolite, the antimetabolites either inhibit critical enzymes involved in DNA synthesis or become incorporated into the nucleic acid, producing incorrect codes. Both mechanisms result in inhibition of DNA synthesis and ultimately, cell death. Because of their primary effect on DNA synthesis, the antimetabolites are most effective against actively dividing cells and are largely cell-cycle phase specific. There are three classes of antimetabolites; purine analogs, pyrimidine analogs and folic acid analogs, also termed antifolates. FOLOTYN is a folic acid analog.

The selectivity of antifolates for tumor cells involves their conversion to a polyglutamylated form by the enzyme folypolyglutamyl synthetase. Polyglutamylation is a time- and concentration-dependent process that occurs in tumor cells, and to a lesser extent, normal cells. The selective activity of the folic acid analogs in malignant cells versus normal cells likely is due to the relative difference in polyglutamylate formation. Polyglutamylated metabolites have

prolonged intracellular half-life, increased duration of drug action and are potent inhibitors of several folate-dependent enzymes, including DHFR.

We believe that the resistance of malignant cells to the effects of the folic acid analogs may, in part, be due to impaired polyglutamylation. We believe the improved antitumor effects of FOLOTYN in comparison to methotrexate, as observed in preclinical studies, is likely due to the more effective uptake and transport of FOLOTYN into the cell followed by the greater accumulation of FOLOTYN and its metabolites within the tumor cell through the formation of the polyglutamylated derivatives.

ZEVALIN (ibritumomab tiuxetan) Injection for intravenous use: 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 April 2012, we acquired licensing rights to market ZEVALIN outside of the U.S from Bayer Pharma AG, or Bayer, as further described below.

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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 tumors 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 lymphatic fluid from the peripheral tissues and returns lymphatic fluid to circulation. There are many different types of NHL which can be divided into aggressive NHL, a more rapidly spreading and refractory form of the disease, and indolent NHL, which progresses more slowly. NHL 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. 70,130 people were expected to be newly diagnosed with NHL in 2012. Additionally, approximately 18,940 were expected to die from this disease in 2012.

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.

In December 2012 at the Annual Meeting of the American Society of Hematology in Atlanta, Georgia, 19 abstracts were presented featuring clinical and scientific data for our commercial products, ZEVALIN and FOLOTYN, as well as our late-stage drug candidate, belinostat. The presentations included two oral presentations and 10 poster presentations for ZEVALIN® (ibritumomab tiuxetan) injection for intravenous use, three poster presentations for FOLOTYN® (pralatrexate injection), and four poster presentations for belinostat, a novel histone deacetylase (HDAC) inhibitor.

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.

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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. Pursuant to the terms of the agreement, as amended, (i) upon the achievement of the specified FDA approval milestone, which was achieved in 2009, RIT (as successor to CTI) paid Biogen an additional amount of $5.5 million, (ii) RIT may be required to make an additional $10.0 million milestone payment upon the achievement of an additional FDA approval milestone, and (iii) RIT is required to make yearly royalty payments determined as a mid-single to mid-teen digits percentage of yearly net sales for the preceding year, increasing with the passage of time, with specific rates subject to confidential treatment pursuant to an order by the SEC. The agreement has an indefinite term and is no longer subject to termination; provided, however, that the royalty obligations automatically terminate upon the latest to occur of expiration of the subject patents, the sale by a third party of a biosimilar product in the U.S. or December 31, 2015. 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. Pursuant to the terms of this agreement, as amended, we are required to purchase from Biogen certain kits to make single doses as part of one treatment to a patient, of either (i) Indium-111 Ibritumomab Tiuxetan (In-111 ZEVALIN) or (ii) Yttrium-90 Ibritumomab Tiuxetan (Y-90 ZEVALIN) or packages containing one dose of each for sale to end-users in the U.S. at a cost plus manufacturing price, with specific rates subject to confidential treatment pursuant to an order by the SEC. There are no milestone or royalty payments required pursuant to this agreement. The term of the agreement is until a manufacturing technology transfer occurs. Either party may generally terminate this agreement due to a bankruptcy of the other party or due to such other party s material noncompliance with the agreement or certain other related agreements. CTI s rights and obligations, including its payment obligations to Biogen, under both the CTI/Biogen Supply Agreement and the amendment were

assigned to and assumed by RIT in connection with the closing of the joint venture transaction.

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

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

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Pursuant to the transfer of the ZEVALIN assets from CTI to RIT in December 2008, RIT assumed certain agreements with various third parties related to ZEVALIN intellectual property. These currently effective agreements relate to the manufacture, use and sale of ZEVALIN in the United States and include (i) a license from Biogen, (ii) a license-back to Biogen for limited uses including fulfillment of a supply obligation to CTI, (iii) a sublicense from Biogen to certain ZEVALIN patents held by Genentech, Inc., (iv) a sublicense from Biogen to certain ZEVALIN patents held by GlaxoSmithKline and Glaxo Group Limited, and (v) a sublicense from Biogen to certain ZEVALIN patents held by Corixa Corporation, Coulter Pharmaceutical, Inc., The Regents of the University of Michigan and GlaxoSmithKline. In accordance with the terms of such agreements, RIT is required to meet specified payment obligations including a commercial milestone payment to Corixa Corporation of $5,000,000 based on ZEVALIN sales in the United States, which has not been met, as well as U.S. net sales-based royalties of low to mid-single digits to Genentech, Inc. and mid-single digits to Corixa Corporation. Such agreements generally continue until the last to expire of the licensed patents unless earlier terminated in accordance with the terms of the agreement for bankruptcy or material breaches that remain uncured. The patents that are subject to the agreements expire between 2014 and 2018.

On April 1, 2012, through a subsidiary, Spectrum Pharmaceuticals Cayman, L.P., we completed the acquisition of licensing rights to market ZEVALIN outside of the U.S., referred to as the ZEVALIN Ex-US Rights, from Bayer Pharma AG, or Bayer. Pursuant to the terms of the agreement, Spectrum acquired all rights including marketing, selling, intellectual property and access to existing inventory of ZEVALIN from Bayer. We currently market ZEVALIN in the U.S. and this agreement expands our commercial efforts to the rest of the world. ZEVALIN is currently approved 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. In consideration for the rights granted under the agreement, concurrent with the closing, Spectrum paid Bayer a one-time fee of Euro 19 million or US $25.4 million and will pay Bayer royalties based on a mid-teen digits percentage of net sales of the licensed products in all territories worldwide except the U.S., with specific rates subject to confidential treatment pursuant to an order by the SEC. Under the agreement, we also acquired access to existing inventory of ZEVALIN and concurrent with the closing, entered into certain ancillary agreements including but not limited to a transition services agreement to transition the business. Unless earlier terminated, the term of the agreement continues until the expiration of our royalty payment obligations which, in turn, run until the last-to-expire patent covering the sale of a licensed product in the relevant country or fifteen (15) years from the date of first commercial sale of the licensed product in such country, whichever is longer. This agreement may be terminated in the event of a material default, which is defined to include: (i) our failure to timely pay royalty payments under this agreement or payments under certain related agreements; (ii) our insolvency; and (iii) our breach and the resulting termination of an Amended and Restated License Agreement between Biogen and Bayer, dated as of January 16, 2012.

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 2012 incidence and prevalence of bladder cancer in the U.S. would be approximately 73,510 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 to attempt a 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 FDA 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).

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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. Apaziquone is inactivated in the systemic circulation by the red blood cell fraction. The proposed dose therefore carries a minimal risk of systemic toxicity which could arise from absorption of a drug through the bladder wall into the bloodstream. Additionally, the current proposed dose is a fraction of the systemic toxic dose. These features of apaziquone are distinct from other intravesical agents currently in use for the treatment of recurrent bladder cancer.

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

Phase 2 data has confirmed anti-tumor activity in patients with multiple, recurrent NMIBC, as evidenced by 31 of 46 patients (67%) showing a complete response after receiving six weekly treatments with 4 mg of apaziquone instilled into the urinary bladder in this marker lesion study. Apaziquone was well-tolerated, with no significant systemic toxicity, and local toxicity limited to temporary chemical cystitis (inflammation of the urinary bladder) resulting in increased urinary frequency, dysuria (painful urination) and hematuria (blood in the urine) in a few patients. At the two-year follow up, eighteen patients (38%) were disease free.

In September 2005, we initiated an open label, multi-center clinical study in Europe in high-risk NMIBC in 53 patients. Patients with high-risk NMIBC usually have more aggressive bladder cancer with higher incidence of recurrence and/or progression to a more invasive stage, where the cancer invades the muscle wall of the bladder, which may require total surgical removal of the bladder. 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 TaG1-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 very similar 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. In April 2012, we announced that the single instillation Phase 3 clinical trials for apaziquone did not meet their primary endpoint however the pooled data from the studies did show a statistically significant treatment effect. A meeting with the FDA was held in December 2012 to discuss the results from these clinical trials. Based on the discussions with the FDA, we understand that the FDA can accept the NDA filing with the current Phase III data and will likely convene an Advisory Committee meeting. Further, based on

discussions with the FDA, we have agreed to conduct one additional Phase III study following consultation with the FDA on its design.

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.

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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 provided that Allergan had 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 concurrently entered into a co-promotion agreement with Allergan providing for the joint commercialization of apaziquone in the U.S., whereby we and Allergan agreed to share equally all profits and commercialization expenses. Pursuant to the terms of the license, development, supply and distribution agreement, Allergan paid us an up-front non-refundable $41.5 million at closing and was obligated to make additional payments based on the achievement of certain development, regulatory and commercialization milestones, of which $1.5 million was achieved following completion of enrollment in clinical trials. In January 2013, we entered into an amendment to the license, development, supply and distribution agreement to restructure the collaboration with Allergan, with Spectrum buying back the rights it originally licensed to Allergan in the U.S., Europe and other territories in exchange for a tiered single digit royalty not to exceed mid-single digits on certain products containing apaziquone, and Allergan being relieved of its obligations for development, commercialization and other activities. The license, development, supply and distribution agreement, as amended, will continue until the expiration of the last royalty payment obligation in the last country in the Allergan territory (as defined in the agreement) with certain provisions surviving.

In November 2009, we entered into a collaboration agreement with the Nippon Kayaku Co., LTD., or Nippon Kayaku, for the development and commercialization of apaziquone in Asia, except North and South Korea, collectively referred to as the Nippon Kayaku Territory. 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. Further, Nippon Kayaku will be responsible for all expenses relating to the development and commercialization of apaziquone in the Nippon Kayaku Territory. Pursuant to the terms of this agreement, Nippon Kayaku paid Spectrum an upfront fee of $15 million and is obligated to make additional payments based on the achievement of certain development, regulatory and commercialization milestones. Under the terms of the agreement, we are entitled to payment of $10 million and $126 million upon achievement of certain regulatory and commercialization milestones, respectively. Also, Nippon Kayaku has agreed to pay Spectrum royalties based on a percentage of net sales of the subject products in the defined territory in the mid-teen digits, which specific royalty rates are subject to confidential treatment pursuant to an order by the SEC. The agreement will remain in effect, on a country-by-country basis, until the expiration of the obligation of Nippon Kayaku to pay royalties on sales of the subject products in such country. Nippon Kayaku may terminate the agreement at its election upon nine months notice to Spectrum. Additionally, either party may terminate the agreement for an uncured material breach by the other party.

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 agreed to make additional milestone payments of up to $18.6 million 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.

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

Pursuant to the terms of this agreement, Spectrum paid TopoTarget an upfront fee of $30 million. In addition, on the successful achievement of certain development, regulatory and sales milestones, none of which have been achieved to date, Spectrum is obligated to issue one million (1,000,000) shares of its common stock (subject to certain resale conditions) and pay TopoTarget up to $313 million. Also, Spectrum will pay TopoTarget royalties in the mid-teen digits based on net sales of the subject product in the defined territory, which specific royalty rates are subject to confidential treatment pursuant to an order by the SEC. None of such royalties have been earned or paid since inception of the agreement.

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 have assumed all responsibility for future costs of the ongoing registrational PTCL trial while TopoTarget assumed all responsibility for costs of the 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.

