SPECTRUM PHARMACEUTICALS INC
Form 10-K
March 12, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

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

For the fiscal year ended December 31, 2013

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

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

As of June 30, 2013, the aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant was $449,722,900 (based upon the $7.46 closing sale price for shares of the Registrant s Common Stock as reported by the NASDAQ Global Select Market on June 28, 2013, the last trading date of the Registrant s most recently completed second fiscal quarter).

As of February 28, 2014, approximately 65,287,782 shares of the Registrant s Common Stock, $0.001 par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s Proxy Statement for the registrant s 2014 Annual Meeting of Shareholders, to be filed on or before April 30, 2014, are incorporated by reference into Part III, Items 10-14 of this Annual Report on Form 10-K.

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Cautionary Note Concerning Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934 as amended (the Exchange Act). These forward looking statements are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995 and speak only as of the time this Annual Report on Form 10-K was filed with the Securities and Exchange Commission, or SEC. You can identify forward-looking statements by the use of forward-looking terminology such as, believes, expects, may, will, intends, plans, should, c pro forma, anticipates, estimates, continues, or other variations thereof, including their use in the negative, or by discussions of strategies, opportunities, plans or intentions. In addition, any statements that refer to projections of our future financial performance, trends in our businesses, or other characterizations of future events or circumstances are forward-looking statements. We have based these forward-looking statements largely on our current expectations based on information currently available to us and projections about future events and trends affecting the financial condition of our business. These 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:

our ability to successfully develop, obtain regulatory approval for and market our products;

our ability to continue to grow sales revenue of our marketed products;

risks associated with doing business internationally;

our ability to generate and maintain sufficient cash resources to fund our business;

our ability to enter into strategic alliances with partners for manufacturing, development and commercialization;

efforts of our development partners;

the ability of our manufacturing partners to meet our timelines;

the ability to timely deliver product supplies to our customers;

our ability to identify new product candidates and to successfully integrate those product candidates into our operations;

the timing and/or results of pending or future clinical trials, and our reliance on contract research organizations;

our ability to protect our intellectual property rights;

competition in the marketplace for our drugs;

delay in approval of our products or new indications for our products by the U.S. Food and Drug Administration, or the FDA;

actions by the FDA and other regulatory agencies, including international agencies;

securing positive reimbursement for our products;

the impact of any product liability, or other litigation to which we are, or may become a party;

the impact of legislative or regulatory reform of the healthcare industry and the impact of recently enacted healthcare reform legislation;

the availability and price of acceptable raw materials and components from third-party suppliers, and their ability to meet our demands;

our ability, and that of our suppliers, development partners, and manufacturing partners, to comply with laws, regulations and standards, and the application and interpretation of those laws, regulations and standards, that govern or affect the pharmaceutical and biotechnology industries, the non-compliance with which may delay or prevent the development, manufacturing, regulatory approvals and sale of our products;

defending against claims relating to improper handling, storage or disposal of hazardous chemical, radioactive or biological materials which could be time consuming and expensive;

our ability to maintain the services of our key executives and technical and sales and marketing personnel;

the difficulty in predicting the timing or outcome of product development efforts and regulatory approvals; and

demand and market acceptance for our approved products.

In addition, past financial or operating performance is not necessarily a reliable indicator of future performance, and you should not use our historical performance to anticipate results or future period trends. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our results of operations and financial condition. Except as required by law, we do not undertake to update any such forward-looking statements and expressly disclaim any duty to update the information contained in this Annual Report on Form 10-K.

Unless the context otherwise requires, all references in this Annual Report on Form 10-K to the Company , we, us, our, Spectrum and Spec Pharmaceuticals refer to Spectrum Pharmaceuticals, Inc. and its subsidiaries and other consolidated entities, as a consolidated entity. We primarily conduct our business activities as Spectrum Pharmaceuticals.

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PART I

ITEM 1. BUSINESS

Company Overview

Spectrum Pharmaceuticals, Inc. and its wholly-owned subsidiaries (Spectrum , the Company , we , our , or us), is a biotechnology company wi 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.

We currently market four oncology drugs:

FUSILEV injection for patients in the U.S. with advanced metastatic colorectal cancer and to counteract certain side effects of methotrexate therapy;

ZEVALIN injection for patients in the U.S. and various international markets with follicular non-Hodgkin s lymphoma;

FOLOTYN injection for patients in the U.S. with relapsed or refractory peripheral T-cell lymphoma; and

MARQIBO injection for patients in the U.S. with relapsed Philadelphia chromosome negative acute lymphoblastic leukemia.

We also have ongoing indication expansion studies with several of our marketed products, and a diversified pipeline of product candidates in advanced-stage Phase 2 and Phase 3 studies. 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 business strategy described in detail below.

Business Strategy

Our business strategy is comprised of the following three initiatives:

Maximizing the revenue potential of our four currently-marketed drugs for the treatment of cancer.

Our near-term outlook largely depends on sales and marketing successes for our four marketed drugs. It is this base business, along with potential additional indications for these drugs, that provides the working capital needed to operate our daily business and provides the necessary capital for opportunistic acquisitions.

Developing and commercializing the drugs for the treatment of cancer within our pipeline.
Our strategy for our development portfolio is to focus on late-stage development drugs. We strive to complete clinical studies to demonstrate the safety and efficacy of these drugs in order to obtain regulatory approval in a timely manner. Upon obtaining approval, our sales and marketing function educates physicians on the safety of the drug and its effectiveness in treating patients for the approved indication, with the goal of achieving maximum commercial success.

Expanding our pipeline of development-stage and commercial-stage drugs through business development activities.
It is our goal to identify new strategic opportunities that are synergistic with our currently-marketed drugs. We will continue to (i) explore strategic collaborations as they relate to drugs that are either in clinical trials or are currently on the market, and (ii) identify and secure drugs that have significant growth potential through enhanced marketing and sales efforts and/or through pursuit of additional clinical development. We may also identify and pursue partnerships for out-licensing certain of our drugs in development.

Cancer Background and Market Size

Cancer is a group of diseases characterized by the uncontrolled growth and spread of abnormal cells, which can result in death. The development of cancer is multi-factorial and includes both external factors (tobacco, infectious organisms, chemicals, and radiation) and internal factors (inherited mutations, hormones, immune conditions, and mutations that occur from exposure to environmental factors or errors in making DNA (deoxyribonucleic acid) during normal cell division). These causal factors may act together or in sequence to initiate or promote the development of cancer. Ten or more years often pass between exposure to these factors and the development of detectable cancer. Cancer is treated through surgery, radiation, chemotherapy, hormone therapy, immune therapy, and/or targeted drug therapy.

According to the American Cancer Society s publication *Cancer Facts & Figures 2014*, cancer is the second leading cause of death in the U.S. (only behind heart disease). In the U.S., approximately 1.7 million new cancer cases are expected to be diagnosed in 2014 and over 585,000 persons are expected to die from the disease in 2014. Anyone can develop cancer. Since the risk of being diagnosed with cancer increases with age, most cases occur in adults who are middle aged or older. About 77% of all cancers are diagnosed in people 55 years of age and older. In the U.S., men have slightly less than a 1 in 2 lifetime risk of developing cancer; for women, the risk is a little more than 1 in 3. These probabilities are estimated based on the overall experience of the general population. Individuals within the population may have higher or lower risk because of differences in exposures (e.g., smoking), and/or genetic susceptibility. In addition, currently available treatments are variably effective in the different cancers and individual patients. Together these patients risks and the treatment limitations suggest a significant current and long-term demand for improved and novel cancer treatments.

All cancers involve the malfunction of genes that control cell growth and division. Only a small proportion of cancers are strongly hereditary, in that an inherited genetic alteration confers a very high risk for developing cancer. Inherited factors play a larger role in determining risk for some cancers (e.g., colorectal, breast, and prostate) than for others. It is now thought that many familial cancers arise from the interplay between common gene variations and lifestyle/environmental risk factors. However, most cancers do not result from inherited genes but rather from damage to genes occurring during a person s lifetime. Genetic damage may result from internal factors, such as hormones or the metabolism of nutrients within cells, or external factors, such as tobacco, or excessive exposure to chemicals, sunlight, or ionizing radiation.

Cancer cell growth is different from normal cell growth. Instead of being regulated and stopping to grow in a controlled manner, cancer cells continue to grow and form new, abnormal cells. Cancer cells can also invade (grow into) other tissues, something that normal cells do not do. Cells become cancer cells because of DNA damage. DNA is in every cell and it directs all of the cell s actions. In a normal cell, when DNA is damaged, the cell either repairs the damage, or the cell dies. In cancer cells, the damaged DNA is not repaired, and the cell doesn t die. Instead, it continues to make new cells in an uncontrolled manner that the body doesn t require. People can inherit abnormal DNA, but most DNA damage is caused by abnormal cellular reproduction, usually triggered by environmental causes. In most cases, the cancer cells form a tumor, though some cancers, like leukemia, involve the blood and blood-forming organs and circulate through other tissues where they grow.

Cancer cells often travel to other parts of the body where they begin to grow and form new tumors. This happens when the cancer cells get into the body s bloodstream or lymph vessels; this process of cancer spreading is called metastasis. No matter where a cancer may spread, it is always named for the place where it originated. For example, breast cancer that has spread to the liver is called metastatic breast cancer, not liver cancer. Likewise, prostate cancer that has spread to the bone is called metastatic prostate cancer, not bone cancer. Different types of cancer can behave very differently. For instance, lung cancer and skin cancer are very different diseases. They grow at different rates and respond to different treatments.

Product Portfolio

We have a product portfolio consisting of both commercial stage and development stage products that address various cancer types (see Research & Development section below for our pipeline of cancer therapeutics that are in various development stages). We remain committed to growing the sales of our currently marketed products, as we strive to maintain a robust development pipeline.

Commercialized Products

Our commercialized drug products, and their approved indications, are summarized in the following table:

FUSILEV

FUSILEV (levoleucovorin), a novel folate analog formulation and the pharmacologically active isomer (the *levo*-isomer) of the racemic compound, calcium leucovorin. Leucovorin is a mixture of equal part 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 is approved as a ready-to-use solution, and as freeze-dried powder.

FUSILEV has the following indications for use:

- in combination chemotherapy with 5-fluorouracil in the palliative treatment of patients with advanced metastatic colorectal cancer.
- for rescue after high-dose methotrexate therapy in osteosarcoma.
- to diminish the toxicity and counteract the effects of impaired methotrexate elimination and of inadvertent overdosage of folic acid antagonists.

The product similar to FUSILEV is marketed outside the U.S. by Pfizer, Sanofi-Aventis, and Takeda.

FOLOTYN

FOLOTYN, (pralatrexate injection), a folate analogue metabolic inhibitor, was discovered by Memorial Sloan-Kettering Cancer Center, SRI International and Southern Research Institute and developed by Allos Therapeutics, Inc. (Allos). In September 2009, the FDA granted accelerated approval for FOLOTYN for use as a single agent for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL). FOLOTYN was the first chemotherapy approved by the FDA for the treatment of relapsed or refractory PTCL and has been available to patients in the U.S. since October 2009.