The agreement will continue until the expiration of the last royalty payment period in the last country in the defined territory with certain provisions surviving, unless earlier terminated in accordance with its terms. Spectrum may terminate the agreement at its election upon one hundred eighty (180) days notice to TopoTarget. Generally, Spectrum may also terminate immediately upon a prohibition on the use of the subject product or clinical hold by the FDA. TopoTarget may also terminate immediately in the event of a challenge (without TopoTarget s consent) by Spectrum of the patents that cover the product. Either party may terminate the agreement upon a bankruptcy by the other party, or in the event of an uncured material breach by the other party.

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.

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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.

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 and as a radiosensitizing agent in various tumor models in man.

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.

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

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

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

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 2013.

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 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 2012. In early January 2013 we announced positive data from the Phase 1 clinical trial evaluating the safety and tolerability of RenaZorb in healthy volunteers.

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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.

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, or Hanmi, for SPI-2012 based on Hanmi s proprietary LAPSCOVERY Technology.

Granulocyte colony-stimulating factor, or 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. In October 2012, we amended our supply agreement with our ZEVALIN contract manufacturer in order to transfer manufacturing to a new contract manufacturer. The terms of the agreement include the purchase of certain inventory and equipment payable in four installments through January 2014 of $1,250,000 each.

The production of FOLOTYN employs small molecule organic chemistry procedures standard for the pharmaceutical industry. We have arrangements with two third-party manufacturers to produce FOLOTYN bulk drug substance and two third-party manufacturers to produce FOLOTYN formulated drug product. We believe these third-party manufacturers have the capability to meet our projected worldwide clinical trial and commercial requirements for FOLOTYN although we cannot assure you of this. 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, ZEVALIN and FOLOTYN. In late 2012, we strengthened our senior management team with the addition of an Executive Vice President and Chief Operating Officer and new Chief Commercial Officer. Under their direction, we undertook a strategic strengthening of our sales force in the U.S., implementing a structure of six geographic regions and expanding the sales team to 60 professionals in order to provide the ability to effectively and efficiently add more oncology products in the future.

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In addition, 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 FUSILEV and FOLOTYN. The same third party logistics company also stores and ships ZEVALIN kits containing the CD20 MAB.

Customers

Our product sales are concentrated in a limited number of customers. A summary of our customers that represent 10% or more of our total consolidated gross product sales are as follows:

	2012	2011	2010
Oncology Supply	26.5%	57.0%	45.7%
McKesson Specialty	23.2%	19.1%	*
ICS	19.4%	*	*
Cardinal Health	15.7%	*	*

(*) Less than 10%

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. A summary of our customers that represent 10% or more of our net receivables as of December 31, 2012 and 2011 are as follows:

	2012	2011
Oncology Supply	37.7%	26.8%
McKesson Specialty	26.0%	54.1%
ICS	19.1%	*

(*) Less than 10%

No other single customer owed us more than 10% of net receivables during the prior fiscal years.

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.

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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, BiPar Sciences, Inc., Genzyme Corporation, Shire Pharmaceuticals, Abbott Laboratories, Poniard Pharmaceuticals, Inc., Roche Pharmaceuticals and Johnson & Johnson each of 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 as our product. 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.

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.

With respect to FOLOTYN, it became the first agent approved by the FDA for the treatment of patients with relapsed or refractory PTCL. In June 2011, the FDA granted accelerated approval for romidepsin, marketed by Celgene, Inc., for the treatment of patients with PTCL who have received at least one prior therapy. This was the second indication approved for romidepsin, which was initially approved by the FDA in November 2009 for the treatment of patients with CTCL who have received at least one prior systemic therapy. The FDA also granted accelerated approval of brentuximab vedotin, marketed by Seattle Genetics, Inc., in August 2011 for two indications, one of which was for the

treatment of patients with systemic anaplastic large cell lymphoma, or ALCL, after failure of at least one prior multi-agent chemotherapy regimen. ALCL is one of the subtypes of PTCL included in the labels of both FOLOTYN and romidepsin. In addition, we are aware of multiple investigational agents that are currently being studied in clinical trials for PTCL, including belinostat and alisertib, which, if approved, may compete with FOLOTYN in the United States. In addition, there are many existing approaches used in the treatment of relapsed or refractory PTCL, including combination chemotherapy and single agent regimens, which represent competition for FOLOTYN.

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

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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 $41.6 million, $26.7 million and $56.7 million, respectively, in 2012, 2011 and 2010 broken out by product as follows:

	Year Ended December 31,		
	2012 (As Restated)	2011 (As Restated)	2010 (As Restated)
	($ in 000 s)		
Apaziquone	$ 6,642	$ 7,695	$ 6,086
Belinostat	3,742	7,207	35,583
FUSILEV	1,416	1,239	1,265
FOLOTYN	1,586		
ZEVALIN	5,040	167	416
GCS	1,049		
Lucanthone	792		
Ozarelix	724	740	1,891
Ortataxel	554	107	707
Renazorb	1,299	476	1,533
Other development drugs	4,695	1,417	1,891
Total Direct Costs	27,539	19,048	49,372
Indirect Costs (including non-cash share-based compensation of $1.8 million, $1.6 million and $2.4 million, respectively)	21,404	16,502	14,838
Partner Reimbursement	(7,383)	(8,888)	(7,550)
Total Research & Development	$ 41,560	$ 26,662	$ 56,660

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, FOLOTYN, ZEVALIN, ozarelix, ortataxel, lucanthone, belinostat and SPI-1620, in each case for the remaining life of the applicable patents. Except for FUSILEV, and belinostat, 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 RenaZorb and SPI-1620, we own patent and other intellectual property rights related to these products.

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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 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 U.S. patents covering the compounding process expiring in 2019, and will consider filing more patent applications, if the opportunity arises. For FOLOTYN we have a composition of matter patent due to expire in 2022 following a five-year patent term extension in U.S. The composition of patent is due to expire in Europe in 2017 but is eligible for a similar patent term extension following regulatory approval in Europe. We also have patents covering the use of FOLOTYN for PTCL that will not expire until 2025. Additionally, we have issued patents and pending patent applications in US and many other countries claiming different uses of FOLOTYN, and we may consider filing new 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, corresponding European patents expiring in 2014 and multiple manufacturing and synthesis patents in US and Europe that do not begin to expire until 2021. We anticipate filing new method of use and formulation patent applications for the ortataxel product in the future. 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, manufacturing process 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.

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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®, FOLOTYN flower design associated with FOLOTYN and RenaZorb®. We also have the FOLOTYN trademark and the associated flower design registered in Europe and other countires. 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 that is in the process of being assigned to us.

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. It is possible that these agreements will be breached or will not be enforceable in every instance, and that we will not have adequate remedies for any such breach. It is also possible that our trade secrets or know-how will otherwise become known or independently developed by competitors. The protection of know-how is particularly important because the know-how is often the necessary or useful information that allows us to practice the claims in the patents related to our proprietary drug products.

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

The Patent Process

The 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

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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, 2007 and 2012.

Generic Approval and Patent Certification

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

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

With respect to the illegal settlement prong, the MMA amendments require that certain types of settlement agreements entered into between branded and generic pharmaceutical companies related to the manufacture, marketing and sale of generic versions of branded drugs are required to be filed with the Federal Trade Commission and the Department of Justice for review of potential anti-competitive practices. This requirement could affect the manner in which generic drug manufacturers resolve intellectual property litigation and other disputes with branded pharmaceutical companies, and could result generally in an increase in private-party litigation against pharmaceutical companies. The impact of this requirement, and the potential governmental investigations and private-party lawsuits associated with arrangements between brand name and generic drug manufacturers, remains uncertain and could adversely affect our business. In addition, Congress has considered enacting legislation that would prohibit such settlements between brand name and generic drug manufacturers. Such a provision was considered as part of the 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.

The PPACA provides 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.

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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.

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, FOLOTYN has been granted an orphan drug designation for PTCL and CTCL and 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.

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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.

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.

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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.

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.

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With respect specifically to information submitted to FDA in support of marketing applications, the FDA, under its Fraud, Untrue Statements of Material Facts, Bribery and Illegal Gratuities Policy, can significantly delay the approval of a marketing application, or seek to withdraw an approved application where it identifies fraud or discrepancies in regulatory submissions. Such actions by the FDA may significantly delay or suspend substantive scientific review of a pending application during validity assessment or remove approved products from the market until the assessment is complete and questions regarding reliability of the data are resolved. In addition, the Generic Drug Enforcement Act of 1992 established penalties for wrongdoing in connection with the development or submission of an ANDA. Under this Act, the FDA has the authority to permanently or temporarily bar companies or individuals from submitting or assisting in the submission of an ANDA, and to temporarily deny approval and suspend applications to market generic drugs. The FDA may also suspend the distribution of all drugs approved or developed in connection with certain wrongful conduct and/or withdraw approval of an ANDA and seek civil penalties.

Healthcare Reform

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

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

Foreign Regulation

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

Under the EU regulatory systems, we may submit marketing authorization applications either under a centralized procedure or decentralized procedure or the mutual recognition procedure. The centralized procedure is mandatory for medicines produced by a biotechnological process. The procedure is also mandatory for new active substances which are indicated for treatment of several diseases or conditions, including cancer and orphan conditions. Companies may apply for centralized assessment if the product contains a new active substance or the 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, 2012, we had 193 employees, of which 10 held a M.D. degree and 12 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

FUSILEV

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 remain 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. A summary of our FUSILEV customers that represent 10% or more of our total consolidated gross product sales is as follows:

	2012	2011	2010
Oncology Supply	25.8%	57.0%	45.7%
McKesson Specialty	23.2%	19.1%	*
ICS	16.1%	*	*
Cardinal Health	15.7%	*	*

(*) Less than 10%

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 FUSILEV or similar products, our own efforts to successfully market and sell FUSILEV in our markets may be adversely impacted.

FOLOTYN

Even though we have obtained accelerated approval to market FOLOTYN for the treatment of patients with relapsed orrefractory PTCL, we are subject to ongoing regulatory obligations and review, including post-approval requirements.

FOLOTYN was approved for the treatment of patients with relapsed or refractory PTCL under the FDA s accelerated approval regulations, which allow the FDA to approve products for cancer or other serious or life threatening diseases

based on initial positive data from clinical trials. Under these provisions, we are subject to certain post-approval requirements pursuant to which we are required to conduct two randomized Phase 3 trials to confirm FOLOTYN s clinical benefit in patients with T-cell lymphoma. The FDA has also required that we conduct two Phase 1 trials to assess whether FOLOTYN poses a serious risk of altered drug levels resulting from organ impairment. Failure to complete the studies or adhere to the timelines established by the FDA could result in penalties, including fines or withdrawal of FOLOTYN from the market. The FDA may also initiate proceedings to withdraw approval or request that we voluntarily withdraw FOLOTYN from the market if our Phase 3 studies fail to confirm FOLOTYN s clinical benefit. Further, the FDA may require us to amend the FOLOTYN package insert, including by strengthening the warnings and precautions section or institute a Risk Evaluation and Mitigation Strategy based on the results of these studies or clinical experience. We are also subject to additional, continuing post-approval regulatory obligations, including the possibility of additional clinical studies required by the FDA, safety reporting requirements and regulatory oversight of the promotion and marketing of FOLOTYN. In addition, we or our third-party manufacturers are required to adhere to the FDA s current Good Manufacturing Practices, or cGMP. The cGMP regulations cover all aspects of the manufacturing, storage, testing, quality control and record keeping relating to FOLOTYN. Furthermore, we or our third-party manufacturers are subject to periodic inspection by the FDA and foreign regulatory authorities to ensure compliance with cGMP or other applicable government regulations and corresponding foreign standards. We have limited control over a third-party manufacturer s compliance with these regulations and standards. If we or our third-party manufacturers fail to comply with applicable regulatory requirements, we may be subject to fines, suspension, modification or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

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We are dependent upon a small number of customers for a significant portion of FOLOTYN revenue, and the loss of, or significant reduction or cancellation in sales to, any one of these customers could adversely affect our results of operations.

In the United States, we sell FOLOTYN to a small number of distributors who in turn sell-through to patient health care providers. These distributors also provide multiple logistics services relating to the distribution of FOLOTYN, including transportation, warehousing, cross-docking, inventory management, packaging and freight-forwarding. We do not promote FOLOTYN to these distributors and they do not set or determine demand for FOLOTYN. For the years ended December 31, 2012, 2011 and 2010, three companies affiliated with AmerisourceBergen Corporation accounted for substantially all of Allos FOLOTYN sales. We expect significant customer concentration to continue for the foreseeable future. The loss of any large customer, a significant reduction in sales we make to them, any cancellation of orders they have made with us or any failure to pay for the products we have shipped to them could materially and adversely affect our results of operations.

Our collaboration partner, Mundipharma, may not be successful in obtaining regulatory approval for FOLOTYN in a number of countries and FOLOTYN is subject to numerous complex regulatory requirements.

Our collaboration partner, Mundipharma ,may not be successful in obtaining regulatory approval for FOLOTYN in a number of countries and FOLOTYN is subject to numerous complex regulatory requirements. Failure to comply with, or changes to, the regulatory requirements that are applicable to FOLOTYN outside the United States may result in a variety of consequences, including the following:

- restrictions on FOLOTYN or our manufacturing processes;
- warning letters;
- withdrawal of FOLOTYN from the market;
- voluntary or mandatory recall of FOLOTYN;
- fines against us;
- suspension or withdrawal of regulatory approvals for FOLOTYN;
- suspension or termination of any of our ongoing clinical trials of FOLOTYN;
- refusal to permit import or export of FOLOTYN;

refusal to approve pending applications or supplements to approved applications that we submit;

denial of permission to file an application or supplement in a jurisdiction;

product seizure;

our strategic collaborator, Mundipharma, terminating our arrangement to co-develop FOLOTYN globally and commercialize FOLOTYN outside the United States and Canada, which would delay development and may increase the cost of developing and commercializing FOLOTYN; and

injunctions, consent decrees, or the imposition of civil or criminal penalties against us.

GENERAL

If the distributors that we rely upon to sell our products fail to perform, our business may be adversely affected.

Our success depends on the continued customer support efforts of our network of distributors. The use of distributors involves certain risks, including, but not limited to, risks that these distributors will:

not provide us with accurate or timely information regarding their inventories, the number of patients who are using our products or complaints about our products;

not effectively distribute or support our products;

reduce or discontinue their efforts to sell or support our products;

be unable to satisfy financial obligations to us or others; and

cease operations.

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Any such failure may result in decreased sales of our products, which would harm our business.

Reports of adverse events or safety concerns involving our products or similar agents could delay or prevent us from obtaining or maintaining regulatory approval or negatively impact sales.

Certain of our products may cause serious adverse events. These adverse events could interrupt, delay or halt clinical trials of such products, including the FDA-required post-approval studies, and could result in the FDA or other regulatory authorities denying or withdrawing approval of our products for any or all indications. The FDA, other regulatory authorities or we may suspend or terminate clinical trials at any time. We may also be required to update the package inserts based on reports of adverse events or safety concerns or implement a risk evaluation and mitigation Strategy, which could adversely affect such products acceptance in the market. In addition, the public perception of our products might be adversely affected, which could harm our business and results of operations and cause the market price of our common stock to decline, even if the concern relates to another company s product or product candidate. Our planned trials to demonstrate efficacy in a variety of indications and to better manage side effect profiles of certain of our products may not be successful.

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, including, without limitation, due to a change in the composition of our sales over time, our financial position, results of operations and cash flows may be materially and negatively impacted.

We recognize product revenue net of estimated allowances for discounts, returns, rebates and chargebacks. Such estimates require our most subjective and complex judgment due to the need to make estimates about matters that are inherently uncertain. Based on industry practice, pharmaceutical companies, including us, have liberal return policies. Generally, we are obligated to accept from customers the return of pharmaceuticals that have reached their expiration date up to twelve months after their expiration. We authorize returns for damaged products and exchanges for expired products in accordance with our return goods policy and procedures. In addition, like our competitors, we also give credits for chargebacks to wholesale customers that have contracts with us for their sales to hospitals, group purchasing organizations, pharmacies or other retail customers. A chargeback is the difference between the price the wholesale customer (in our case, the GPOs) pays (wholesale acquisition cost) and the price that the GPO s end-customer pays for a product (contracted customer). For instance, our products are subject to certain programs with federal government qualified entities whereby pricing on products is discounted to such entities and results in a chargeback claim to us. To the extent that our sales to discount purchasers, such as federal government qualified entities, increases, our chargebacks will also increase. 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 chargebacks exceed the estimates we made at the time of the sale of our products.

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

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 our products 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 our products 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 and other developmental products, which may yield new data that could adversely impact the use of our products in their current and potential future indications. The introduction of competitive products could significantly reduce our sales , which, in turn would adversely impact our financial and operating results.

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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. We rely upon our ability to generate positive cash flow from operations to fund our business. If we are not able to generate positive cash flow from operations, we may need to utilize sources of financing such as our credit agreement or other sources of cash. While our credit agreement with Bank of America, N.A., as the administrative agent and an initial lender and Wells Fargo Bank, National Association, as an initial lender, dated September 5, 2012, or the Credit Agreement, provides us with limited additional sources of liquidity, we may need to raise additional funds through public or private debt or equity financings in order to fund existing operations or to take advantage of opportunities, including acquisitions of complementary businesses or technologies. In addition, if our business deteriorates, we may not be able to maintain compliance with the covenants or representations and warranties in our Credit Agreement which could result in reduced availability under the Credit Agreement, an event of default under the Credit Agreement, or could make the Credit Agreement unavailable to us. In the event of a default, the lenders could elect to declare all the indebtedness thereunder to be immediately due and payable, together with accrued and unpaid interest, which would prevent us from using our cash flows for other purposes and, if we are unable to pay amounts outstanding and declared immediately due and payable, the holders of such indebtedness could proceed against the collateral granted to them to secure the indebtedness. Any such event would have a material adverse impact on our business, results of operations and financial condition.

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.

Current economic conditions may not only limit our access to capital, but may 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.

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.

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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 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.

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

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

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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.

Expansion into international markets is important to our long-term success, and our inexperience in international operations increases the risk that our international expansion efforts will not be successful.

We currently maintain offices outside of the United States and have sales personnel or independent consultants in several countries. Additionally, we conduct clinical trials and manufacture our drug products internationally. We have limited experience operating in foreign jurisdictions and are rapidly building our international operations. Managing a global organization is difficult, time consuming and expensive. Our inexperience in operating our business outside of the United States increases the risk that any international expansion efforts that we may undertake will not be successful. In addition, conducting international operations subjects us to new risks that we have not generally faced in the United States, many of which are beyond our control. These risks include, among other things:

- challenges caused by distance, language and cultural differences;
- maintaining compliance with foreign legal requirements, including employment law;
- unexpected changes in foreign regulatory requirements, including quality standards and other certification requirements;
- potentially adverse tax consequences, including the complexities of foreign value added tax systems and restrictions on the repatriation of earnings;
- tariffs, customs, duties and other trade barriers;
- increased financial accounting and reporting burdens and complexities;

changing economic conditions in countries where our products are manufactured;

exchange rate risks;

product liability, intellectual property and other claims;

reduced or varied protection for intellectual property rights in some countries;

political and social instability;

new export license requirements; and

difficulties in managing and staffing foreign operations.

Operating in international markets also requires significant management attention and financial resources. The investment and additional resources required to establish operations and manage growth in other countries may not produce the desired levels of revenue or profitability, which 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 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;

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

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

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

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

attempts by either party to terminate the collaboration;

our ability to maintain or defend our intellectual property rights may be compromised by our partner s acts or omissions;

a partner may utilize our intellectual property rights in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability;

a partner may change the focus of its development and commercialization efforts due to internal reorganizations, mergers, consolidations and otherwise;

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

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

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

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

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

To remain competitive and grow our business, our long-term strategy includes the acquisition or in-license of additional drug products. We are actively seeking to acquire, or in-license, additional commercial drug products as well as drug products that have demonstrated positive pre-clinical and/or clinical data. We have certain criteria that we

are looking for in any drug product acquisition and in-license and we may not be successful in locating and acquiring, or in-licensing, additional desirable drug products on acceptable terms.

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

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From time to time we may need to license patents, intellectual property and proprietary technologies from third parties, which may be difficult or expensive to obtain.

We may need to obtain licenses to patents and other proprietary rights held by third parties to successfully develop, manufacture and market our drug products. As an example, it may be necessary to use a third party s proprietary technology to reformulate one of our drug products in order to improve upon the capabilities of the drug product. If we are unable to timely obtain these licenses on reasonable terms, our ability to commercially exploit our drug products may be inhibited or prevented.

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

Many companies, both public and private, including well-known pharmaceutical companies and smaller niche-focused companies, are developing products to treat many, if not all, of the diseases we are pursuing or are currently distributing drug products that directly compete with the drugs that we sell or that we intend to develop, market and distribute. Many of these companies have substantially greater financial, research and development, manufacturing, marketing and sales experience and resources than us. As a result, our competitors may be more successful than us in developing their products, obtaining regulatory approvals and marketing their products to consumers.

Competition for branded or proprietary drugs is less driven by price and is more focused on innovation in the treatment of disease, advanced drug delivery and specific clinical benefits over competitive drug therapies. We may not be successful in any or all of our current clinical studies; or if successful, and if one or more of our drug products is approved by the FDA, we may encounter direct competition from other companies who may be developing products for similar or the same indications as our drug products. Companies that have products on the market or in research and development that target the same indications as our products target include, among others, Abraxis Bioscience, Inc., Astra Zeneca LP, Bayer AG, Endo Pharmaceuticals, Eli Lilly and Co., Novartis Pharmaceuticals Corporation, Genentech, Inc., Bristol-Myers Squibb Company, GlaxoSmithKline, Biogen-IDEC Pharmaceuticals, Inc., OSI Pharmaceuticals, Inc., Cephalon, Inc., Sanofi-aventis, Inc., Pfizer, Inc., Genta Incorporated, Merck, Celgene Corporation, 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.

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

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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.

Our Credit Agreement contains restrictions that limit our flexibility in operating our business.

Our Credit Agreement contains various covenants that limit our ability to engage in specified types of transactions. For example, the Credit Agreement includes covenants that, subject to exceptions, limit our ability to, among other things:

- incur additional indebtedness;
- create liens on assets;
- make capital expenditures;
- engage in mergers, consolidations, liquidations and dissolutions;
- sell assets (including pursuant to sale leaseback transactions);
- pay dividends and distributions on or repurchase capital stock;
- make investments (including acquisitions), loans, or advances;
- prepay certain junior indebtedness;
- engage in certain transactions with affiliates;
- enter into restrictive agreements;
- amend material agreements governing certain junior indebtedness; and

change our lines of business.

The terms of the Credit Agreement also include financial performance covenants applicable to us and our subsidiaries, which include, among other things, a maximum consolidated leverage ratio and a minimum consolidated interest coverage ratio. A breach of these or other covenants could allow the lenders to accelerate all amounts due under the Credit Agreement and, in certain circumstances, proceed against the collateral. At December 31, 2012, we were in compliance with all debt covenants.

Changes in our effective income tax rate could adversely affect our profitablity.

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 profitability.

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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;

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

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be challenged, invalidated or circumvented, which could limit our ability to prevent competitors from marketing related product candidates or could limit the length of the term of patent protection of our product candidates. In addition, our competitors may independently develop similar technologies. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

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We also rely on trade secret protection and contractual protections for our unpatented, confidential and proprietary technology. Trade secrets are difficult to protect. While we enter into confidentiality agreements with our employees, consultants and others, these agreements may not successfully protect our trade secrets or other confidential and proprietary information. It is possible that these agreements will be breached, or that they will not be enforceable in every instance, and that we will not have adequate remedies for any such breach. Likewise, although we conduct periodic trade secret audits of certain partners, vendors and contract manufacturers, these trade secret audits may not protect our trade secrets or other confidential and proprietary information. It is possible that despite having certain trade secret audited security measures in place, trade secrets or other confidential and proprietary information may still be leaked or disclosed to a third party. It is also possible that our trade secrets will become known or independently developed by our competitors.