According to the Lymphoma Research Foundation, lymphoma is the most common blood cancer. Hodgkin s lymphoma and non-Hodgkin s lymphoma (NHL) are the two main forms of lymphoma. Lymphoma occurs when lymphocytes, a type of white blood cell, grow abnormally and accumulate in one or more lymph nodes or lymphoid tissues. The body has two main types of lymphocytes that can develop into lymphomas: B-lymphocytes (B-cells) and T-lymphocytes (T-cells). PTCL comprises a group of rare and aggressive NHLs that develop from mature T-cells. PTCL accounts for approximately 10 to 15% of all NHL cases in the United States.

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.

We are exploring additional settings for FOLOTYN where methotrexate (MTX), a drug in the same category as FOLOTYN, has been successfully used for decades in the treatment of breast cancer, bladder cancer, and lung cancer. We will be testing FOLOTYN s benefits in these settings because FOLOTYN is designed to provide greater activity than MTX. In addition to its use alone as a single agent, we are evaluating FOLOTYN as part of different chemotherapy combinations.

ZEVALIN

ZEVALIN (ibritumomab tiuxetan) injection for intravenous use is a prescription medication that is part of a three step treatment regimen consisting of: two treatments of rituximab and one treatment of Yttrium-90 (Y-90) ZEVALIN. Rituximab is used to reduce the number of B-cells in the blood and Y-90 ZEVALIN is then given to treat non-Hodgkin s lymphoma. It is currently approved in the U.S. and more than 40 countries outside the U.S. including countries in Europe, Latin America and Asia for the treatment of patients with:

Recurring, low-grade or follicular B-cell NHL, after other anticancer drugs are no longer working.

Newly diagnosed follicular NHL following a response to initial anticancer therapy.

We are currently working towards a new indication for ZEVALIN for diffuse large B-cell lymphoma (DLBCL). An estimated 40,000 new cases of DLBCL were diagnosed in major markets in 2010. The need for improved treatments for DLBCL is high because the two-year progression-free survival rate is only approximately 55% and the estimated two-year overall survival rate is 71%.

ZEVALIN would be used as an add-on to frontline therapy in which there is currently no competitor. A number of Phase 2 studies have been completed by investigators with high response rates in this indication. We plan to complete our Phase 3 study enrollment in early 2016 and file a supplemental Biologics License Application (sBLA) in 2018.

MARQIBO

MARQIBO is a novel, sphingomyelin/cholesterol liposome-encapsulated formulation of the FDA-approved anticancer drug vincristine. MARQIBO s approved indication is for the treatment of adult patients with Philadelphia chromosome-negative acute lymphoblastic leukemia (ALL) in second or greater relapse or whose disease has progressed following two or more lines of anti-leukemia therapy. In the U.S., approximately 6,000 patients per year are diagnosed with ALL, of which approximately 1,600 can be categorized as ALL in second or greater relapse.

MARQIBO is also currently being explored for the treatment of the broader ALL indication as well as in NHL in addition to its approved treatment for Philadelphia chromosome-negative ALL. During 2014, we also intend to conduct an additional Phase 2 study for MARQIBO in patients with NHL.

Product Pipeline

BELEODAQ

BELEODAQ (belinostat) is a histone deacytelase, (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. Its anticancer effect is thought to be mediated through multiple mechanisms of action, including the inhibition of cell proliferation, induction of apoptosis (programmed cell death), inhibition of angiogenesis, induction of differentiation, and the activity in tumors that had become resistant to anticancer agents such as the platinums, taxanes and topoisomerase II inhibitors. We are currently seeking FDA approval for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma.

BELEODAQ is differentiated from other HDAC inhibitors that selectively inhibit a single class of HDAC enzymes because it inhibits all 3 classes of the zinc-dependent HDAC enzymes (Class I, Class II and Class IV); this leads to different alterations in histone and non-histone protein acetylation that, in turn, could importantly influence chromatin accessibility, gene transcription, and activity in different cancer patients, including those who develop drug resistant disease.

Based on the data from the clinical studies, we believe there are many potential attributes associated with BELEODAQ that separate it from other currently marketed HDACs, including efficacy when used alone and in combination, less toxicities (when compared to the reported rates of some adverse events with the 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, BELEODAQ is currently being investigated in multiple indications, both as monotherapy and in combination with other treatment regimens. Numerous studies have been conducted, or are ongoing, through the National Cancer Institute (the NCI) and other well-known oncologic academic institutions. Additionally, we have a comprehensive development plan for BELEODAQ, 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 BELEODAQ potentially has broad applicability and hence, commercial potential beyond that of its currently targeted indication.

BELEODAQ 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 BELEODAQ a significant competitive advantage.

In December 2013, we filed our NDA with the FDA. Our application was subsequently accepted by the FDA with Priority Review in February 2014.

Captisol-Enabled® MELPHALAN

Captisol-enabled MELPHALAN (C-E MELPHALAN) is a novel intravenous formulation of MELPHALAN that has the potential to offer multiple advantages for clinicians and patients in the multiple myeloma transplant setting. Multiple myeloma is a cancer of plasma cells, a type of white blood cell present mainly in the bone marrow that produces antibodies. In multiple myeloma, a group of plasma cells (myeloma cells) become cancerous and multiply, raising the number of plasma cells to a higher-than-normal level, which can crowd out normal blood cells and lead to abnormally high proteins in the blood or urine. Per NCI and the ACS, there were an estimated 22,000 new cases of multiple myeloma in the U.S. in 2013, with the incidence of new cases increasing by approximately 1.7% per year. The current intravenous MELPHALAN market is approximately $130 million annually, with predominant use in stem cell transplants. The rate of autologous stem cell transplantation for patients with multiple myeloma is growing by approximately 3.3% annually.

The C-E MELPHALAN formulation avoids the use of propylene glycol (PG), which is required as a co-solvent in the current MELPHALAN formulation; PG has been reported to cause renal and cardiac side-effects that limit the ability to deliver higher quantities of intended therapeutic compounds. The use of Captisol technology to reformulate MELPHALAN is anticipated to allow for longer administration durations and slower infusion rates, potentially enabling clinicians to safely achieve a higher dose intensity for pre-transplant chemotherapy.

C-E MELPHALAN was granted Orphan Drug status by the FDA for use as a high-dose conditioning regimen prior to hematopoietic progenitor (stem) cell transplantation. If approved, the propylene glycol-free formulation of MELPHALAN will be the first product approved for this indication.

Currently, C-E MELPHALAN is a Phase 2B drug (Pivotal Trial) with an NDA filing anticipated in 2014.

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 Non- muscle Invasive Bladder Cancer (NMIBC), which is a cancer that is only in the innermost layer of the bladder and has not spread to deeper layers of the bladder.

The ACS estimated that the 2013 incidence and prevalence of bladder cancer in the U.S. was approximately 74,690 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.

APAZIQUONE is a bio-reductive alkylating indoloquinone that is enzymatically activated by enzymes that are over expressed by bladder tumors that is being tested in NMIBC. 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 that could arise from absorption of a drug through the bladder wall into the bloodstream. These features of APAZIQUONE are distinct from other intravesical agents currently in use for the treatment of recurrent bladder cancer. 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).

We expect to commence a confirmatory Phase 3 study for APAZIQUONE in 2014 and expect to prepare and submit a NDA at the end of 2014.

SPI-2012

SPI-2012, our third biologic drug, is used for the treatment of chemotherapy-induced neutropenia. In January 2012, we entered into a co-development and commercialization agreement with Hanmi Pharmaceutical Company, for SPI-2012 based on Hanmi s proprietary LAPSCOVERY Technology. Chemotherapy can cause myelosuppression and unacceptably low levels of white blood cells, making patients prone to infections, hospitalizations, and interruption of additional chemotherapy treatments.

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. We believe the worldwide market for GCSF-related drugs was over $5.0 billion in 2013.

We are currently enrolling a Phase 2 study with clinical trial results expected in the second half of 2014.

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 and packaging services, including active pharmaceutical ingredients (API) and finished-dosage products. 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 MARQIBO. We have multiple drug product contract manufacturers for FUSILEV and FOLOTYN.

We believe these third-party manufacturers have the capability to meet our projected worldwide clinical trial and commercial requirements for our products. 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.

Sales and Marketing

We market and sell our drugs through a direct sales force in the U.S., and through distributors in Europe and Japan. We divide the U.S. market between corporate accounts and oncology accounts. The primary decision makers for our products are oncologists and hematologists. As of December 31, 2013, our U.S. sales force (management, representatives, and direct support) numbered 81 employees.

Our corporate accounts are divided among four regions and 20 territories, led by our Vice President of Corporate Accounts and Executive Director of Corporate Accounts Sales. Each region is managed by an Associate Director of Corporate Accounts who oversees four Regional Business Managers.

Our oncology accounts are divided among six regions and 40 territories, led by our Vice President of Sales. Each region is managed by a Regional Sales Director who oversees six or seven Oncology Account Managers (sales representatives), an Oncology Nurse Specialist (sales support), and a Clinical Logistical Specialist (sales support).

Customers

Our product sales are concentrated to large pharmaceutical distributors (that ship and bill to hospitals and clinics). The customers that represent 10% or more of our total product sales in 2013, 2012, and 2011 are as follows:

	2013	2012	2011
Oncology Supply	35.4%	26.5%	57.0%
McKesson Specialty	19.8%	23.2%	19.1%
ICS	15.8%	19.4%	*
Cardinal Health	*	15.7%	*

* Less than 10%

We are exposed to credit risk associated with trade receivables that result from these product sales. We do not require collateral or deposits from our customers due to our assessment of their creditworthiness and our long-standing relationship with them. We maintain reserves for potential bad debt, though credit losses have historically been nominal and within management s expectations. A summary of our customers that represent 10% or more of our accounts receivables, net, as of December 31, 2013 and 2012 are as follows:

	December 31, 2013	December 31, 2012
Oncology Supply	37.7%	37.7%
McKesson Specialty	30.7%	26.0%
ICS	10.3%	19.1%

Competition

The pharmaceutical industry is characterized by rapidly-evolving biotechnology and intense competition, which we expect will continue. Many companies are engaged in research and development of compounds that are similar to ours both commercialized and in development. In the event that one or more of our competitor s 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.

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, 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 be differentiated, i.e., 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 commercially successful.

Companies that have products on the market or in research and development that target the same indications as our product targets include, among others, Astra Zeneca PLC, Bayer AG, Endo Pharmaceuticals, Inc., Eli Lilly and Co., Novartis AG, 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., and Johnson & Johnson.

Each of the aforementioned companies may be more advanced in development of competing drug products. Many of these competitors are large and well-capitalized companies focusing on a wide range of cancers and drug indications, and have substantially greater resources and expertise than we do.

The general competitive landscape for each of our commercialized products is summarized below:

(a) FUSILEV is the levo-isomeric form of the racemic compound calcium, leucovorin, a product already approved for the same indication as FUSILEV. As there are currently three generic companies approved by the FDA to sell the leucovorin product, we are competing with a low-cost alternative.

(b) ZEVALIN has 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.

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. In August 2013, the manufacturer of this product announced the discontinuation of both the manufacture and sale of Bexxar as of February 20, 2014.

(c) FOLOTYN, the first agent approved by the FDA for treatment of patients with relapsed or refractory PTCL, has two competitive products for its currently approved indications:

Romidepsin, marketed by Celgene, Inc., was granted accelerated approval by the FDA in June 2011 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.