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

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

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

The patent positions related to our drug products are inherently uncertain and involve complex legal and factual issues. We believe that there is significant litigation in the pharmaceutical and biotechnology industry regarding patent and other intellectual property rights. A patent does not provide the patent holder with freedom to operate in a way that infringes the patent rights of others. We may be accused of patent infringement at any time. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents in the 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.

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.

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

We sell certain of our products 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.

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Rapid bio-technological advancement may render our drug products obsolete before we are able to recover expenses incurred in connection with their development. As a result, 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.

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.

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

Government agencies such as the Centers for Medicare & Medicaid Services promulgate regulations, and issue guidelines, directly applicable to us and to our products. In addition, third parties such as professional societies, practice management groups, insurance carriers, physicians, private health/science foundations and organizations involved in various diseases from time to time may publish guidelines or recommendations to healthcare providers, administrators and payers, and patient communities. Recommendations may relate to such matters as usage, dosage, route of administration and use of related therapies and reimbursement of our products by government and private payers. Third-party organizations like the above have in the past made recommendations about our products. Recommendations or guidelines that are followed by patients and healthcare providers could result in decreased use and/or dosage of our products. Any recommendations or guidelines that result in decreased use, dosage or reimbursement of our products could adversely affect our product sales and operating results materially.

Our failure to comply with governmental regulations may delay or prevent approval of our drug products and/or subject us to penalties.

The FDA and comparable agencies in foreign countries impose many requirements related to the drug development process through lengthy and rigorous clinical testing and data collection procedures, and other costly and time consuming compliance procedures. While we believe that we are currently in compliance with applicable FDA regulations, if our partners, the contract research organizations or contract manufacturers with which we have relationships, or we fail to comply with the regulations applicable to our clinical testing, the FDA may delay, suspend or cancel our clinical trials, or the FDA might not accept the test results. The FDA, an institutional review board, third party investigators, any comparable regulatory agency in another country, or we, may suspend clinical trials at any time if the trials expose subjects participating in such trials to unacceptable health risks. Further, human clinical testing may not show any current or future drug product to be safe and effective to the satisfaction of the FDA or comparable regulatory agencies, or the data derived from the clinical tests may be unsuitable for submission to the FDA or other regulatory agencies. Once we submit an application seeking approval to market a drug product, the FDA or other regulatory agencies may not issue their approvals on a timely basis, if at all. If we are delayed or fail to obtain these approvals, our business and prospects may be significantly damaged.

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

warning letters;

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.

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

- require sponsors of marketed products to conduct post-approval clinical studies to assess a known serious risk, signals of serious risk or to identify an unexpected serious risk;
- mandate labeling changes to products, at any point in a product s lifecycle, based on new safety information; and
- require sponsors to implement a Risk Evaluation and Mitigation Strategy, or REMS, for a product which could include a medication guide, patient package insert, a communication plan to healthcare providers, or other elements as the FDA deems are necessary to assure safe use of the drug (either prior to approval or post-approval as necessary).

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

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.

Our ability to commercialize any products successfully will 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 in the U.S. and 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 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.

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.

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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. 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.

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.

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

We may be held liable if any product we or our partners develop causes injury or is found otherwise unsuitable during product testing, manufacturing, 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.

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

Our research and development, manufacturing (including a radiolabeling step for ZEVALIN) and administration of our drugs involves the controlled use of hazardous materials, including chemicals, radioactive and biological materials, such as radioactive isotopes. However, we do not physically handle these radioactive isotopes or such hazardous materials. We are subject to federal, state and local laws and regulations governing the storage, use and disposal of these materials and some waste products. We believe that our safety procedures for the storage, use and disposal of these materials comply with the standards prescribed by federal, state and local regulations. However, we cannot completely eliminate the risk of accidental contamination or injury from these materials. If there were to be an accident, we could be held liable for any damages that result, which could exceed our financial resources. We currently maintain insurance coverage for injuries resulting from the hazardous materials we use; however, future claims may exceed the amount of our coverage. Also, we do not have insurance coverage for pollution cleanup and removal. Currently the costs of complying with federal, state and local regulations are not significant, and consist primarily of waste disposal expenses, however, they could become expensive, and current or future environmental regulations may impair our research, development, production and commercialization efforts.

Risks Related to Our Common Stock

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

As of December 31, 2012, there were 60,026,675 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 10.8 million additional shares of common stock. However, we would receive approximately

$70.5 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.

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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;

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, 2012 through February 15, 2013, the closing price of our common stock ranged between $9.51 and $17.05, and the daily trading volume was as high as 10,942,600 shares and as low as 298,200 shares. In addition, due in large part to the current global economic crisis many institutional investors that historically had invested in specialty pharmaceutical companies have ceased operations or further investment in these companies, which has had negatively impacted trading volume for our stock.

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

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

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

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

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

We have a stockholder rights plan pursuant to which we distributed rights to purchase units of our series B junior participating preferred stock. The rights become exercisable upon the earlier of ten days after a person or group of affiliated or associated persons has acquired 15% or more of the outstanding shares of our common stock or ten business days after a tender offer has commenced that would result in a person or group beneficially owning 15% or more of our outstanding common stock. These rights could delay or discourage someone from acquiring our business, even if doing so would benefit our stockholders. We currently have no stockholders who own 15% or more of the outstanding shares of our common stock.

We have identified a material weakness in our internal control over financial reporting which existed as of December 31, 2012, and has not been adequately remediated as of March 31, 2013, June 30, 2013 and September 30, 2013. If we fail to properly remediate this or any future weaknesses or deficiencies or maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired and investors views of us could be harmed.

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.

While preparing our financial statements for the three and nine months ended September 30, 2013, we have determined that we have a material weakness in our internal control over financial reporting, which also existed as of December 31, 2012. The financial misstatements resulting from our material weakness resulted in a restatement of our Consolidated Financial Statements contained herein. See *Item 9A*, *Controls and Procedures* for a complete discussion of this material weakness in our internal control over financial reporting.

Although we are undertaking steps to address this material weakness, the existence of a material weakness is an indication that there is more than a remote likelihood that a material misstatement of our financial statements will not be prevented or detected in the current or any future period. There can be no assurance that we will be able to fully implement our plans and controls, as described in *Item 9A*, to address this material weakness, or that the plans and controls, if implemented, will be successful in fully remediating this material weakness. In addition, we may in the future identify further material weaknesses in our internal control over financial reporting that we have not discovered to date. If we fail to successfully remediate the identified material weakness, or we identify further material weaknesses in our internal controls, our ability to report our financial results on a timely and accurate basis could be impacted in a materially adverse manner.

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 effect on our business. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

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

The reports of publicly-traded companies are subject to review by the SEC from time to time for the purpose of assisting companies in complying with applicable disclosure requirements and to enhance the overall effectiveness of companies public filings, and reviews of such reports are now required at least every three years under the Sarbanes-Oxley Act of 2002. SEC reviews may be initiated at any time, and we could be required to modify or reformulate information contained in prior filings as a result of an SEC review. Any modification or reformulation of information contained in such reports could be significant and could result in material liability to us and have a material adverse impact on the trading price of our common stock.

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 Colorado, New Jersey, Westlake Village, Tokyo, Japan and Mumbai, India. 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 that are complex in nature and have outcomes that are difficult to predict. 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.

FUSILEV ANDA Litigation

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 for the Districts of Nevada and Delaware seeking to enjoin the approval of their 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.

AMAG Merger Transaction Class Action Lawsuits

On July 19, 2011, Allos entered into an Agreement and Plan of Merger and Reorganization, or AMAG Merger Agreement, with AMAG Pharmaceuticals, Inc., or AMAG, and Alamo Acquisition Sub, Inc., as amended on August 8, 2011. On October 21, 2011, the AMAG Merger Agreement was terminated. In July 2011, two lawsuits were filed in the Delaware Court of Chancery relating to the proposed merger between Allos and AMAG, which two cases were later consolidated as In Re Allos Therapeutics, Inc. Shareholders Litigation, Consolidated C.A. No. 6714-VCN. Following announcement of the proposed merger between Allos and Spectrum, the consolidated case

became one of the Allos Transaction Class Action Lawsuits discussed below and part of the settlement memorialized in the memorandum of understanding dated May 7, 2012. On February 11, 2013, as part of the consolidated settlement of the cases discussed below, the AMAG litigation was settled and dismissed.

Allos Transaction Class Action Lawsuits

On April 9, 2012, a putative class action lawsuit captioned *Radmore, et al. v. Allos Therapeutics, Inc., et al.,* No. 1:12-cv-00948-PAB, was filed in the United States District Court for the District of Colorado, or the Radmore Complaint. The Radmore Complaint named as defendants Allos Therapeutics, the members of the Allos board of directors, as well as Spectrum. The plaintiffs alleged that Allos directors breached their fiduciary duties to their stockholders in connection with

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the proposed merger between Allos and Spectrum, and were aided and abetted by Allos and Spectrum. The Radmore Complaint alleged that the merger involves an unfair price, an inadequate sales process, unreasonable deal protection devices, and that the defendants entered into the transaction to benefit themselves personally. The Radmore Complaint sought injunctive relief, including to enjoin the merger, attorneys and other fees and costs, and other relief. On April 12, 2012, a putative class action lawsuit captioned *Keucher v. Berns, et al.,* C.A. No. 7419, was filed in the Delaware Court of Chancery, alleging similar violations. On April 20, 2012, an Amended Class Action Complaint was filed in the Delaware Court of Chancery in the matter captioned Keucher v. Berns, et al., C.A. No. 7419-VCN, adding allegations that the Solicitation/Recommendation Statement on Schedule 14D-9, or the Schedule 14D-9, filed by us with the SEC on April 13, 2012, contains inadequate, incomplete and/or misleading disclosures.

On May 7, 2012, the parties to all three actions executed a memorandum of understanding, or MOU, containing the terms for an agreement-in-principle to resolve all litigation. The MOU provided that the defendants would agree to make certain supplemental disclosures in an amended Schedule 14D-9 and that the parties would use their best efforts to agree upon, enter, and present to the Delaware Chancery court a formal stipulation of settlement. The MOU provides for an award to plaintiffs counsel of $850,000 for their fees and expenses but did not include any payment to stockholders. The parties completed confirmatory discovery on July 18, 2012 and filed a stipulation and agreement of compromise and settlement in the Delaware court on November 8, 2012. On February 11, 2013, the Delaware court approved the settlement, including the payment of $850,000 to counsel for the stockholders, entered final judgment and dismissed the cases.

Item 4. ***Mine Safety Disclosures***

PART II

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

Common Stock

As of February 15, 2013 there were 60,157,023 shares of common stock outstanding and 342 stockholders of record. On February 15, 2013, the closing sale price of our common stock was $11.63 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 2012 and 2011 were as follows:

	High	Low
Year 2012:		
First Quarter	$ 15.87	$ 12.63
Second Quarter	$ 15.56	$ 9.51
Third Quarter	$ 17.05	$ 11.51
Fourth Quarter	$ 12.31	$ 10.64
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

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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, 2007, the last trading day before our 2008 fiscal year, through the end of fiscal 2012 with the cumulative total return on $100 invested for the same period in the Russell 2000 index and a Peer Group.

The Peer Group consists 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

	12/31/07	12/31/08	12/31/09	12/31/10	12/31/11	12/31/12
Spectrum Pharmaceuticals, Inc.	100.00	54.78	163.24	252.57	537.87	416.70
Russell 2000	100.00	66.21	84.20	106.82	102.36	119.09
Peer Group	100.00	100.64	113.08	123.24	132.73	184.43

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

Unregistered Equity Issuances

We did not issue any unregistered securities during the year ended December 31, 2012 that were not otherwise disclosed in a previously filed Quarterly Report on Form 10-Q or a Current Report on Form 8-K.

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Equity Repurchases

During the three months ended December 31, 2012, we purchased 10,000 shares of our common stock under our previously approved repurchase plan for an aggregate purchase price of $108,935. The following table provides information regarding our repurchases for each month comprising the fourth quarter of fiscal year 2012.

Period	Total Number of Shares Purchased	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (1)	Maximum Number of Shares (or Approximate Dollar Value) that May Yet Be Purchased Under the Plans or Programs (1)
October 1, 2012 October 31, 2012		$		$ 88,126,243
November 1, 2012 November 30, 2012		$		$ 88,126,243
December 1, 2012 December 31, 2012	10,000	$ 10.86	10,000	$ 88,017,308
Total	10,000	$ 10.86	10,000	

(1) On August 10, 2012, we announced that our board of directors had authorized the repurchase and retirement of up to $100 million of our common stock in open market transactions, including block purchases, through 10b5-1 plans or in privately negotiated transactions, each in accordance with applicable Securities and Exchange Commission rules, when opportunities become available to purchase shares at prices believed to be attractive. The term for the repurchase program expires August 1, 2013, however, we may suspend or terminate it at any time. The previous authorization was for up to $25 million and covered the period through December 31, 2012.

Dividends

On December 11, 2012 we announced that our Board of Directors had approved the payment of a year-end special dividend of $0.15 to holders of common stock of record at close of business on December 20, 2012. The dividend was paid on or about December 28, 2012. Future cash dividends, if any, will be at the discretion of the Board of Directors and subject to compliance with any applicable restrictions contained in our credit and other agreements.

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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, 2012, 2011 and 2010 and balance sheet data as of December 31, 2012 and 2011 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, 2009 and 2008 and the balance sheet data as of December 31, 2010, 2009 and 2008 from our audited consolidated financial statements that do not appear in this annual report.

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

The information presented in the following table has been restated as a result of the revised accounting for amortization for intangible asset amortization and correction of an error in operating expenses related to certain accounts payable and other accrued obligations accounts, as is more fully described in the Explanatory Note immediately preceding Part I, Item 1 and in Note 1A, Revision of Previously Issued Consolidated Financial Statements, to our Consolidated Financial Statements in Part II, Item 8.

	Years ended December 31,				
Statement of Operations Data:	**2012 (As Restated)**	**2011 (As Restated)**	**2010 (As Restated)**	**2009 (As Restated)**	**2008 (As Restated)**
	(In thousands, except per share data)				
Total revenues	$ 267,707	$ 192,963	$ 74,113	$ 38,025	$ 28,725
Operating expenses:					
Cost of product sales (excludes amortization of purchased intangible assets)	46,633	33,838	17,439	8,148	1,193
Selling, general and administrative	89,922	72,197	47,411	33,607	15,156
Research and development	41,560	26,662	56,660	20,379	26,458
Amortization of purchased intangibles	8,818	3,720	3,720	3,720	158
Acquired in-process research and development					4,700
Income (loss) from operations	80,774	56,546	(51,117)	(27,829)	(18,940)
Change in fair value of common stock warrant liability		(3,488)	2,731	8,075	1,271
Other (expense) income, net	(844)	577	1,279	662	1,165
Income (loss) before provision for income taxes	79,930	53,635	(47,107)	(19,092)	(16,504)
Benefit (provision) for income taxes	14,271	(3,704)	43	(421)	(5)
Net loss attributable to non-controlling interest				1,146	2,538
Net income (loss) attributable to Spectrum Pharmaceuticals, Inc. stockholders	$ 94,201	$ 49,931	$ (47,064)	$ (18,367)	$ (13,791)

Net income (loss) per share	basic	$ 1.61	$ 0.94	$ (0.95)	$ (0.47)	$ (0.44)
Net income (loss) per share	diluted	$ 1.46	$ 0.86	$ (0.95)	$ (0.47)	$ (0.44)
Cash dividend declared per common share		$ 0.15	$	$	$	$

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	As of December 31,				
Balance Sheet Data:	**2012 (As Restated)**	**2011 (As Restated)**	**2010 (As Restated)**	**2009 (As Restated)**	**2008 (As Restated)**
			(In thousands)		
Cash, equivalents and investments	$ 143,008	$ 170,545	$ 104,243	$ 113,341	$ 75,938
Working capital	141,630	151,443	61,308	87,743	54, 983
Total assets	504,955	280,780	163,631	173,133	129,509
Common stock warrant liability (at fair value)			3,904	6,635	765
Long term obligations, less current portion	93,031	14,336	25,833	25,310	42,822
Total stockholders equity (including non-controlling interest)	288,681	192,086	77,241	109,309	53,422

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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.

This MD&A contains restated results related to the revisions for intangible asset amortization and operating expenses related to certain accounts payable and other accrued obligations accounts. See Explanatory Note immediately preceding Part I, Item 1 and Note 2, Revision of Previously Issued Consolidated Financial Statements, to our Consolidated Financial Statements in Part II, Item 8 for a detailed discussion of the revisions and effect of the restatement.

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 three oncology drugs, FUSILEV®, FOLOTYN® and ZEVALIN®, 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 was studied in two large Phase 3 clinical trials for non-muscle invasive bladder cancer, or NMIBC, and is under strategic collaborations with 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, and is 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, *FUSILEV, FOLOTYN and ZEVALIN*. Our near-term outlook largely depends on sales and marketing successes for our three marketed drugs. For FUSILEV, we are working to expand usage in colorectal cancer. We launched FUSILEV in August 2008 and 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. While generic leucovorin supplies and utilization have been negatively impacted by this shortage, we cannot predict how long the shortage may continue or the extent of the impact the shortage may ultimately have on FUSILEV utilization. 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 a Ready-To-Use formulation, or RTU, of FUSILEV. We are now actively engaged in marketing FUSILEV for use in advanced metastatic colorectal cancer.

We added FOLOTYN to our commercial drug portfolio with the acquisition of Allos Therapeutics, Inc., or Allos, in September 2012. FOLOTYN is a folate analogue metabolic inhibitor designed to accumulate preferentially in cancer cells. FOLOTYN targets the inhibition of dihydrofolate reductase, or DHFR, an enzyme critical in the folate pathway, thereby interfering with DNA and RNA synthesis and triggering cancer cell death. FOLOTYN can be delivered as a single agent, for which we currently have approval in the United States for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma, or PTCL, and has the potential to be used in combination therapy regimens. We believe that FOLOTYN s unique mechanism of action offers us the ability to target the drug for development in a variety of hematological malignancies and solid tumor indications, and for autoimmune diseases as well. FOLOTYN has been available for commercial sale in the United States since October 2009.

For ZEVALIN, we continue to work on growing the ZEVALIN brand and are working to expand indications for use beyond follicular non-Hodkins lymphoma through additional trials. Effective April 2, 2012, with the acquisition of licensing rights from Bayer Pharma AG, we began the sales of ZEVALIN outside of the U.S. 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, to expand utilization. We have formed

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a dedicated commercial organization comprised of highly experienced and motivated sales representatives, account managers, and a complement of other support marketing personnel to manage the sales and marketing of these drugs. In addition, our scientific department supports field activities through various MDs, PhDs and other medical science liaison personnel.

Optimizing our development portfolio and maximizing the asset values of its components. While over the recent few years, we have evolved from a development-stage to a commercial-stage pharmaceutical company, we have maintained a highly focused development portfolio. Our strategy with regard to our development portfolio is to focus on late-stage drugs and to develop them 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 MDs, PhDs, clinical research associates and a complement of other support personnel to develop these drugs. In April 2012, we announced that the single instillation Phase 3 clinical trials for apaziquone did not meet their primary endpoint, however, the pooled data from the studies did show a statistically significant treatment effect. A meeting with the FDA was held in December 2012 to discuss the results from these clinical trials. Based on the discussions with the FDA, we understand that the FDA can accept the NDA filing with the current Phase III data and will likely convene an Advisory Committee meeting. Further, based on discussions with the FDA, we have agreed to conduct one additional Phase III study following consultation with the FDA on its design.

With regard to our anti-cancer drug belinostat, a novel HDAC inhibitor, we have to date opened more than 100 international sites in the study of relapsed refractory peripheral T Cell Lymphoma. We completed enrollment in this trial in September 2011, announced top line results in December 2012 and expect to file a NDA in 2013.

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.

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 2012. This policy includes the pursuit of dilutive and 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 three 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 dilutive and 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 to be 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

We reported net income in 2011 and 2012 and remain dependent upon revenues from our three commercial drugs, specifically FUSILEV, FOLOTYN and ZEVALIN. Our long-term strategy is to continue to generate profits from the sale and licensing of our drug products.

While we believe that the approximately $143.0 million in cash, equivalents and investments we had available at December 31, 2012, which includes long term marketable securities (after payment of $25.4 million for the purchase of the licensing rights to market ZEVALIN outside the U.S. and $133.3 million for the purchase of Allos), will allow us to fund our current planned operations for at least the next twelve to eighteen months, we may seek to obtain additional capital through the sale of debt or equity securities, if necessary, especially in conjunction with opportunistic acquisitions or licensing arrangements. 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.

On September 5, 2012, we entered into a credit agreement with Bank of America, N.A., as the administrative agent and an initial lender and Wells Fargo Bank, National Association, as an initial lender, for a $75.0 million revolving line of credit, which can be increased up to $125.0 million, subject to meeting certain customary conditions and obtaining commitments for such increase from the lenders. The terms of the credit agreement contain financial performance covenants applicable to us and our subsidiaries, which include, among other things, a maximum consolidated leverage ratio and a minimum consolidated interest coverage ratio. We were in compliance with all such covenants as of December 31, 2012. The terms of the credit agreement also provide for an interest rate based on the London Interbank Offer Rate or the base rate, as selected by management, plus an applicable margin, of between 0.75% and 1.00% for base rate loans and between 1.75% and 2.25% for London Interbank Offer Rate loans. Additionally, an unused line fee is payable quarterly in an amount ranging from .375% to 0.625% of the sum of the average daily unused portion of the facilities during any quarter based upon consolidated leverage ratio as at the last test date. As of December 31, 2012, $75.0 million has been drawn down on the revolving line of credit, of which the entire amount is outstanding and there are no amounts available to borrow, and the interest rate on the outstanding balance was 4.25%.

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). During the year ended December 31, 2012, our total research and development expenditure, including indirect expenditures, was approximately $41.6 million (net of $7.4 million received from Allergan pursuant to the collaboration agreement).

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.

	Year Ended December 31,		
	2012 (As Restated)	2011 (As Restated)	2010 (As Restated)
	($ in 000s)		
Apaziquone	$ 6,642	$ 7,695	$ 6,086
Belinostat	3,742	7,207	35,583
FUSILEV	1,416	1,239	1,265
FOLOTYN	1,586		
ZEVALIN	5,040	167	416
GCS	1,049		
Lucanthone	792		
Ozarelix	724	740	1,891
Ortataxel	554	107	707
Renazorb	1,299	476	1,533

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	Year Ended December 31,		
	2012 (As Restated)	2011 (As Restated)	2010 (As Restated)
		($ in 000 s)	
Other development drugs	4,695	1,417	1,891
Total Direct Costs	27,539	19,048	49,372
Indirect Costs (including non-cash share-based compensation of $1.8 million, $1.6 million and $2.4 million, respectively)	21,404	16,502	14,838
Partner Reimbursement	(7,383)	(8,888)	(7,550)
Total Research & Development	$ 41,560	$ 26,662	$ 56,660

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 approved products (ZEVALIN, FUSILEV and post-approval studies required by the FDA for FOLOTYN). 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, 2013, excluding the cost of in-licensing or acquisitions of additional drugs, if any, is expected to range between approximately $50 and $55 million.

Co-development, collaboration and out-licensing agreements with other companies for certain of our drug products may reduce our R&D expenses. For example, under our collaboration agreement with Mundipharma, Mundipharma is currently responsible for 40% of the joint development costs incurred by the parties related to the FOLOTYN post-approval studies. Other than this 40% reimbursement from Mundipharma, we currently do not receive any funding from third parties for research and development that we conduct for FOLOTYN. We are also party to an agreement with Allergan whereby, commencing January 1, 2009, Allergan has borne 65% of the development costs of apaziquone through December 31, 2012. On January 29, 2013, we entered into a second amendment to the agreement with Allergan to buy back the rights originally licensed to Allergan in the U.S., Europe and other territories in exchange for a tiered single digit royalty on certain products containing apaziquone, and relieved Allergan of its obligations for development, commercialization and other activities.