Brentuximab vedotin, marketed by Seattle Genetics, Inc., was also granted accelerated approval by the FDA in August 2011 for two indications, one of which was for the treatment of patients with systemic anaplastic large cell lymphoma (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.

We are aware of multiple investigational agents that are currently being studied in clinical trials for PTCL, including BELEODAQ and alisertib, which, if approved, may compete with FOLOTYN in the United States. Because of the natural history of PTCL with repeated treatment failures, it is likely that many patients would receive treatment with more than one agent, e.g., BELEODAQ and FOLOTYN. 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.

(d) MARQIBO is a next generation liposomal form of standard vincristine. In its current indication, MARQIBO is approved for adult patients with relapsed or refractory Ph-ALL who have not responded or relapsed after two prior treatments. Currently, standard vincristine is not approved for the same indication as MARQIBO.

Research and Development

New drug development is the process whereby drug product candidates are tested for the purpose of filing a new drug application (NDA) or a Biologistics License Application (BLA) in the U.S. (or similar filing in other countries). Obtaining marketing approval from the FDA or similar 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 particularly uncertain and lengthy.

Our in-development products are summarized below:

Our research and development expenses for drug development are comprised of personnel expenses, contract services, license fees and milestone payments, clinical trials, laboratory supplies and drug products, and certain allocations of corporate costs. The below table summarizes our research and development expenses by project in 2013, 2012, and 2011:

	Research and Development Expenses for the Year Ended December 31, (in thousands)		
	2013	2012	2011
APAZIQUONE	$ 1,078	$ 6,642	$ 7,695
BELEODAQ	6,733	3,742	7,207
FUSILEV	4,517	1,416	1,239
FOLOTYN	2,992	1,586	
ZEVALIN	8,572	5,040	167
SPI-2012	1,403	1,049	
LUCANTHONE	795	792	
MARQIBO	4,099		
MELPHALAN	3,400		
OZARELIX	247	724	740
ORTATAXEL	421	554	107
RenaZorb	346	1,299	476
Other development drugs	1,823	4,695	1,417
Total Direct costs	36,426	27,539	19,048
Add: Indirect costs (including stock-based compensation of $2,000, $1,800, and $1,600, respectively)	13,335	21,404	16,502
(Less): Reimbursements from development partners	(804)	(7,383)	(8,888)
(Less): Mundipharma deferred payment contingency	(2,287)		
Total Research and development expenses	$ 46,670	$ 41,560	$ 26,662

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 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.

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.

We believe that our patents and licenses are critical to operating our business, as summarized below by commercialized and in-development drugs products.

FUSILEV: We have one U.S. composition of matter patent that expires in March 2022.

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 CD-20 MAB to a radioactive isotope to make the patient-ready dosage form of ZEVALIN). These patents expire over a wide range of dates, 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.

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 matter 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 U.S. and many other countries claiming different uses of FOLOTYN, and we may consider filing new patent applications if the opportunity arises.

MARQIBO: We have patents covering the use of MARQIBO for leukemia, lymphoma and melanoma and a patent claiming Marqibo kit in US that expire in 2020. We have filed an application for patent term extension through December 2024 for one of the patents covering the use of MARQIBO for relapsed leukemia and lymphoma in the U.S. However, it is not certain if the patent term extension will be granted by the USPTO. We also have issued patents covering the use of MARQIBO in Europe and other countries that expire in 2020. We have recently filed a PCT application claiming a method of encapsulating vincristine sulphate into liposomes

BELEODAQ: The composition of matter patents that cover BELEODAQ and related compounds do not begin to expire until 2021. Currently, there are multiple U.S. and foreign patent applications pending that cover BELEODAQ 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.

APAZIQUONE: The U.S. formulation patent does not expire until 2022, and method of treatment of bladder cancer using a stabilized formulation that does not expire until 2024. Formulation patents outside U.S. are due to expire in 2022. We have filed and plan to file additional U.S. and foreign patent applications covering new formulations and/or uses for this product.

OZARELIX: In the U.S. as well as outside the U.S., a composition of matter patent expires in 2020, and a formulation patent expires in 2023. We also have method of use patent applications on file.

ORTAXTEL: Two U.S. composition patents expired in 2013. Corresponding European patents expire in 2014, while multiple manufacturing and synthesis patents in U.S. and Europe do not begin to expire until 2021. We anticipate filing new method of use and formulation patent applications in the future.

LUCANTHONE: Our U.S. method of use patent expires in 2019.

RENAZORB: We have one method of use patent that is expiring in 2024, and pending U.S. and foreign patent applications covering compositions of matter, manufacturing process, and methods directed to treating hyperphosphatemia.

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 applications in the U.S. and Europe, and anticipate filing future patent applications pending the continued development of new methods of use and new formulations.

SPI-2012: Composition of matter patents covering SPI-2012 are due to expire in 2025 in the U.S. and in 2024 outside the U.S. SPI-2012 is also covered by additional patents claiming various aspects of the technology that are due to expire between 2024 and 2030 and recently-filed patent applications for its formulation.

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C-E MELPHALAN: Melphalan is covered by issued patents claiming improved Captisol ® technology that are due to expire between 2025 and 2029 in the U.S. Outside the U.S., we have issued patents that cover improved Captisol technology that are due to expire in 2025 and pending applications with anticipated expiry in 2029, if issued. We also have a recently filed patent application covering Captisol-based formulation of melphalan in the U.S. and a number of other countries.

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We are constantly evaluating our patent portfolio and are currently prosecuting patent applications for our drug products and are considering new patent applications in order to maximize the life cycle of each of our products.

While the U.S. and the European Union are currently the largest potential markets for most of our products, we also have patents issued and patent applications pending outside of the U.S. and Europe. Limitations on patent protection in these countries, and the differences in what constitutes patentable subject matter in countries outside the U.S., may limit the protection we have on patents issued or licensed to us outside of the U.S. In addition, laws of foreign countries may not protect our intellectual property to the same extent as would laws in the U.S.

To minimize our costs and expenses and to maintain effective protection, we usually focus our patent and licensing activities within the U.S., the European Union, Canada and Japan. In determining whether or not to seek a patent or to license any patent in a certain foreign country, we weigh the relevant costs and benefits, and consider, among other things, the market potential and profitability, the scope of patent protection afforded by the law of the jurisdiction and its enforceability, and the nature of terms with any potential licensees. Failure to obtain adequate patent protection for our proprietary drugs and technology would impair our ability to be commercially competitive in these markets.

In 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.

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

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 instructs 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.

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Product Exclusivity

Under the Hatch-Waxman Act, drug products are provided exclusivity whereby the FDA will not accept applications to market a generic form of an innovator reference listed drug product until the end of the prescribed period. A product is granted a five-year period of exclusivity if it contains a chemical entity never previously approved by the FDA either alone or in combination, although generic applications may be submitted after four years if they contain a certification of patent invalidity or non-infringement as further discussed below. A three-year period of exclusivity is granted to a previously approved product based on certain changes, *e.g.,* in strength, dosage form, route of administration or conditions of use, where the application is supported by new clinical investigations that are essential to approval. In addition, in 1997 Congress amended the law to provide an additional six months of exclusivity as a reward for studying drugs in children. This pediatric exclusivity, which can be obtained during the approval process or after approval, effectively delays the approval of a generic application until six months after the expiration of any patent or other exclusivity that would otherwise delay approval, thus providing an additional six months free of generic competition. In order to qualify for pediatric exclusivity, the FDA must make a written request for pediatric studies, the application holder must agree to the request and complete the studies with required timeframe, and the studies must be accepted by the FDA based on a determination that the studies fairly respond to the request. The provisions were enacted with a five-year sunset date, and have been reauthorized in 2002, 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.

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

Governmental Regulation

The development, production and marketing of our proprietary and generic drug and biologic products are subject to regulation for safety, efficacy and quality by numerous governmental authorities in the U.S. and other countries. In the U.S., drugs and biologics are subject to rigorous regulation. The Federal Food, Drug, and Cosmetic Act, as amended from time to time, and the regulations promulgated there under, as well as other federal and state statutes and regulations, govern, among other things, the development, approval, manufacture, safety, labeling, storage, record keeping, distribution, promotion, and advertising of our products. Product development and approval within this regulatory framework, including for drugs already at a clinical stage of development, can take many years and require the expenditure of substantial resources, and to obtain FDA approval, a product must satisfy mandatory quality, safety and efficacy requirements. In addition, each drug-manufacturing establishment must be registered with the FDA. Domestic manufacturing establishments must comply with the FDA s current good manufacturing practice (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. While all of our compounds are currently in clinical trials, it is possible that additional pre-clinical testing could be requested by a regulatory authority for any of our compounds.

Investigational New Drug Application: After certain pre-clinical studies are completed, an Investigational New Drug (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 and 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. BELEODAQ has received both Fast Track status and its NDA as a Priority Review.

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. The 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 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.

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.

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

As of December 31, 2013, we had 226 employees (as compared to 193 employees as of December 31, 2012), 13 of whom hold an M.D. degree, and eight of whom hold a Ph.D. degree. We believe that the success of our business will depend, in part, on our ability to attract and retain qualified personnel. Our employees are not subject to any collective bargaining agreements. We believe that we have good relations with our employees.

General Information

We are a Delaware corporation. We originally incorporated in Colorado in December 1987 as Americus Funding Corporation. We changed our corporate name in August 1996 to NeoTherapeutics, Inc., and reincorporated in Delaware in June 1997. We changed our corporate name in December 2002 to Spectrum Pharmaceuticals, Inc.

Our principal executive office is located at 11500 South Eastern Avenue, Suite 240, Henderson, Nevada 89052. Our telephone number is (702) 835-6300. Our website is located at *www.sppirx.com* and *www.spectrumpharm.com*. The information on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K and should not be considered to be a part hereof.

We make our proxy statements, annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K (and related amendments to these reports, as applicable) available on our website free of charge as soon as practicable after filing or furnishing with the SEC.

All such reports are also available free of charge via EDGAR through the SEC website at *www.sec.gov*. In addition, the public may read and copy materials filed by us with the SEC at the SEC s public reference room located at 100 F Street, NE, Washington, D.C., 20549. Information regarding operation of the SEC s public reference room can be obtained by calling the SEC at 1-800-SEC-0330.

ITEM 1A. RISK FACTORS

Before deciding to invest in our company, or to maintain or increase your investment, you should carefully consider the risks described below, in addition to the other information contained in this Annual Report on Form 10-K and other reports we have filed with the SEC. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us, or that we currently deem immaterial, may also affect our business operations. If any of these risks are realized, our business, financial condition, or results of operations could be seriously harmed and in that event, the market price for our common stock could decline, and you may lose all or part of your investment.

These risk factors should be considered in connection with evaluating the forward-looking statements contained in this Annual Report on Form 10-K. These factors could cause actual results and conditions to differ materially from those projected in our forward-looking statements.

Risks Related to Our Business

Our drug product FUSILEV may not be more cost-effective than competing drugs and otherwise may not have any competitive advantage, which could adversely affect sales performance.

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 FUSILEV 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 continue to be accepted by the medical field or remain commercially successful.

Our revenue may not be sustainable and our customer concentration for FUSILEV AND FOLOTYN is significant. The loss of, or significant reduction or cancellation in sales to, any one of these customers could adversely affect our results of operations.