With respect to belinostat, we have a collaboration agreement with TopoTarget, whereby, commencing February 2, 2010, TopoTarget bears 100% of the CUP trial costs for belinostat and 30% of other development costs unrelated to the belinostat 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 $72.0 million for 2012 which includes net income in the period of $94.2 million adjusted for net non-cash credits of $15.4 million, of which, $34.6 million relates to a deferred income tax benefit, $14.9 million for stock-based compensation, $12.3 million for amortization of deferred revenue offset by

$12.2 million of depreciation and amortization and $4.3 million for the provision for inventory obsolescence. These non-cash items were offset primarily by uses of cash by a $33.5 million increase in accounts receivable as a result of increased product sales and a $9.7 million decrease in accrued compensation and related expenses which were offset by sources of cash which included an increase of $24.0 million in accounts payable and other accrued obligations and a $9.5 million decrease in prepaid expenses and other current assets.

Net Cash Used In Investing Activities

Net cash used in investing activities of $114.7 million in 2012 was primarily due to the $205.2 million purchase of Allos, net of $71.9 million cash acquired, the $25.4 million purchase of the ZEVALIN rights outside of the U.S. and purchases of $26.4 million of marketable securities, which was partially offset by a $72.5 million in maturities of marketable securities.

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Net Cash Provided By Financing Activities

Net cash provided by financing activities of $61.0 million in 2012 primarily relates to the $75.0 million in net proceeds from the revolving line of credit, the $5.9 million in proceeds from the issuance of common stock as a result of the exercise of 1,287,430 stock options and exercise of 50,000 common stock warrants as well as $606,000 in purchases of shares under our Employee Stock Purchase Plan. These proceeds were partially offset by the $9.1 million purchase of treasury stock, $9.0 million dividend payment and the $1.4 million repurchase of shares to satisfy minimum tax withholding for the vesting of restricted stock.

Results of Operations

Results of Operations for Fiscal 2012 Compared to Fiscal 2011

Total Revenues. A summary of our total revenues is as follows:

	Year Ended December 31,			
	2012	2011	$ Change	% Change
	($ in 000 s)			
Product sales, net:				
FUSILEV	$ 204.3	$ 153.1	$ 51.2	33.4%
FOLOTYN	20.4		20.4	n/a
ZEVALIN	30.3	27.6	2.7	9.8%
	$ 255.0	$ 180.7	$ 74.3	41.1%
License and contract revenue	12.7	12.3	0.4	3.3%
Total revenues	$ 267.7	$ 193.0	$ 74.7	38.7%

Revenues from the sale 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 which abated in late 2012.

Gross product revenues are reduced by estimated provisions for product returns, sales discounts and rebates, distribution and data fees, and estimates for chargebacks established at the time revenues are recognized to arrive at product sales, net. Management considers various factors in determination of such provisions, which are described more in detail below. Product sales, net may vary from quarter to quarter based on customer mix and whether said customers are entitled to government mandated pricing which will be reflected in chargeback deductions from revenue.

During 2012 and 2011, we also recognized $12.3 million of licensing revenues from the amortization of a $41.5 million upfront payment we received from Allergan in 2008, $16.0 million upfront payment we received from Nippon Kayaku and Handok in the first quarter of 2010.

Operating Costs and Expenses

Our operating costs and expenses are summarized in the following table:

	Year Ended December 31,			
	2012 (As Restated)	2011 (As Restated)	$ Change	% Change
	($ in 000s)			
Operating costs and expenses:				
Cost of product sales (excludes amortization of purchased intangibles)	$ 46.6	$ 33.8	$ 12.8	37.9%
Selling, general and administrative	89.9	72.2	17.7	24.5%
Research and development	41.6	26.7	14.9	55.8%
Amortization of purchased intangible assets	8.8	3.7	5.1	>100.0%
Total operating costs and expenses	$ 186.9	$ 136.4	$ 50.5	37.0%
Change in the fair value of common stock warrant liability		(3.5)	(3.5)	(100.0%)
Other (expense) income, net	(0.8)	0.6	(1.4)	>(100.0%)

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Cost of Product Sales. The increase in total cost of product sales relates to an increase in product revenues for all products and an increase in inventory reserves of approximately $3.0 million primarily relating to the ZEVALIN inventory estimated to be in excess of anticipated usage.

Selling, General and Administrative. Selling, general and administrative expenses increased as a result of the inclusion of Allos and is primarily due to:

- $7.0 million increase in compensation and associated benefits, of which $4.3 million is attributable to sales and marketing expenses as a result of the expansion of our sales force, and the inclusion of Allos personnel. We expect that sales and marketing activities will increase as we invest in additional commercial resources to increase market expansion of FUSILEV, FOLOTYN and ZEVALIN.
- $4.8 million increase in advertising, branding, printing, marketing and promotion
- $5.6 million in legal and professional fees related to the Allos acquisition and $687,000 in transaction costs related to the acquisition of ZEVALIN Rights
- $2.0 million increase for transitional services related to sales of ZEVALIN outside the U.S.
- $1.7 million severance and related expenses in connection with the Allos acquisition
- $1.6 million increase in sales travel and expenses

These increases were partially offset by a $7.6 million decrease in non-cash stock compensation expense primarily related to the management incentive plan expenses.

Research and Development. Research and development expenses increased as a result of the inclusion of Allos and is primarily due to:

- $5.0 million increase for drug product and a payment related to the co-development and commercialization agreement with Hamni Pharmaceutical Company for SPI-2012
- $2.7 million increase in compensation and associated benefits
- $2.2 million increase in on-going clinical trials
- $1.2 million increase in continuing medical education grants and symposiums

$519,000 severance and related expenses in connection with the Allos acquisition

We expect research and development expenses to range between approximately $50.0 and $55.0 million for 2013, excluding the cost of in-licensing or acquisitions of additional drugs, if any.

Amortization of Purchased Intangibles. We incurred a non-cash charge of $8.8 million and $3.7 million in 2012 and 2011, respectively, due to the amortization of intangibles recognized in the acquisition of ZEVALIN Rights and the amortization of intangibles recognized in the acquisition of Allos.

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. No warrants recorded as a liability were outstanding in 2012.

Other Income (Expense), net. The principal components of other net income (expense) consisted primarily of a $653,000 increase in interest expense in connection with the revolving line of credit, an increase of $132,000 for the sale of property and equipment due to the downsizing of the Allos facilities and a decrease of $139,000 of interest income due to the sale of marketable securities at the end of Q2 2012 which was partially offset by $95,000 of a net gain on life insurance assets. 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.

	Year Ended December 31,			
	2012 (As Restated)	2011 (As Restated)	$ Change	% Change
	($ in 000s)			
Benefit (provision) for income taxes	14.3	(3.7)	18.0	>(100.0%)

Benefit/(Provision) for Income Taxes. As of December 31, 2011, we maintained a $44.6 million valuation allowance against our domestic deferred tax assets and a $1.0 valuation allowance against our foreign deferred tax assets. Based on the

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weight of both positive and negative evidence, we concluded that it was more likely than not that the domestic net deferred tax assets would be realized, and therefore, we released $23.5 million of our domestic valuation allowance as a discrete tax benefit through December 31, 2012 with the remaining $21.1 million domestic valuation allowance being released through our annual effective tax rate based upon projected current year earnings. We maintain a valuation allowance against our foreign net deferred tax assets as we continue to conclude it is not more likely than not that the foreign net deferred tax assets will be realized.

The annual effective rate for fiscal 2012 is below the statutory rate principally as a result of tax benefits realized from the release of our valuation allowance against domestic deferred tax assets. The year-to-date tax benefit of $14.3 million in 2012 is primarily the result of $44.6 million in tax benefits recognized through December 31, 2012 related to the release of our valuation allowance on domestic deferred tax assets.

Results of Operations for Fiscal 2011 Compared to Fiscal 2010

Total Revenues.

A summary of our total revenues is as follows:

	Year Ended December 31,			
	2011	2010	$ Change	% Change
	($ in 000s)			
Product sales, net:				
FUSILEV	$ 153.1	$ 32.0	$ 121.1	>100.0%
ZEVALIN	27.6	28.9	(1.3)	(4.5%)
	$ 180.7	$ 60.9	$ 119.8	>100.0%
License and contract revenue	12.3	13.2	(0.9)	(6.8%)
Total revenues	$ 193.0	$ 74.1	$ 118.9	>100.0%

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 an aggregate $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.

Operating Costs and Expenses

Our operating costs and expenses are summarized in the following table:

	Year Ended December 31,			
	2011 (As Restated)	2010 (As Restated)	$ Change	% Change
	($ in 000s)			
Operating costs and expenses:				
Cost of product sales (excludes amortization of purchased intangibles)	$ 33.8	$ 17.4	$ 16.4	94.3%
Selling, general and administrative	72.2	47.4	24.8	52.3%
Research and development	26.7	56.7	(30.0)	(52.9%)
Amortization of purchased intangible assets	3.7	3.7		
Total operating costs and expenses	$ 136.4	$ 125.2	$ 11.2	8.9%
Change in the fair value of common stock warrant liability	(3.5)	2.7	(6.2)	>(100.0%)
Other income, net	0.6	1.3	(0.7)	(53.8%)

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Cost of Product Sales. 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. The increase in selling general and administrative expense 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. The decrease in research and development 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. 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, 2012.

Other Income, net. The principal components of other income, net 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.

	Year Ended December 31,			
	2011 (As Restated)	2010 (As Restated)	$ Change	% Change
	($ in 000 s)			
(Provision)/benefit for income taxes	(3.7)	0.04	(3.7)	>(100.0%)

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

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 inherently judgmental and subject to change, as described more in detail below. Such estimated amounts are deducted from our gross sales to determine our product sales, net. 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. Actual results could differ materially from the amounts estimated. If we materially over or under estimate the amount, there could be a material impact on our consolidated financial statements.

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For the periods ended December 31, 2012 and 2011, 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:

	Chargebacks and Discounts	Rebates	Returns	Data and Distribution Fees	Doubtful accounts	Total
			($ in 000s)			
Period ended December 31, 2012:						
Balances at beginning of the period	$ 1,942	$ 8,114	$ 4,000	$ 5,866	$ 471	$ 20,393
Allos accruals acquired:	447	1,924	941	182		3,494
Add provisions/(recovery):	53,630	29,492	145	19,472	(128)	102,611
Less: Credits or actual allowances:	(39,416)	(28,507)	(30)	(17,071)	(115)	(85,139)
Balances at the close of the period	$ 16,603	$ 11,023	$ 5,056	$ 8,449	$ 228	$ 41,359
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

Amounts recorded as allowances on our consolidated balance sheets for 2012 and 2011 are reflected in the table above. The basis and methods of estimating these allowances, used by management, are in more fully described in Critical Accounting Policies, Estimates and Assumptions below.

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 facility and equipment leases, as of December 31, 2012, approximately:

($ in 000s)	Total	Less than 1 Year	2-3 Years	4-5 Years	After 5 Years
Contractual Obligations(1)					
Operating Lease Obligations(2)	$ 3,062	$ 1,044	$ 1,644	$ 374	$
Purchase Obligations(3)	28,906	25,008	3,768	130	
Contingent Milestone Obligations(4)	207,119	21,415	41,065	20,729	123,910
Deferred development costs (5)	12,233	728	1,907	1,788	7,810
Debt obligations (6)	75,000		75,000		

Total	$ 326,320	$ 48,195	$ 123,384	$ 23,021	$ 131,720

(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 Agreements.

(2) 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.

(3) 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, 2012. 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.

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(4) 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, 2012, 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.

(5) Research and development services under the Mundipharma Collaboration Agreement over the period required to complete the jointly agreed-upon clinical development activities.

(6) Debt obligations represent amount due under the revolving line of credit.

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 payable by 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.

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 Agreements

We have entered into an employment agreement with Dr. Shrotriya, our President and Chief Executive Officer, which expires January 2, 2014. 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.

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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.

We have also entered into an employment agreement with Joseph Keller, our Executive Vice President and Chief Operating Officer, dated August 28, 2012. Pursuant to the terms of the agreement, Mr. Keller s employment is at-will, for no specified term, and may be terminated by Mr. Keller or Spectrum at any time for any reason or for no reason. The employment agreement requires Mr. Keller 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 an annual base salary of $525,000, an annual bonus of up to 50% of his base salary, and certain equity awards. Additionally, the employment agreement provides Mr. Keller with reimbursement of up to $3,500 per month for reasonable and necessary travel and temporary living expenses during his relocation period (up to six months) and a one-time relocation bonus of $30,000.

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

Product sales, net represent product sales less adjustments which include distributor fees and estimated allowances for product returns, distributor rebates, government rebates and chargebacks to be incurred on the selling price. Distributor rebates are based on contractual agreements. We estimate adjustments based upon third-party information, including information obtained from our primary distributors with respect to their inventory levels and ultimate sell-through to the distributors s customers. Due to estimates and assumptions inherent in determining the amount of returns, rebates and chargebacks, the actual amounts may differ materially from our estimates, at which time we would adjust our reserves accordingly. There is generally a lag time between the date we determined these estimated accrued liabilities and when we pay the liability or adjust the reserves for actual experience. Due to this time lag, we record adjustments to our accrued liabilities over several periods which can result in an increase or decrease to earnings in those periods. Material differences may result in the amount of revenue we recognize from product sales if the actual amount of reserves, rebates and chargebacks differ materially from the amount estimated by management.

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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 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.

Government chargebacks

Our products are subject to certain programs with federal government qualified entities whereby pricing on products is discounted below distributor list price to participating entities. These entities purchase products through distributors at the discounted price, and the distributors charge the difference between their acquisition cost and the discounted price back to us. We account for chargebacks by establishing an accrual in an amount equal to our estimate of chargeback claims at the time of product sale. We also evaluate the adequacy of previously recorded chargebacks based on data regarding specific entities claims activity over time to adjust current period chargebacks for these same distributors. Due to estimates and assumptions inherent in determining the amount of government chargebacks, the time lag to receive information from distributors, the actual amount of claims for chargebacks may be materially different from our estimates, at which time we would adjust our reserves accordingly.

Discounts

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

estimate the discount accrual.

Rebates

Customer rebates are estimated at every period end, based on direct purchases, depending on whether any rebates have been offered based on definitive contractual agreements. The rebates are recognized when products are purchased and a periodic credit is given.

Medicaid Rebates

Our products are subject to state government-managed Medicaid programs whereby discounts and rebates are provided to participating state governments. We record estimated rebates payable under governmental programs, including Medicaid, as a reduction of revenue in the same period the related sale is recorded. Our calculations related to these rebate accruals require estimates, including estimates of customer mix primarily based on a combination of market and clinical research, to determine which sales will be subject to rebates and the amount of such rebates. Our estimate of utilization is based on historical claims and supplemented by management s judgment with respect to many factors, including changes in sales trends, an evaluation of current laws and regulations and product pricing. We update our estimates and assumptions each

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period and record any necessary adjustments to our reserves. Additionally, there is a time lag between the date we determine the estimated liability and when we actually pay the liability. Although allowances and accruals are recorded at the time of product sale, certain rebates are typically paid out, on average, up to six months or longer after the sale.

Product returns allowances

Customers are typically permitted to return products within thirty days after shipment, if incorrectly shipped or not ordered, and six months after the expiration of product dating for FUSILEV, 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. 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, historical rates of actual returns and based on experience of our management with selling similar oncology products. We record an allowance for future returns by debiting revenue, thereby reducing product sales and crediting a reserve for returns to reduce other accrued obligations. FOLOTYN returns are limited to defective product or product that was shipped in error.

Distribution and Data Fees

Distribution and data fees are paid to authorized wholesalers and specialty distributors of FUSILEV and FOLOTYN 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 and FOLOTYN revenues that are set and governed by distribution agreements.

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

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.

License fees

We recognize license fees, royalties and reimbursement income for services provided as other revenues based on the facts and circumstances of each contractual agreement. In general, we recognize income upon the signing of a contractual agreement that grants rights to products or technology to a third party if we have no further obligation to provide products or services to the third party after entering into the contract. We recognize contingent consideration earned from the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. We defer income under contractual agreements when we have further obligations that indicate that a separate earnings process has not been completed.

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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.

Fair Value of Acquired Assets

The accounting for acquisitions requires extensive use of estimates and judgments to measure the fair value of the identifiable tangible and intangible assets acquired, including in-process research and development, and liabilities assumed. Additionally, we must determine whether an acquired entity is considered to be a business or a set of net assets, because the excess of the purchase price over the fair value of net assets acquired can only be recognized as goodwill in a business combination.

The fair value of acquired tangible and identifiable intangible assets and liabilities assumed, including in process research and development, are 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.

We accounted for the acquisition of ZEVALIN Rights in April 2012 and Allos in September 2012 in accordance with accounting literature which establishes principles and requirements for recognizing and measuring the total consideration transferred to and the assets acquired and liabilities assumed in the acquired target in a business combination. The consideration paid to acquire ZEVALIN Rights and Allos is required to be measured at fair value. The total consideration transferred was the cash consideration paid and the basis upon which we assigned the purchase price of ZEVALIN Rights and Allos to the fair value assets acquired and liabilities assumed. This resulted in recognition of intangible assets, goodwill and a committed R&D expenditure estimate. The determination and allocation of the consideration transferred requires management to make significant estimates and assumptions, especially at the acquisition date with respect to the fair value of the intangible assets acquired.

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.

As of each balance sheet date, we review purchase commitments and accrue drug development expenses based on factors such as estimates of work performed, patient enrollment, completion of patient studies and other events.

Accrued clinical study costs are subject to revisions as trials progress to completion. Revisions are recorded in the period in which the facts that give rise to the revision become known.

Amortization and Impairment of Intangible Assets

Identifiable intangible assets with definite lives are amortized on a straight-line basis over their estimated useful lives.

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;

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(ii) a significant adverse change in the extent or manner in which an asset is used; or

(iii) an accumulation of costs significantly in excess of the amount originally expected for the acquisition of an asset.

We measure the carrying amount of the intangible asset against the estimated and 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.

Income Taxes

The provision for income taxes is determined using an estimated annual effective tax rate, which is generally less than the U.S. federal statutory rate, primarily because of lower tax rates in certain non-U.S. jurisdictions, research and development, or R&D, tax credits available in California and other foreign jurisdictions and deductions available in the United States for domestic production activities. Our effective tax rate may be subject to fluctuations during the year as new information is obtained, which may affect the assumptions used to estimate the annual effective tax rate, including factors such as the mix of pre-tax earnings in the various tax jurisdictions in which we operate, valuation allowances against deferred tax assets, the recognition or derecognition of tax benefits related to uncertain tax positions, expected utilization of R&D tax credits and changes in or the interpretation of tax laws in jurisdictions where we conduct business. The American Taxpayer Relief Act of 2012 was enacted on January 2, 2013 and retroactively reinstated the U.S. R&D tax credit to January 1, 2012. The retroactive benefit of the U.S. R&D tax credit for fiscal year 2012 is estimated to be approximately $1.0 million and will be recognized in the first quarter of 2013. We recognize deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of our assets and liabilities along with net operating loss and tax credit carryovers.

We record a valuation allowance against our deferred tax assets to reduce the net carrying value to an amount that we believe is more likely than not to be realized. When we establish or reduce the valuation allowance against our deferred tax assets, our provision for income taxes will increase or decrease, respectively, in the period such determination is made. Valuation allowances against deferred tax assets were $1.1 million and $45.6 million at December 31, 2012 and 2011, respectively. Changes in the valuation allowances, when they are recognized in the provision for income taxes, are included as a component of the estimated annual effective tax rate.

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.

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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***

In the normal course of business, our operations are exposed to risks associated with fluctuations in interest rates and foreign currency exchange rates.

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 and our Credit Agreement, (2) credit risk of the companies bonds in which we invest, (3) general credit market risks as have existed since late 2007 and (4) the financial viability of the institutions which hold our capital and through which we have invested our funds. We manage such risks on our investment portfolio by investing in highly liquid, highly rated instruments and not investing in long-term maturity instruments.

In response to the dislocation in the credit markets since the latter part of 2007, in early 2008 we converted substantially all of our investments, including all of our market auction debt securities, into highly liquid and safe instruments. Our investments, as of December 31, 2012 and December 31, 2011, 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, 2012 or December 31, 2011, any decline in the fair value of our investments or increase in our obligations under our Credit Agreement 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.

In connection with the Allos acquisition, we entered into a credit agreement on September 5, 2012, or Credit Agreement, with Bank of America, N.A, as the administrative agent and Wells Fargo Bank, N.A, as an initial lender. The Credit Agreement provides us with a committed $75 million revolving line of credit facility which may be increased up to $125 million, subject to meeting certain customary conditions and obtaining commitments for such increase from the lenders. The Credit Agreement contains certain financial covenants and expires on September 5,

2014.

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

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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 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, or CEO (our principal executive officer) and Chief Financial Officer, or CFO (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.

In connection with the restatement discussed in the Explanatory Note to this Form 10-K/A and in Note 1A. to our Consolidated Financial Statements, as required by SEC Rule 13a-15(b), we carried out a reevaluation, under the supervision and with the participation of our management, including our CEO and our CFO, of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2012, the end of the period covered by this report, referred to as the Evaluation Date.

At the time that our Annual Report on Form 10-K for the year ended December 31, 2012 was filed on February 28, 2013, our CEO and CFO concluded that our disclosure controls and procedures were effective as of the Evaluation Date. However, solely as a result of identifying a material weakness in our internal control over financial reporting during the reevaluation as described below, our CEO and CFO have revised their conclusions relative to the effectiveness of our internal control over financial reporting. Accordingly, our CEO and CFO now conclude that our disclosure controls and procedures, as of the end of the period covered by this report [and of the date of this filing], were not effective in timely alerting them to material information relating to the Company required to be included in our periodic SEC filings.

(ii) Internal Control Over Financial Reporting

(a) Management s Annual Report on Internal Control Over Financial Reporting

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

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

misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In connection with the restatement discussed in the Explanatory Note to this Form 10-K/A and in Note 1A. to our Consolidated Financial Statements, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted a reevaluation 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 (1992 framework), or COSO. Based on the evaluation and the criteria set forth in the COSO report, management identified a material weakness in internal control over financial reporting as described below. A material weakness is a deficiency, or a combination of deficiencies, in internal controls over financial reporting, such that there is a reasonable possibility that a material misstatement of a company s annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

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We have excluded from our assessment the internal control over financial reporting of Allos Therapeutics, Inc. (Allos), which we acquired September 5, 2012, as it was determined that management could not complete an assessment of the internal control over financial reporting of the acquired business in the period between the acquisition date and the date of management s assessment date. Total assets and revenues of this acquisition represent approximately 6% and 8%, respectively, of the related consolidated financial statement amounts as of and for the year ended December 31, 2012.

Management identified a material weakness in internal control over financial reporting related to the accurate and timely reporting of its accounting for accruals. Specifically, controls over the review of purchase order related accruals were not designed and operating effectively to timely review and accurately record purchase order accruals in the consolidated financial statements. The components of the overstatement comprise excess accruals that correspond with (i) research and development and sales and marketing activities that accumulated over multiple reporting periods from January 1, 2007 through June 30, 2013, and (ii) liabilities that were recorded as part of our business combination accounting for the 2009 acquisition of RIT Oncology, LLC that did not require settlement, and were not identified as such within a timely manner.

We have concluded that as of December 31, 2012, the deficiency described above represents a material weakness in our internal controls over financial reporting, based on the results of our evaluation under the framework in COSO. Accordingly, our management now concludes that our internal control over financial reporting was not effective as of December 31, 2012.

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

Notwithstanding our material weakness, we have concluded that the financial statements and other financial information included in this Annual Report on Form 10-K/A fairly present in all material respects our financial condition, results of operations and cash flows as of, and for, the periods presented.

(b) Remediation Steps to Address Material Weakness

We have developed, and are currently implementing, a remediation plan for this material weakness. We will continue to execute our remediation plan, which includes, among other things, hiring additional experienced accounting personnel and expanding training for our accounting personnel. The successful remediation of this material weakness will require review and evidence of the effectiveness of the related internal controls as part of our next annual assessment of our internal controls over financial reporting as of December 31, 2013. As we continue to evaluate and work to enhance internal control over financial reporting, we may determine that additional measures should be taken to address these or other control deficiencies, and/or that we should modify the remediation plan described above.