There is no assurance that FUSILEV sales will be sustainable at their 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 in 2013, 2012, and 2011 is as follows:

	2013	2012	2011
Oncology Supply	32.0%	25.8%	57.0%
McKesson Specialty	19.8%	23.2%	19.1%
ICS	*	16.1%	*
Cardinal Health	*	15.7%	*

* Less than 10%

For the years ended December 31, 2013, 2012 and 2011, three companies affiliated with AmerisourceBergen Corporation accounted for substantially all of Allos Therapeutics 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, as it would likely take time for those sales to transition to another customer.

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. In the United States, we sell our products 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 our products, including transportation, warehousing, cross-docking, inventory management, packaging and freight-forwarding. We do not promote products to these distributors and they do not set or determine demand for products. 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 purchase sufficient inventory on hand to fulfill end user orders in a timely manner;
- be unable to satisfy financial obligations to us or others; and

cease operations.

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

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.

Even though we have obtained accelerated approval to market FOLOTYN for the treatment of patients with relapsed or refractory 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.

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;

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

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.

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. Discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, 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.

The marketing and sale of our products may be adversely affected by the marketing and sales efforts of third parties who sell our products or similar products outside of our territories.

We have only licensed the rights to develop, market and our products in limited territories. 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 our products or similar products, our own efforts to successfully market and sell our products in our markets may be adversely impacted.

Our sales depend on coverage and reimbursement from third-party payors and a reduction in the coverage and/or reimbursement for our products could have a material adverse effect on our product sales, business and results of operations.

Sales of our products are dependent on the availability and extent of coverage and reimbursement from third-party payors, including government programs and private insurance plans. Governments and private payors may regulate prices, reimbursement levels and/or access to our products to contain costs or to affect levels of use. We rely in large part on the reimbursement of our products through government programs such as Medicare and Medicaid in the United States, and a reduction in the coverage and/or reimbursement for our products could have a material adverse effect on our product sales, business and results of operations.

A substantial portion of our U.S. business relies on reimbursement from the U.S. federal government under Medicare Part B coverage. Most of our products furnished to Medicare beneficiaries in both a physician office setting and hospital outpatient setting are reimbursed under the Medicare Part B Average Sales Price, or ASP, payment methodology. ASP-based reimbursement of our products under Medicare may be below or could fall below the cost that some medical providers pay for such products, which could materially and adversely affect sales of our products. We also face risks relating to the reporting of pricing data that affect the U.S. reimbursement of and discounts for our products. ASP data are calculated by the manufacturer based on a formula defined by statute and regulation and are then submitted to the Centers for Medicare & Medicaid Services, the agency responsible for administering the Medicare program, or CMS, on a quarterly basis. CMS uses those ASP data to determine the applicable reimbursement rates for our products under Medicare Part B. However, the statute, regulations and CMS guidance do not define specific methodologies for all aspects of the reporting of ASP data. For example, CMS has not provided specific guidance regarding administrative fees paid to group purchasing organizations, or GPOs, in the ASP calculation. CMS directs that manufacturers make reasonable assumptions in their calculation of ASP data in the absence of specific CMS guidance on a topic. As a result, we are required to apply our reasonable judgment to certain aspects of calculating ASP data. If our submitted ASP data are incorrect, we may become subject to substantial fines and penalties or other government enforcement actions, which could have a material adverse impact on our business and results of operations.

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 target. 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 pending applications 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.

Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.

We had $120 million of long term debt as of December 31, 2013. Any such indebtedness will require the dedication of a portion of our expected cash flow from operations to service our indebtedness, thereby reducing the amount of our cash flow available for other purposes. In addition, our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including our convertible notes, depends on our future performance, which is subject to regulatory, economic, financial, competitive and other factors beyond our control, and our ability to raise equity capital. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

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, uncertain, 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, data are susceptible to varying interpretations, and 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.

Moreover, the commencement and completion of clinical trials may be delayed by many factors that are beyond our control, including:

- delays obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with contract research organizations, or CROs, and clinical trial sites;
- obtaining institutional review board, or IRB, approval at each site;
- slower than anticipated patient enrollment;
- scheduling conflicts with participating clinicians and clinical institutions;
- lack of funding;
- negative or inconclusive results;
- patient noncompliance with the protocol;
- adverse medical events or side effects among patients during the clinical trials;
- negative or problematic FDA inspections of our clinical operations or manufacturing operations; and
- real or perceived lack of effectiveness or safety of mifepristone.

We could encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the clinical trial sites in which such trials are being conducted, or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. For example, any delay in final data results in the second quarter of 2014 in the pivotal

trial of our Captisol-enabled MELPHALAN product candidate for use as a conditioning treatment prior to autologous stem cell transplant for patients with multiple myeloma could delay a new drug application filing with respect to that product candidate.

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, we are in the process of transitioning to a new supplier for ZEVALIN cold kits, 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.

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 or other sources of cash. 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 any covenants or representations and warranties in any such financings which could result in reduced availability of such financings, an event of default under such financings, or could make other sources of financing unavailable to us. 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, an economic downturn 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.

Volatile 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, adverse economic conditions 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.

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.

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.

Our commercial sales history is limited and we have had to increase our personnel to accommodate such sales, 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.

We may not be able to successfully integrate our recent acquisitions and any additional businesses we may acquire.

We regularly evaluate and, as appropriate, may make selective acquisitions of businesses that we believe complement or augment our existing business. In September 2012, we acquired Allos Therapeutics, pursuant to which we obtained FOLOTYN, and in July 2013, we acquired Talon, pursuant to which we obtained MARQIBO. 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 from such drug product:

- unwillingness on the part of a partner to pay us milestone payments or royalties that we believe are due to us under a collaboration;
- uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations;
- unwillingness by the partner to cooperate in the development or manufacture of the product, including providing us with product data or materials;
- unwillingness on the part of a partner to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities;
- initiation of litigation or alternative dispute resolution options by either party to resolve the dispute;
- attempts by either party to terminate the collaboration;
- our ability to maintain or defend our intellectual property rights may be compromised by our partner s acts or omissions;
- a partner may utilize our intellectual property rights in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability;
- a partner may change the focus of its development and commercialization efforts due to internal reorganizations, mergers, consolidations and otherwise;
- unwillingness of a partner to fully fund or commit sufficient resources to the testing, marketing, distribution or development of our products;
- unwillingness or ability of a partner to fulfill their obligations to us due to the pursuit of alternative products, conflicts of interest that arise or changes in business strategy or other business issues; and/or
- we may not be able to guarantee supplies of development or marketed products.

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

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

To remain competitive and grow our business, our long-term strategy includes the acquisition or in-license of additional drug products. We are actively seeking to acquire, or in-license, additional commercial drug products as well as drug products that have demonstrated positive pre-clinical and/or clinical data. We have certain criteria that we are looking for in any drug product acquisition and in-license and we may not be successful in locating and acquiring, or in-licensing, additional desirable drug products on acceptable terms.

To accomplish our acquisition and in-license strategy, we intend to commit efforts, funds and other resources to research and development and business development. Even with acquired and in-licensed drug products, a high rate of failure is inherent in the development of such products. We must make ongoing substantial expenditures without any assurance that our efforts will be commercially successful. Failure can occur at any point in the process, including after significant funds have been invested. For example, promising new drug product candidates may fail to reach the market or may only have limited commercial success because of efficacy or safety concerns, failure to achieve positive clinical outcomes, inability to obtain necessary regulatory approvals, limited scope of approved uses, excessive costs to manufacture, the failure to establish or maintain intellectual property rights or infringement of the intellectual property rights of others.

In addition, many other large and small companies within the pharmaceutical and biotechnology industry seek to establish collaborative arrangements for product research and development, or otherwise acquire products in late-stage clinical development, in competition with us. We face additional competition from public and private research organizations, academic institutions and governmental agencies in establishing collaborative arrangements for drug products in late-stage clinical development. Many of the companies and institutions that compete against us have substantially greater capital resources, research and development staffs and facilities than we have, and greater experience in conducting business development activities. These entities represent significant competition to us as we seek to expand our portfolio through the in-license or acquisition of compounds. Finally, while it is not feasible to predict the actual cost of acquiring and developing additional drug products, that cost could be substantial and we may need to raise additional financing for such purpose, which may further dilute existing stockholders.

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

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

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

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

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

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

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.

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 or man-made 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 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. For example, 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. On December 9, 2013, three parties collaborating with Innopharma were joined to Innopharma case: Mylan Teoranta, Mylan Institutional LLC; and Mylan Institutional, Inc. (collectively Mylan). While we believe our patent rights are strong, the ultimate outcome of these cases is uncertain, and if we do not prevail in the litigation, Sandoz Inc. and Innopharma Inc.,/Mylan, subject to fulfilling the applicable regulatory requirements, may be able to launch a generic version that would compete with FUSILEV, which could result in an immediate and substantial decrease in our revenues. In addition, our competitors may independently develop similar technologies. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

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

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

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

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

The patent positions related to our drug products are inherently uncertain and involve complex legal and factual issues. We believe that there is significant litigation in the pharmaceutical and biotechnology industry regarding patent and other intellectual property rights. A patent does not provide the patent holder with freedom to operate in a way that infringes the

patent rights of others. We may be accused of patent infringement at any time. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents in the U.S.

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

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.

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. A failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. 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 involving 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 payors and the medical community. The degree of market acceptance of any approved drug products will depend on a number of factors, including:

the effectiveness of the drug product;

the prevalence and severity of any side effects;

potential advantages or disadvantages over alternative treatments;

relative convenience and ease of administration;

the strength of marketing and distribution support;

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

sufficient third-party coverage and reimbursement.

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

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

Government agencies such as the Centers for Medicare & Medicaid Services promulgate regulations, and issue guidelines, directly applicable to us and to our products. In addition, third parties such as professional societies, practice management groups, insurance carriers, physicians, private health/science foundations and organizations involved in various diseases from time to time may publish guidelines or recommendations to healthcare providers, administrators and payors, and patient communities. Recommendations may relate to such matters as utilization, dosage, route of administration and use of related therapies and coverage and reimbursement of our products by government and private payors. 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 utilization and/or dosage of our products, any of which could adversely affect our product sales and operating results materially.

The sale of our products is subject to regulatory approvals, and our business is subject to extensive regulatory requirements, and if we are unable to obtain regulatory approval for our product candidates, or if we fail to comply with governmental regulations we will be limited in our ability to commercialize our products and product candidates and/or subject us to penalties.

We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. Obtaining regulatory approval of a new drug is an uncertain, lengthy and expensive process, and success is never guaranteed. Despite the time, resources and effort expended, failure can occur at any stage. In order to receive approval from the FDA for each product candidate, we must demonstrate that the new drug product is safe and effective for its intended use and that the manufacturing processes for the product candidate comply with the FDA s cGMPs. cGMPs include requirements related to production processes, quality control and assurance, and recordkeeping. The FDA has substantial discretion in the approval process for human medicines.

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. In addition, any regulatory approvals that we receive for our future product candidates may also be subject to limitations on the indicated uses for which they may be marketed or contain requirements for potentially costly post-marketing follow-up studies and surveillance to monitor the safety and efficacy of the product.