(c) Changes in internal control over financial reporting

Except as disclosed above, there were no changes in our internal control over financial reporting during the fiscal quarter ended December 31, 2012 that has 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, 2012, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 framework) (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.

As indicated in the accompanying Management s Annual Report on Internal Control Over Financial Reporting, management s assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of Allos Therapeutics, Inc., which is included in the 2012 consolidated financial statements of Spectrum Pharmaceuticals, Inc. and Subsidiaries and constituted $29.1 million and $19.9 million of total and net assets, respectively, as of December 31, 2012 and $20.8 million and $5.9 million of revenues and net income, respectively, for the year then ended. Our audit of internal control over financial reporting of Spectrum Pharmaceuticals, Inc. and Subsidiaries also did not include an evaluation of the internal control over financial reporting of Allos Therapeutics, Inc.

In our report dated February 27, 2013, we expressed an unqualified opinion on the effectiveness of internal control over financial reporting as of December 31, 2012. As described in the following paragraph, the Company subsequently identified a material weakness in its internal control over financial reporting. Accordingly, our opinion on the effectiveness of the Company s internal control over financial reporting as of December 31, 2012 expressed herein is different from that expressed in our previous report.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company s annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and included in management s assessment. Management has identified a material weakness in internal control over financial reporting related to the accurate and timely accounting for accruals. Specifically, controls over the review of purchase order related accruals were not designed and operating effectively to timely review and accurately record purchase order accruals in the consolidated financial statements. We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Spectrum Pharmaceuticals, Inc. and Subsidiaries as of December 31, 2012 and 2011, and the related consolidated statements of operations, comprehensive income (loss), stockholders equity,

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and cash flows for each of the three years in the period ended December 31, 2012. This material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of those consolidated financial statements, and this report does not affect our report dated February 27, 2013, except for the effects on the consolidated financial statements of the restatement described in Note 1A, as to which the date is December 6, 2013, which expressed an unqualified opinion on those consolidated financial statements.

In our opinion, because of the effect of the material weakness described above on the achievement of the objectives of the control criteria, Spectrum Pharmaceuticals, Inc. and Subsidiaries have not maintained effective internal control over financial reporting as of December 31, 2012, based on the COSO criteria.

/s/ Ernst & Young LLP

Irvine, California

February 27, 2013,

except for the effects of the material weakness described in the seventh paragraph above, as to which the date is

December 6, 2013

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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 2013 Annual Meeting of Stockholders, or the Proxy Statement, to be filed pursuant to Regulation 14A, on or before April 30, 2013.

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 (As Restated):

(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.)
2.4#	License and Asset Purchase Agreement between Spectrum Pharmaceuticals Cayman, L.P. and Bayer Pharma AG, dated January 23, 2012. (Filed as Exhibit 2.1 to Form 10-Q, as filed with the Securities and Exchange Commission on April 27, 2012, and incorporated herein by reference.)
2.5	Agreement and Plan of Merger, dated as of April 4, 2012, by and among the Registrant, Sapphire Acquisition Sub, Inc. and Allos Therapeutics, Inc., including a Form of Contingent Value Rights Agreement and a Form of Tender and Voting Agreement. (Filed as Exhibits 2.1, 2.2 and 2.3, respectively, to Form 8-K, as filed with the Securities and Exchange Commission on April 5, 2012, and incorporated herein by reference.)
3.1	Certificate of Incorporation, as amended through June 24, 2011. (Filed as Exhibit 3.1 to Form 10-K, as filed with the Securities and Exchange Commission on March 2, 2012, and incorporated herein by reference.)
3.2	Second Amended and Restated Bylaws of the Registrant. (Filed as Exhibit 3.2 to Form 8-K, as filed with the Securities and Exchange Commission on August 8, 2012, 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. (Filed as Exhibit 10.2 to Form 10-K, as filed with the Securities and Exchange Commission on March 2, 2012, and incorporated herein by reference.)

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.)

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Exhibit

No.	Description
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.)
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\\	Second Amendment to Sublease Agreement, dated November 12, 2012, between the Registrant and Del Webb Corporation.
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.)
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.)

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Exhibit

No.	Description
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 (Revised July 2012). (Filed as Exhibit 10.2 to Form 10-Q, as filed with the Securities and Exchange Commission on November 9, 2012, 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.)
10.32#	License Agreement for 10-Propargyl-10-Deazaaminopterin PDX dated December 23, 2002 and amended May 9, 2006 between Allos Therapeutics, Inc. and SRI International, Sloan-Kettering Institute for Cancer Research and Southern Research Institute. (Filed as Exhibit 10.1 to Allos Therapeutics, Inc. s Form 10-Q/A, File No. 000-29815, as filed with the Securities and Exchange Commission on August 17, 2012, and incorporated herein by reference.)
10.33#	Second Amendment to License Agreement for 10-Propargyl-10-Deazaaminopterin PDX dated November 6, 2007 between Allos Therapeutics, Inc. and SRI International, Sloan-Kettering Institute for Cancer Research and Southern Research Institute. (Filed as Exhibit 10.13.1 to Allos Therapeutics, Inc. s Form

10-K, File No. 000-29815, as filed with the Securities and Exchange Commission on March 1, 2010, and incorporated herein by reference.)

10.34# Third Amendment to License Agreement for 10-Propargyl-10-Deazaaminopterin PDX dated May 10, 2011 between Allos Therapeutics, Inc. and SRI International, Sloan-Kettering Institute for Cancer Research and Southern Research Institute. (Filed as Exhibit 10.3 to Allos Therapeutics, Inc. s Form 10-Q, File No. 000-29815, as filed with the Securities and Exchange Commission on August 4, 2011, and incorporated herein by reference.)

10.35# License, Development and Commercialization Agreement, dated May 10, 2011, by and between Mundipharma International Corporation Limited and Allos Therapeutics, Inc. (Filed as Exhibit 10.25 to Allos Therapeutics, Inc. s Form 10-K, File No. 000-29815, as filed with the Securities and Exchange Commission on March 26, 2012, and incorporated herein by reference.)

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Exhibit No.	Description
10.36#	Supply Agreement dated May 10, 2011, by and between Mundipharma Medical Company and Allos Therapeutics, Inc. (Filed as Exhibit 10.2 to Allos Therapeutics, Inc. s Form 10-Q, File No. 000-29815, as filed with the Securities and Exchange Commission on August 4, 2011, and incorporated herein by reference.)
10.37	License Agreement, dated December 21, 2007, by and between Biogen Idec Inc. and Cell Therapeutics, Inc. (Filed as Exhibit 10.8 to Form 10-Q, as filed with the Securities and Exchange Commission on November 9, 2012, and incorporated herein by reference.)
10.38	License-Back Agreement, dated December 21, 2007, by and between Biogen Idec Inc. and Cell Therapeutics, Inc. (Filed as Exhibit 10.9 to Form 10-Q, as filed with the Securities and Exchange Commission on November 9, 2012, and incorporated herein by reference.)
10.39#	Sublicense Agreement, dated December 21, 2007, by and between Cell Therapeutics, Inc. and Biogen Idec Inc. (Filed as Exhibit 10.10 to Form 10-Q, as filed with the Securities and Exchange Commission on November 9, 2012, and incorporated herein by reference.)
10.40#	Sublicense Agreement, dated December 21, 2007, by and among Cell Therapeutics, Inc., Biogen Idec Inc., SmithKline Beecham Corporation d/b/a GlaxoSmithKline and Glaxo Group Limited. (Filed as Exhibit 10.11 to Form 10-Q, as filed with the Securities and Exchange Commission on November 9, 2012, and incorporated herein by reference.)
10.41#	Sublicense Agreement, dated December 21, 2007, by and among Cell Therapeutics, Inc., Biogen Idec Inc., Corixa Corporation, Coulter Pharmaceutical, Inc., The Regents of the University of Michigan and SmithKline Beecham Corporation d/b/a GlaxoSmithKline. (Filed as Exhibit 10.12 to Form 10-Q, as filed with the Securities and Exchange Commission on November 9, 2012, and incorporated herein by reference.)
10.42*	Employment Agreement by and between the Registrant and Joseph Kenneth Keller, entered into August 28, 2012, as amended September 5, 2012, and effective as of September 1, 2012. (Filed as Exhibit 10.13 to Form 10-Q, as filed with the Securities and Exchange Commission on November 9, 2012, and incorporated herein by reference.)
10.43#	Omnibus Amendment to Zevalin Supply Arrangements, dated October 1, 2012, by and between Biogen Idec US Corporation and RIT Oncology, LLC, a wholly-owned subsidiary of the Registrant. (Filed as Exhibit 10.14 to Form 10-Q, as filed with the Securities and Exchange Commission on November 9, 2012, and incorporated herein by reference.)
10.44#	Supply Agreement, dated June 9, 1999, by and between IDEC Pharmaceuticals Corporation and Schering Aktiengesellschaft, as amended December 14, 2004 and January 16, 2012, by and between Idec Pharmaceuticals Corporation and Schering Aktiengesellschaft. (Filed as Exhibit 10.15 to Form 10-Q, as filed with the Securities and Exchange Commission on November 9, 2012, and incorporated herein by reference.)
10.45	License Agreement, dated May 23, 2006, by and between Merck Eprova AG and Spectrum Pharmaceuticals, Inc. (Filed as Exhibit 10.16 to Form 10-Q, as filed with the Securities and Exchange Commission on November 9, 2012, and incorporated herein by reference.)
10.46	Manufacturing and Supply Agreement, dated May 23, 2006, by and between Merck Eprova AG and Spectrum Pharmaceuticals, Inc. (Filed as Exhibit 10.17 to Form 10-Q, as filed with the Securities and

	Exchange Commission on November 9, 2012, and incorporated herein by reference.)
10.47	Credit Agreement, dated September 5, 2012, by and among the Registrant, the Guarantors named therein, the Lenders named therein and Bank of America, N.A, as the administrative agent. (Filed as Exhibit 10.1 to Form 8-K, as filed with the Securities and Exchange Commission on September 5, 2012, and incorporated herein by reference.)
10.48+#\\	Second Amendment, dated January 29, 2013, to License, Development, Supply and Distribution Agreement, dated October 28, 2008, as amended June 13, 2011, by and among the Registrant, Allergan Sales, LLC, Allergan USA, Inc. and Allergan, Inc.

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Exhibit

No.	Description
10.49+*\\	First Amendment, dated September 5, 2012, to Employment Agreement by and between the Registrant and Joseph Kenneth Keller, entered into August 28, 2012 and effective as of September 1, 2012.
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.
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.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* 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.
XBRL (Extensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections or otherwise incorporated by reference.
\\ Previously filed with Original Report.

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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/A 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: December 6, 2013

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints each of Rajesh C. Shrotriya and Kurt A. Gustafson 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/A, 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/A has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ RAJESH C. SHROTRIYA, M.D. Rajesh C. Shrotriya, M.D.	Chairman of the Board, Chief Executive Officer, and President (Principal Executive Officer)	December 6, 2013
/s/ KURT A. GUSTAFSON Kurt A. Gustafson	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	December 6, 2013
/s/ Dolatrai M. Vyas, PH.D. Dolatrai M. Vyas, Ph.D.	Director	December 6, 2013
/s/ LUIGI LENAZ, M.D. Luigi Lenaz, M.D.	Director	December 6, 2013
/s/ STUART M. KRASSNER, SC.D., PSY.D. Stuart M. Krassner, Sc.D., Psy.D.	Director	December 6, 2013
/s/ ANTHONY E. MAIDA, III, M.A., M.B.A., PH.D Anthony E. Maida, III, M.A., M.B.A., Ph.D	Director	December 6, 2013

/s/ Raymond W. Cohen Raymond W. Cohen	Director	December 6, 2013
/s/ Gilles Gagnon Gilles Gagnon, M.Sc., M.B.A	Director	December 6, 2013

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Spectrum Pharmaceuticals, Inc. and Subsidiaries

Consolidated Financial Statements

As of December 31, 2012 and 2011 and

For Each of the Three Years Ended December 31, 2012

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Spectrum Pharmaceuticals, Inc. and Subsidiaries

Consolidated Financial Statements (As Restated)

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