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. FDA and foreign regulatory authorities strictly regulate the promotional claims that may be made about prescription products and our product labeling, advertising and promotion is subject to continuing regulatory review. Physicians may nevertheless prescribe our product to their patients in a manner that is inconsistent with the approved label, or that is off-label. The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and if we are found to have improperly promoted off-label uses we may be subject to significant sanctions, civil and criminal fines and injunctions prohibiting us from engaging in specified promotional conduct. Moreover, our failure to comply with any applicable regulatory requirements could, among other things, result in:

warning letters;

fines;

changes in advertising;

revocation or suspension of regulatory approvals of products;

product recalls or seizures;

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

civil or criminal sanctions;

suspension or termination of ongoing clinical trials;

imposition of restrictions on our operations;

close the facilities of our contract manufacturers; and

refusals to approve new products.

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

The later discovery of previously unknown safety risks with our products may result in the imposition of restrictions on distribution or use of the drug product, including withdrawal from the market. The FDA may revisit and change its prior determinations with regard to the safety and efficacy of our products. If the FDA s position changes, we may be required to change our labeling or to cease manufacture and marketing of the products at issue. Even prior to any formal regulatory action, we could voluntarily decide to cease the distribution and sale or recall any of our products if concerns about their safety or effectiveness develop.

The FDA has significant authority to take regulatory actions in the event previously unknown safety risks are identified or if data suggest that our products may present a risk to safety. For example, the FDA may:

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, coverage 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 coverage and reimbursement from third-party payors such as government 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. Coverage and reimbursement by governmental and other third-party payors may depend upon a number of factors, including a governmental or other third-party payor s determination that use of a product is:

a covered benefit under its health plan;

safe, effective and medically necessary;

appropriate for the specific patient;

cost-effective; and

neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product from each third-party and governmental payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payor. We may not be able to provide data sufficient to obtain coverage and adequate 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 coverage and reimbursement that could impact our ability to sell our products profitably. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively referred to as the Healthcare Reform Law, was signed into law on March 30, 2010. The Healthcare Reform Law substantially changed the way healthcare is financed by both governmental and private insurers and significantly impacted the pharmaceutical industry. The Healthcare Reform Law included, among other things, an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, revisions to the definition of average manufacturer price for reporting purposes, increases in the amount of rebates owed by drug manufacturers under the Medicaid Drug Rebate Program, expansion of the 340B drug discount program that mandates discounts to certain hospitals, community centers and other qualifying providers, and changes to affect the Medicare Part D coverage gap, or donut hole. 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 Healthcare Reform Law. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products.

The high cost of pharmaceuticals continues to generate substantial government interest. It is possible that proposals will be adopted, or existing regulations that affect the coverage and reimbursement of pharmaceutical and other medical products may change, that may impact our products currently on the market and any of our products approved for marketing in the future. Cost control initiatives could decrease the price that we receive for any of our products or product candidates. In addition, third-party payors are increasingly challenging the price and cost-effectiveness of medical products and services. Significant uncertainty exists as to the coverage and reimbursement status of newly-approved pharmaceutical products. 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 coverage and reimbursement of our

products are 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 fraud and abuse laws, we may be subject to civil or criminal penalties, including exclusion from participation in government health care programs.

As a pharmaceutical company, even though we do not provide healthcare services or receive payments directly from or bill directly to Medicare, Medicaid or other third-party payors for our products, certain federal and state healthcare laws and regulations pertaining to fraud and abuse are and will be applicable to our business. We are subject to healthcare fraud and abuse by both the federal government and the states in which we conduct our business.

The laws that may affect our ability to operate include the federal health care program Anti-Kickback Statute, which 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 exceptions and regulatory safe harbors protecting certain common activities, the exceptions 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 exception 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 Drug Rebate Program.

The Health Insurance Portability and Accountability Act of 1996 also created prohibitions against health care fraud and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians. The Healthcare Reform Law imposed new requirements on manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children s Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by physicians (as defined above) and their immediate family members and payments or other transfers of value to such physician owners and their immediate family members. Manufacturers were required to begin data collection on August 1, 2013 and will be required to report such data to the government by March 31, 2014 and by the 90th calendar day of each year thereafter.

The majority of states also have statutes or regulations similar to these federal laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. In addition, some states have laws that require pharmaceutical companies to adopt comprehensive compliance programs. For example, under California law, pharmaceutical companies must comply with both the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and the PhRMA Code on Interactions with Healthcare Professionals, as amended. Certain states also mandate the tracking and reporting of gifts, compensation, and other remuneration paid by us to physicians and other health care providers. 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.

Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management s attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state laws may prove costly.

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 Law also make several important changes to the federal Anti-Kickback Statute, false claims laws, and health care fraud statute 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. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Health Care Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. In addition, the Healthcare Reform Law increases penalties for fraud and abuse violations. If our past, present or future operations are found to be in violation of any of the laws described above or other similar governmental regulations to which we are subject, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and negatively impact our financial results.

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

We may be held liable if any product we or our partners develop causes injury or is found otherwise unsuitable during product testing, manufacturing, clinical trials, marketing or sale. Regardless of merit or eventual outcome, product liability claims could result in decreased demand for our product candidates, injury to our reputation, withdrawal of patients from our clinical trials, substantial monetary awards to trial participants and the inability to commercialize any products that we may develop. These claims might be made directly by consumers, health care providers, pharmaceutical companies or others selling or testing our products. Although we currently carry product liability insurance in the amount of at least $15.0 million in the aggregate, it is possible that this coverage will be insufficient to protect us from future claims. Additionally, our insurance may not reimburse us or may not be sufficient to reimburse us for expenses or losses we may suffer. Moreover, if insurance coverage becomes more expensive, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. Failure to maintain sufficient insurance coverage could have a material adverse effect on our business, prospects and results of operations if claims are made that exceed our coverage.

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

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. We are subject to federal, state, local and foreign environmental laws and regulations governing, among other matters, the handling, storage, use and disposal of these materials and some waste products. We cannot completely eliminate the risk of contamination or injury from these materials and 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 such federal, state, local and foreign environmental regulations are not significant, and consist primarily of waste disposal expenses. However, they could become expensive, and current or future environmental laws or 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, 2013, there were 64,104,173 shares of our common stock outstanding. Security holders held outstanding options, warrants, preferred stock and convertible notes which, if vested, exercised or converted, would obligate us to issue up to approximately 11.9 million additional shares of common stock. A substantial number of those shares, when

we issue them upon vesting, conversion or exercise, will be available for immediate resale in the public market. In addition, we have reserved an aggregate of 16.2 million shares of our common stock for future issuance under our equity compensation plans. We may also 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. Certain issuances by us of equity securities may be at or below the prevailing market price of our common stock and may have a dilutive impact on our existing stockholders. These issuances or other dilutive issuances would also cause our net income, if any, per share to decrease in future periods. The market price of our common stock could fall as a result of sales of any of these shares of common stock due to the increased number of shares available for sale in the market.

The convertible note hedge and warrant transactions that we entered into in December 2013 may affect the value of our common stock.

In connection with the pricing of our convertible notes in December 2013, we entered into convertible note hedge transactions and separate warrant transactions with RBC Capital Markets, LLC, or RBC. The convertible note hedge transactions are expected generally to reduce the potential dilution upon any conversion of the notes and/or offset any cash payments we are required to make in excess of the principal amount of converted notes, as the case may be. The warrant transactions could separately have a dilutive effect to the extent that the market price per share of our common stock exceeds the strike price of the warrants. RBC and/or its affiliates may modify their hedge positions by entering into or unwinding various derivatives with respect to our common stock and/or purchasing or selling our common stock in secondary market transactions prior to the maturity of the convertible notes (and is likely to do so during any observation period related to a conversion of notes). This activity could cause or avoid an increase or a decrease in the market price of our common stock.

In addition, if the convertible note hedge and warrant transactions fail to become effective, through the failure of counterparties to perform or otherwise, RBC and/or its affiliates may unwind its hedge positions with respect to our common stock, which could adversely affect the value of our common stock. The potential effect, if any, of these transactions and activities on the market price of our common stock will depend in part on market conditions and cannot be ascertained at this time. Any of these activities could adversely affect the value of our common stock.

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;

hedging or arbitrage transactions by holders of our convertible notes;

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 2, 2013 through February 28, 2014, the closing price of our common stock ranged between $7.00 and $13.01, and the daily trading volume was as high as 22,555,500 shares and as low as 143,200 shares.

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

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

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

the ability of our board of directors to amend our bylaws without stockholder approval;

the inability of stockholders to call special meetings;

the ability of members of the board of directors to fill vacancies on the board of directors;

the inability of stockholders to act by written consent, unless such consent is unanimous; and

the establishment of advance notice requirements for nomination for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

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

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 as of December 31, 2013, which also existed as of December 31, 2012, and has not yet been adequately remediated. The continuation of this material weakness, or any others, could impact our ability to produce accurate and timely financial statements. As a result, our stock price could be adversely impacted and investors views of us could be harmed.

We have determined that we have a material weakness in our internal control over financial reporting which also existed as of December 31, 2012. 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, the market s confidence in our financial statements could decline and the market price of our common stock could be adversely impacted.

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 lease our principal executive office in Henderson, Nevada under a lease agreement expiring April 30, 2014. We are in process of negotiating an extension to this lease, while also evaluating alternative locations in Henderson for our corporate headquarters.

In addition, we lease our research and development and administrative facility in Irvine, California, and lease administrative space in Colorado, New Jersey, California, Japan, the Netherlands, and India.

We believe that these leased facilities, and our planned facility alternatives/additions, are adequate to meet our current and future business needs.

ITEM 3. LEGAL PROCEEDINGS

We are involved with various legal matters arising in the ordinary course of business. We make provisions for liabilities when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. Such provisions are reviewed at least quarterly and adjusted to reflect the impact of any settlement negotiations, judicial and administrative rulings, advice of legal counsel, and other information and events pertaining to a particular case. Litigation is inherently unpredictable. Although the ultimate resolution of these various matters cannot be determined at this time, we do not believe that such matters, individually or in the aggregate, will have a material adverse effect on our consolidated results of operations, cash flows or financial condition.

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 (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. On December 9, 2013, three Mylan entities collaborating with Innopharma were joined to Innopharma case. While we believe our patent rights are strong, the ultimate outcome of these cases is uncertain.

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, (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

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.

Shareholder Litigation

John Perry v. Spectrum Pharmaceuticals, Inc. et al. (Filed March 14, 2013 in United States District Court, District of Nevada; Case Number 2:2013-cv-00433-LDG-CWH); Junqian Carroll v. Spectrum Pharmaceuticals, Inc. et al. (Filed March 22, 2013 in United States District Court, District of Nevada; Case Number 2:2013-cv-00498-RBJ-CF); Gary Santi v. Spectrum Pharmaceuticals, Inc. et al. (Filed March 22, 2013 in United States District Court, District of Nevada; Case Number 2:2013-cv-00502-LDG-CWH); William Skene v. Spectrum Pharmaceuticals, Inc. et al. (Filed April 10, 2013 in United States District Court, District of Nevada; Case Number 3:2013-cv-00175-RBJ-VPC); and Rubin v. Spectrum Pharmaceuticals, Inc. et al. (Filed April 24, 2013 in the United States District Court, District of Nevada; Case Number 3:2013-cv-00212-RCJ-VPC). These putative class actions raise substantially identical claims and allegations against defendants Spectrum Pharmaceuticals, Inc., Dr. Rajesh C. Shrotriya, Brett L. Scott, and Joseph Kenneth Keller. The alleged class period is August 8, 2012 to March 12, 2013. The lawsuits allege a violation of Section 10(b) of the Securities Exchange Act of 1934 against all defendants and control person liability, as a violation of Section 20(b) of the Securities Exchange Act of 1934, against the individual defendants. The claims purportedly stem from the Company s March 12, 2013 press release, in which it announced that it anticipated a change in ordering patterns of FUSILEV. The complaints allege that, as a result of the March 12, 2013 press release, the Company s stock price declined. The complaints further allege that during the putative class period certain defendants made misleadingly optimistic statements about FUSILEV sales, which inflated the trading price of Company stock. The lawsuits seek relief in the form of monetary damages, costs and fees, and any other equitable or injunctive relief that the court deems appropriate. The court entered a consolidation order on April 29, 2013, designating the Perry action as the consolidated action.

Timothy Fik v. Rajesh C. Shrotriya, et al. (Filed April 11, 2013 in United States District Court, District of Nevada; Case Number 2:2013-cv-00624-JCM-CWH); Christopher J. Watkins v. Rajesh C. Shrotriya, et al. (Filed April 22, 2013 in United States District Court, District of Nevada; Case Number 2:2013-cv-00684-JCM-VCF); and Stefan Muenchhagen v. Rajesh C. Shrotriya, et al. (Filed May 28, 2013; Case Number 2:2013-cv-00942-APG-PAL). These derivative complaints are brought by the respective purported shareholders on behalf of nominal plaintiff Spectrum against defendants Krishan K. Arora, Gilles Gagnon, Anton Gueth, Joseph Kenneth Keller, Stuart M Krassner, Luigi Lenaz, Anthony E. Maida, Brett L. Scott, and Dr. Rajesh C. Shrotriya. The Fik and Watkins complaints allege six counts against all defendants: breach of fiduciary duty for disseminating false and misleading information; breach of fiduciary duty for failing to properly oversee and manage the company; unjust enrichment; abuse of control; gross mismanagement; and waste of corporate assets. The Fik and Watkins complaints also allege a seventh count for breach of fiduciary duties for insider selling and misappropriation of information against defendants Dr. Raj Shrotriya, Brett Scott, and Anthony Maida. The Muenchhagen complaint alleges five counts against all defendants: breach of fiduciary duty for disseminating false and misleading information; breach of fiduciary duty for failing to properly oversee and manage the company; abuse of control; gross mismanagement; and waste of corporate assets. The Muenchhagen complaint also alleges two counts against defendants Dr. Raj Shrotriya, Brett Scott, and Anthony Maida for unjust enrichment and for breach of fiduciary duties for insider selling and misappropriation of information. These substantially identical complaints allege that defendants knew or should have known that the Company s statements about future FUSILEV sales were misleadingly optimistic and that these statements inflated the trading price of Company stock. The complaints allege that, as a result of the March 12, 2013 press release, the Company s stock price declined. The complaints seek compensatory damages, corporate governance reforms, restitution and disgorgement of defendants alleged profits, and costs and fees. On May 15, 2013, the court entered a consolidation order staying the actions pending resolution of the federal securities class action.

Hardik Kakadia v. Rajesh C. Shrotriya, et al. (Filed April 23, 2013 in the Eighth Judicial District Court of the State of Nevada in and for Clark County; Case Number A-13-680643-B); and Joel Besner v. Rajesh C. Shrotriya, et al. (Filed May 31, 2013; Case Number A-13-682668-C) (collectively the State Derivative Actions). The State Derivative Actions are brought by the respective purported shareholders on behalf of nominal plaintiff Spectrum Pharmaceuticals, Inc. against defendants Krishan K. Arora, Gilles Gagnon, Anton Gueth, Joseph Kenneth Keller, Stuart M Krassner, Luigi Lenaz, Anthony E. Maida, Brett L. Scott and Dr. Rajesh C. Shrotriya. The Kakadia complaint alleges three counts against all defendants: breach of fiduciary duty; waste of corporate assets; and unjust enrichment. The Besner complaint alleges five counts against all defendants: breach of fiduciary duty for disseminating false and misleading information; breach of fiduciary duty for failing to properly oversee and manage the company; abuse of control; gross mismanagement; and waste of corporate assets. The Besner complaint also alleges two counts against defendants Dr. Raj Shrotriya, Brett Scott, and Anthony Maida for unjust enrichment and for breach of fiduciary duties for insider selling and misappropriation. The complaints similarly allege that defendants knew or should have known that the Company s statements about future FUSILEV sales were misleadingly optimistic and that these statements inflated the trading price of Company stock. The complaints allege that, as a result of the March 12, 2013 press release, the Company s stock price declined. The complaints seek compensatory damages, corporate governance reforms, restitution and disgorgement of defendants alleged profits, equitable and/or injunctive relief, and costs and fees. On July 10, 2013, the court entered a consolidation order staying the actions pending resolution of the federal securities class action.

Mark J. Sherwin v. Spectrum Pharmaceuticals, Inc. (Filed September 3, 2013 in the Court of Chancery of the State of Delaware; Case Number 8858). The complaint seeks inspection of Spectrum s books and records under Delaware Code section 220. Specifically, the complaint seeks inspection of books and records concerning whether Spectrum s officers and directors breached their fiduciary duties by causing the Company to make false statements concerning the performance of FUSILEV. The complaint also seeks fees and costs. On December 27, 2013, plaintiff filed a notice of dismissal of the books and records action. On January 7, 2014, the court granted plaintiff s dismissal of the action.

SEC Subpoena

On April 1, 2013, the Company received a subpoena from the SEC for documents pursuant to a formal order of investigation. The subpoena followed the Company s March 12, 2013 announcement that it anticipated a change in ordering patterns of FUSILEV. The Company is cooperating with the SEC investigation. The Company cannot predict when the SEC will conclude its investigation or the outcome of the investigation.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY 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 2013 and 2012 were as follows:

	High	Low
Year Ended December 31, 2013:		
First Quarter	$ 13.01	$ 7.01
Second Quarter	$ 8.55	$ 7.00
Third Quarter	$ 8.89	$ 7.29
Fourth Quarter	$ 9.82	$ 8.11
Year Ended December 31, 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

On February 28, 2014, the closing price of our common stock on the NASDAQ Global Select Market was $8.35 per share, and there were 325 holders of record of our common stock.

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, 2008, the last trading day before our 2009 fiscal year, through the end of fiscal 2013 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 PLC

Amarin Corporation PLC

BioMarin Pharmaceutical, Inc.

Celgene Corporation

Dendreon Corporation

Jazz Pharmaceuticals PLC

Regeneron Pharmaceuticals, Inc.

Vertex Pharmaceuticals, Inc.

	12/31/08	12/31/09	12/31/10	12/31/11	12/31/12	12/31/13
Spectrum Pharmaceuticals, Inc.	100.00	297.99	461.07	981.88	760.69	601.83
Russell 2000	100.00	127.17	161.32	154.59	179.86	249.69
Peer Group	100.00	113.83	123.34	132.04	181.13	341.09

(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.

Dividend Policy

We currently intend to retain all earnings, if any, for use in the expansion of our business and therefore do not anticipate paying any dividends in the foreseeable future. However, the payment of dividends, if any will be at the discretion of the Board of Directors and subject to compliance with any applicable restrictions contained in our agreements.

ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data has been derived from our audited Consolidated Financial Statements. The audited Consolidated Financial Statements for the fiscal years ended December 31, 2013, 2012, and 2011 are included elsewhere in this Annual Report on Form 10-K. The information set forth below should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations in *Item 7* and the Consolidated Financial Statements and Notes thereto in *Item 8*. The information set forth below is not necessarily indicative of our future financial condition or results of operations.

	Year ended December 31,				
Selected Statement of Operations Data:	**2013**	**2012**	**2011**	**2010**	**2009**
	(In thousands, except per share data)				
Total revenues	$ 155,854	$ 267,707	$ 192,963	$ 74,113	$ 38,025
Operating costs and expenses:					
Cost of product sales (excludes amortization of intangible assets)	28,580	46,633	33,838	17,439	8,148
Selling, general and administrative	99,315	89,922	72,197	47,411	33,607
Research and development	46,670	41,560	26,662	56,660	20,379
Amortization and impairment of intangible assets	20,074	8,818	3,720	3,720	3,720
Income (loss) from operations	(38,785)	80,774	56,546	(51,117)	(27,829)
Change in fair value of common stock warrant liability			(3,488)	2,731	8,075
Change in fair value of contingent consideration related to acquisition	2,871				
Other (expense) income, net	(722)	(844)	577	1,279	662
(Loss) income before provision for income taxes	(36,636)	79,930	53,635	(47,107)	(19,092)
(Provision) benefit for income taxes	(25,498)	14,271	(3,704)	43	(421)
Net income attributable to non-controlling interest					1,146
Net (loss) income attributable to Spectrum Pharmaceuticals, Inc. stockholders	$ (62,134)	$ 94,201	$ 49,931	$ (47,064)	$ (18,367)
Net (loss) income per share basic	$ (1.02)	$ 1.61	$ 0.94	$ (0.95)	$ (0.47)
Net (loss) income per share diluted	$ (1.02)	$ 1.46	$ 0.86	$ (0.95)	$ (0.47)
Cash dividend declared per common share	$	$ 0.15	$	$	$

Selected Balance Sheet Data:	As of December 31, 2013	2012	2011	2010	2009
			(In thousands)		
Working capital (current assets *minus* total current liabilities)	$ 145,206	$ 141,630	$ 151,443	$ 61,308	$ 87,743
Total assets	$ 499,155	$ 504,955	$ 280,780	$ 163,631	$ 173,133
Long term obligations, less current portion	$ 127,565	$ 93,031	$ 14,336	$ 25,833	$ 25,310
Total stockholders equity (including non-controlling interest in 2009)	$ 281,606	$ 288,681	$ 192,086	$ 77,241	$ 109,309

ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with Selected Financial Data and our consolidated financial statements and the related notes included in this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of various factors including the risks we discuss in *Item 1A* of Part I, Risk Factors and elsewhere in this Annual Report on Form 10-K.

OVERVIEW

Our Business

We are a biotechnology company with fully integrated commercial and drug development operations, with a primary focus in oncology and hematology. Our strategy is comprised of acquiring, developing, and marketing a diverse pipeline of late-stage clinical and commercial products. We currently market four drugs:

FUSILEV injection for patients in the U.S. with advanced metastatic colorectal cancer and to counteract certain effects of methotrexate therapy;

ZEVALIN injection for patients in the U.S. and various international markets with follicular non-Hodgkin s lymphoma;

FOLOTYN injection for patients in the U.S. with relapsed or refractory peripheral T-cell lymphoma; and

MARQIBO injection for patients in the U.S. with Philadelphia chromosome negative acute lymphoblastic leukemia.

We also have a diversified pipeline of product candidates in advanced-stage Phase 2 and Phase 3 studies. 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 business strategies.

Our business strategy is comprised of the following three initiatives:

Maximizing the revenue potential of our four currently-marketed drugs for the treatment of cancer.

Our near-term outlook largely depends on sales and marketing successes for our four marketed drugs. It is this base business, along with potential additional indications for these drugs, that provides the working capital needed to operate our daily business and provides the necessary capital for opportunistic acquisitions.

Developing and Commercializing the drugs for the treatment of cancer within our pipeline.

Our strategy for our development portfolio is to focus on late-stage development drugs. We strive to complete clinical studies to demonstrate the safety and efficacy of these drugs in order to obtain regulatory approval in a timely manner. Upon obtaining approval, our sales and marketing function educates physicians on the safety of the drug and its effectiveness in treating patients for the approved indication, with the goal of achieving maximum commercial success.

Expanding our pipeline of development-stage and commercial-stage 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 to identify and pursue partnerships for out-licensing certain of our drugs in development. We will continue to (i) explore strategic collaborations as they relate to drugs that are either in clinical trials or are currently on the market, and (ii) identify and secure drugs that have significant growth potential through enhanced marketing and sales efforts and/or through pursuit of additional clinical development.

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See *Item 1*, Business, for a discussion of:

Company Overview

Cancer Background & Market Size

Product Portfolio

Manufacturing

Sales and Marketing

Customers

Competition

Research and Development

2013 Overview

During 2013 we accomplished various critical objectives for our business, which included:

Acquisitions: We completed two strategic acquisitions, including a FDA-approved, patented, proprietary, oncology drug, MARQIBO through the acquisition of a NASDAQ-listed company, Talon Therapeutics, Inc. and we licensed-in a late-stage oncology drug, Captisol-enabled MELPHALAN, from Ligand Pharmaceuticals, Inc.

Commercial: We executed the launch of MARQIBO in less than seven weeks after acquisition, and we continued to focus on the growth of our marketed drugs.

Medical: We filed the NDA for BELEODAQ, for which the FDA has granted a Priority Review and has established an action date of August 9, 2014. We also completed the enrollment in the pivotal study for Captisol-enabled MELPHALAN and initiated a Phase 2 study for SPI-2012.

Corporate: We strengthened our management team with the additions of our new Chief Financial Officer and new Chief Medical Officer. We also continued to invest in our infrastructure for long-term growth and success.

Financial: We maintained fiscal discipline during the year, and ended 2013 with nearly $160 million in aggregate cash and equivalents and marketable securities.

CHARACTERISTICS OF OUR REVENUE AND EXPENSES

The below summarizes the nature of our revenue and operating expense line items within our Consolidated Statements of Operations:

Revenue

The majority of our revenue is derived from sales of our drug products to large pharmaceutical wholesalers and distributors upon title transfer (which is typically at time of shipment), provided our other revenue recognition criteria have been met. To a lesser extent we also derive revenue from license fees (i.e., royalties) and service revenue for our research and development activities conducted for the benefit of third parties.

Cost of Goods Sold

Cost of goods sold includes production materials and supplies expense, third party manufacturing and packaging service expenses, and royalty expenses.

Selling, General and Administrative

Selling, general and administrative expenses primarily consist of compensation (including stock-based compensation) and benefits for our sales force and personnel that support our sales and marketing operations, and our general operations such as information technology, executive management, financial accounting, and human resources. It also includes costs attributable to marketing our products to our customers and prospective customers, patent and legal fees, financial audit fees, insurance, bad debt expense, recruiting fees, and other professional services.

Research and Development

Research and development expenses consist of compensation (including stock-based compensation) and benefits for research and development and clinical and regulatory personnel, materials and supplies, research and development consultants, and regulatory and clinical payments related to studies. Our research and development activities primarily relate to the development and testing of new drugs, and conducting studies in order to gain regulatory approval for the commercialization of our drug products.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The preparation and presentation of financial statements in conformity with generally accepted accounting principles in the United States of America (GAAP) requires management to establish policies and make estimates and assumptions that affect (i) the amounts of assets and liabilities as of the date presented on the accompanying Consolidated Balance Sheets and (ii) the amounts of revenue and expenses for each year presented in the accompanying Consolidated Statements of Operations.

Our management believes its estimates and assumptions are supportable, reasonable, and consistently applied. Nonetheless, estimates are by nature inherently uncertain. As a result, our financial position and operating results could materially differ from the amounts reported within the accompanying Consolidated Financial Statements if management s estimates require prospective adjustment. Our critical accounting policies and estimates arise in conjunction with the following accounts:

Revenue recognition

Inventories lower of cost or market

Fair value of acquired assets and assumed liabilities

Goodwill and intangible assets impairment evaluations

Income taxes

Stock-based compensation

Litigation accruals

Revenue Recognition

Product Sales: We recognize revenue from product sales when all of the following criteria are met:

(*i*) Appropriate evidence of a binding arrangement exists with our customer;

(*ii*) Price is substantially fixed and determinable;

(*iii*) Collection from our customer is reasonably assured;

(*iv*) Our customer s obligation to pay us is not contingent on resale of the product;

(*v*) We do not have significant obligations for future performance to directly bring about the resale of our product; and

(*vi*) We have a reasonable basis to estimate future returns.

Our product sales are reduced by our gross-to-net (GTN) estimates, resulting in our reported Product sales, net in the accompanying Consolidated Statements of Operations. We defer revenue recognition in full if/when these estimates are not reasonably determinable at the time of sale.

Our GTN estimates reduce revenue in the same period that the related sale is recorded and include the following major categories:

(i) Product Returns Allowances

(ii) Government Chargebacks

(iii) Discounts

(iv) Rebates

(v) Medicaid Rebates

(vi) Distribution and Data Fees

Product Returns Allowances: Our FUSILEV customers are typically permitted to return products within six months after its expiration date, subject to certain restocking fees and preauthorization requirements. We estimate potential returns, based on several factors, including historical rates of return, customer and end-user ordering patterns, inventory held by distributors, and sell through data of distributor sales to end users. In general, returned product is not resold.

Government Chargebacks: Our products are subject to certain pricing limits under federal government programs. Qualifying entities purchase products through our distributors at the discounted price. Our distributors charge the difference between the list price and discounted price back to us, for which there may be significant lag time. Due to estimates and assumptions inherent in determining the amount and extent of government chargebacks we will incur, which take in account our estimates of which sales will be subject to government chargebacks and the amount of such chargebacks, the actual amount of government chargeback claims may be materially different from our estimates.

Discounts: Discounts (generally prompt payment discounts) are estimated at each reporting period. We review the terms of the contracts, specifically price and discount structures, and applicable payment terms to estimate its value.

Rebates: Rebates are estimated based on the customer s actual purchase level during the rebate purchase period, and the corresponding contractual rebate tier we expect the customer to achieve.

Medicaid Rebates: Our products are subject to state government-managed Medicaid programs whereby discounts and rebates are provided to participating state governments. 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 forecasting techniques, 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. Due to estimates and assumptions inherent in determining the amount of our product sales subject to Medicaid rebates, and the time lag to receive these rebate notices (generally several months after the sale is made), the actual amount of these claims may be materially different from our estimates. As a result, adjustments may be recorded over several periods after the initial sale is recorded.

Distribution and Data Fees: Distribution and data fees are paid to authorized wholesalers and specialty distributors of FUSILEV and FOLOTYN as a percentage of products sold. The services provided include contract administration, inventory management, product sales reporting by customer, returns processing. We estimate these fees based on a percentage of FUSILEV and FOLOTYN revenues that are governed by distribution agreements.

***License Fees*:** We recognize license fees (i.e., royalties) based on the terms of each contractual agreement. In general, this results in periodic revenue recognition as the third-party licensee has sales for which we are entitled to a royalty, or in certain cases, a lump-sum fee in which revenue is recognized in that period.

***Service Revenue*:** We receive fees under certain arrangements for our research and development services. These services are generally undertaken in connection with a collaboration agreement with another pharmaceutical company. Payment may be triggered by the successful completion of a phase of development, results from a clinical trial, acceptance of an NDA or an equivalent filing, and/or regulatory approval. We recognize revenue when the corresponding milestone is achieved, or the revenue is otherwise earned through our on-going activities.

Inventories Lower of Cost or Market

We adjust our inventory value for estimated amounts of excess, obsolete, or unmarketable items. Such assumptions involve projections of future customer demand, as driven by economic and market conditions, and the product s shelf life. If actual demand, or economic or market conditions are less favorable than those projected by us, incremental inventory write-downs may be required.

Fair Value of Acquired Assets and Assumed Liabilities

The accounting for business combination and asset 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 the acquisition meets the criteria for business combination accounting (rather than an asset acquisition), 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, are based on their estimated fair values at the acquisition date and requires extensive use of accounting estimates, judgments, and assumptions, including but not limited to: likelihood, timing, and costs to complete the in-process projects, probability of achieving regulatory approvals, cash flows to be derived from the acquired assets, and the application of appropriate discount rates. For each acquisition, we engage an independent third-party valuation specialist to assist management in determining the fair value of in-process research and development, identifiable intangible assets, and any contingent consideration.

In connection with certain of our acquisitions, we must record a contingent consideration liability for cash or stock payments upon the completion of certain future performance milestones. In these cases, a liability is recorded on the acquisition date for an estimate of the acquisition date fair value of the contingent consideration by applying the income approach utilizing variable inputs such as probability of achievement and risk-free adjusted discount rates. Any change in the fair value of the contingent consideration subsequent to the acquisition date is recognized in earnings.

Goodwill and Intangible Assets Impairment Evaluations

Goodwill and other intangible assets with indefinite lives are not subject to amortization, but are evaluated for impairment annually as of October 1, or whenever events or changes in circumstance indicate that the asset might be impaired. We evaluate the possible impairment (i) if/when events or changes in circumstances occur that indicate that the carrying value of assets may not be recoverable; or (ii) in the case of goodwill and indefinite lived intangible assets, our annual impairment assessment date of October 1. These evaluations require significant judgment by our management in forecasting net cash flows to be derived by these intangible assets in our on-going operations. The discounted value of such cash flows (or our market capitalization in the case of goodwill) are compared to each asset s carrying value to assess whether there is an indication of impairment and related charges to record.

Income Taxes

Our consolidated balance sheets reflect net deferred tax assets (net of a valuation allowance) that primarily represent the tax benefit of net operating loss and tax credit carryforwards, and credits and timing differences between book and tax. When it is more likely than not that all or some portion of deferred tax assets may not be realized, we establish a valuation allowance for the amount that may not be realized. Each quarter, we evaluate the need to retain all or a portion of the valuation allowance on our net deferred tax assets. Our evaluation considers historical earnings, estimated future taxable income and ongoing prudent and feasible tax planning strategies. Adjustments to the valuation allowance increase or decrease net income or loss in the period such adjustments are made. If our estimates require adjustments, it could have a significant impact on our consolidated financial statements.

Stock-Based Compensation

We recognize stock-based compensation expense for employees and directors over the equity award vesting period, based on its fair value at the date of grant. The fair value of equity awards that are expected to vest is amortized on a straight-line basis over the requisite service period. Stock-based compensation expense recognized is net of an estimated forfeiture rate, which is updated as appropriate.

We use the Black-Scholes option pricing model to determine the fair value of stock option grants with service conditions for vesting and the Monte Carlo valuation model to value certain equity awards with market conditions and service conditions for vesting. These models require the use of highly subjective assumptions, including the probability of the achievement of certain market capitalization levels.

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Litigation Accruals

From time-to-time we are involved in various claims and legal proceedings of a nature considered normal and incidental to our business. These matters may include product liability, intellectual property, employment, and other general claims. We accrue for contingent liabilities when it is probably that a liability has been incurred and the amount can be reasonably estimated. The accruals are adjusted periodically as assessments change or as additional information becomes available.

RESULTS OF OPERATIONS

Operations Overview 2013, 2012, and 2011

	Year Ended December 31,					
	2013		2012		2011	
	($ in thousands)					
Total revenues	$ 155,854	100.0%	$ 267,707	100.0%	$ 192,963	100.0%
Operating costs and expenses:						
Cost of product sales (excludes amortization of intangible assets)	28,580	18.3%	46,633	17.4%	33,838	17.5%
Selling, general and administrative	99,315	63.7%	89,922	33.6%	72,197	37.4%
Research and development	46,670	29.9%	41,560	15.5%	26,662	13.8%
Amortization and impairment of intangible assets	20,074	12.9%	8,818	3.3%	3,720	1.9%
Total operating costs and expenses	194,639	124.9%	186,933	69.8%	136,417	70.7%
(Loss) income from operations	(38,785)	(24.9)%	80,774	30.2%	56,546	29.3%
Change in fair value of common stock warrant liability					(3,488)	(1.8%)
Change in fair value of contingent consideration from acquisition	2,871	1.8%				
Other (expense) income, net	(722)	(0.5)%	(844)	(0.3)%	577	0.3%
(Loss) income before income tax	(36,636)	(23.5)%	79,930	29.9%	53,655	27.8%
Income tax (expense) benefit	(25,498)	(16.4)%	14,271	5.3%	(3,704)	(1.9)%
Net (loss) income	$ (62,134)	(39.9)%	$ 94,201	35.2%	$ 49,931	25.9%

YEAR ENDED DECEMBER 31, 2013 VERSUS DECEMBER 31, 2012

Total Revenues

	Year Ended December 31,		$ Change	% Change
	2013	2012		
	($ in millions)			
Product sales, net:				
FUSILEV	$ 68.4	$ 204.3	$ (135.9)	(66.5)%
FOLOTYN	44.4	20.4	24.0	>100.0%
ZEVALIN	29.4	30.3	(0.9)	(3.0)%
MARQIBO	1.3		1.3	>100.0%
	$ 143.5	$ 255.0	$ (111.5)	(43.7)%
License fees and service revenue	12.4	12.7	(0.3)	(2.4)%

Total revenues	$ 155.9	$ 267.7	$ (111.8)	(41.8)%

Product sales, net: 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 within Critical Accounting Policies and Estimates above.

FUSILEV revenue decrease is primarily due to a change in buying patterns of wholesalers, a lower average net sales price, and a decrease in underlying demand by end-users, as the shortage in generic leucovorin abated in late 2012. In addition, government rebates as a percentage of gross sales increased by 17% as compared to the same period in 2012, driven primarily by a change in customer mix, and to a lesser extent, a refinement to our methodology to estimate rebate claims remaining in channel inventory. This revenue decrease was partially offset by a refinement in our estimate of future products returns. As compared to 2012, this refinement reduced our percentage of 2013 sales that we expect will be subject to reversal for future product returns.

FOLOTYN revenue increase is due to a full year of recognition of product sales in 2013, as compared to the prior year. We acquired this drug through our acquisition of Allos in September 2012.

ZEVALIN revenue decreased slightly in 2013. The slight decrease is attributable to less U.S. product demand and a minor decrease in our average net sales price per unit, which was not fully offset by an increase in European product demand. Beginning in the second quarter of 2013, we terminated our ZEVALIN services agreement with Bayer, and transitioned to a sales distribution model in Europe. This transition has had a favorable impact on 2013 unit sales in Europe.

MARQIBO revenue derived in 2013 is a result of our acquisition of Talon in July 2013.

License fees and service revenue: In 2013 and 2012, we recognized $12.4 million and $12.7 million, respectively, from the amortization of deferred revenue that corresponded with our contracted research and development services. This revenue is associated with a $41.5 million upfront payment we received from Allergan in 2008, and an aggregate of $16.0 million in upfront payments we received from Nippon Kayaku and Handok in 2010. As of December 31, 2013, these upfront payments have been recognized through license fees and service revenue in full.

Operating Expenses

	Year Ended December 31,			
	2013	2012	$ Change	% Change
	($ in millions)			
Operating expenses:				
Cost of product sales (excludes amortization of intangibles)	$ 28.6	$ 46.6	$ (18.0)	(38.6%)
Selling, general and administrative	99.3	89.9	9.4	10.5%
Research and development	46.6	41.6	5.0	12.0%
Amortization and impairment of intangible assets	20.1	8.8	11.3	> 100.0%
Total operating costs and expenses	$ 194.6	$ 186.9	$ 7.7	4.1%
Other (expense) income, net	$ 2.1	$ (0.8)	$ 2.9	> 100.0%

Cost of Product Sales. The decrease in the cost of product sales is primarily driven by an overall 44% decrease in product sales. Gross margins in 2013 and 2012 remained largely consistent.

Selling, General and Administrative. Selling, general and administrative expenses increased due to:

$1.3 million increase in professional fees which include legal costs for patent and trademark matters, audit fees, and tax consulting services.

$3.0 million increase in legal and professional fees related to our Talon acquisition.

$3.1 million increase in marketing expenses and commercial costs related to our sales outside the U.S.

$2.7 million increase in employee severance costs related to the Talon acquisition.

$5.7 million increase in legal and professional fees related to ongoing shareholder and patent litigation.

$1.0 million increase in consulting, compensation and associated benefits, which is mainly attributable to the addition of senior management positions, and the inclusion of personnel in Japan and Netherlands, and also includes a $0.5 million increase in recruitment fees.

$0.8 million increase in other expenses consisting of computer software and services, as well as rent and utilities for new facilities in Japan, Colorado, and the Netherlands.

These increases were partially offset by 2012 expenses that did not recur in 2013, including:

$5.5 million in legal and professional fees related to our 2012 acquisitions of Allos and rights to market ZEVALIN outside of the U.S.

$1.9 million for Allos employee severance costs.

Research and Development. Research and development expenses increased due to:

$0.9 million increase in continuing medical education grants.

$1.3 million increase in consulting, compensation and associated benefits.

$7.1 million increase in expenses incurred following the amendment of our agreement with Allergan in the first quarter of 2013. This resulted in a decrease in the reimbursement of expenses compared to 2012.

These increases were partially offset by:

$2.4 million decrease in 2013 of our drug development liability as a result of our amendment to the Mundipharma agreement, which had the corresponding effect of reducing 2013 research and development expenses.

$0.6 million reduction in licensing, quality, and regulatory fees.

$0.6 million reduction in depreciation.

Amortization and Impairment of Intangible Assets. The amortization and impairment of intangible assets increased $11.3 million in 2013, of which $1.0 million is due to the impairment of our FOLOTYN distribution rights as a result of our Mundipharma contract amendment in May 2013. The remaining amount is due to the amortization of definite-lived intangible assets from our acquisitions of ZEVALIN Rights, Allos, and Talon.

Other Income (Expense), net. Other income (expense), net increased by $2.9 million and was primarily due to the $2.9 million decrease to our acquisition-related contingent obligations liability, which resulted in an equal credit to our change in fair value of contingent consideration related to acquisition. This change in value corresponds to our acquisition of Talon and rights to C-E MELPHALAN. This amount is partially offset by an increase in interest expense from our convertible senior notes issued in December 2013.

	Year Ended December 31,			
	2013	2012	$ Change	% Change
	($ in millions)			
Benefit (provision) for income taxes	$ (25.5)	$ 14.3	$ (39.8)	>(100.0%)

Benefit (Provision) for Income Taxes. In 2013 we recognized an income tax provision of $25.5 million. This provision was due to the recording of a full valuation allowance against our deferred tax assets. As of December 31, 2013, we determined that there are uncertainties regarding the realization of our deferred tax assets (which were primarily generated by our cumulative net operating losses and from the tax attributes of acquired entities) due to multiple quarterly consecutive net losses.

In 2012, we recorded a $14.3 million tax benefit. The tax benefit in 2012 was the result of a change in judgment in the first quarter of 2012 regarding the realizability of our deferred tax assets due to positive earnings trends and operating income realized in 2011 and 2012. These positive factors resulted in a $44.5 million tax benefit from the release of our valuation allowance on deferred tax assets.

YEAR ENDED DECEMBER 31, 2012 VERSUS DECEMBER 31, 2011

Revenue

	Year Ended December 31, 2012	2011	$ Change	% Change
	($ in millions)			
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 fees and service revenue	12.7	12.3	0.4	3.3%
Total revenues	$ 267.7	$ 193.0	$ 74.7	38.7%

Product sales, net:

FUSILEV revenues 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.

FOLOTYN revenues increased due to acquiring the drug through the acquisition of Allos on September 5, 2012.

ZEVALIN revenues increased between the 2012 and 2011 periods due to an increase in product demand.

License fees and service revenue: During 2012 and 2011, we recognized $12.7 million and 12.3 million, respectively, of service revenue from the amortization of a $41.5 million upfront payment we received from Allergan in 2008, and a $16.0 million upfront payment we received from Nippon Kayaku and Handok in the first quarter of 2010.

Operating Expenses

Our operating expenses are summarized in the following table:

	Year Ended December 31, 2012	2011	$ Change	% Change
	($ in millions)			
Operating 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%)

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.

$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 $0.7 million 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 force travel and expenses.

These increases were partially offset by a $7.6 million decrease in stock compensation expense.

Research and Development. Research and development expenses increased 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.

Amortization and Impairment of Intangible Assets. 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 as part of 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 outstanding warrants to non-employees during 2011, which were not outstanding in 2012.

Other Income (Expense), net. The principal components of other income (expense) consisted primarily of a $0.7 million increase in interest expense in connection with the revolving line of credit, an increase of $0.1 million for the sale of property and equipment due to the downsizing of the Allos facilities, and a decrease of $0.1 million of interest income due to the sale of marketable securities at the end of the second quarter of 2012.

	Year Ended December 31,			
	2012	2011	$ Change	% Change
	($ in millions)			
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 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.

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.

LIQUIDITY AND CAPITAL RESOURCES

	December 31,	
	2013	2012
	(in thousands, except financial metrics data)	
Cash and cash equivalents	$ 156,306	$ 139,698
Marketable securities	$ 3,471	$ 3,310
Accounts receivable, net	$ 49,483	$ 92,169
Total current assets	$ 235,190	$ 264,873
Total current liabilities	$ 89,984	$ 123,243
Working capital surplus (a)	$ 145,206	$ 141,630
Days sales outstanding (DSO) (b)	110	121
Current ratio (c)	2.6	2.1

(a) Total current assets at period end *minus* total current liabilities at period end.
(b) Net accounts receivable at period end *divided by* revenue, net for the fourth quarter *multiplie*d by 92 days.
(c) Total current assets at period end *divided by* total current liabilities at period end.

Net Cash (Used In) Provided By Operating Activities

Cash used in operating activities was $2.1 million for 2013, as compared to cash provided by operating activities of $72.0 million in the prior year. The decrease in cash provided by operating activities during the current year, as compared to the prior year is primarily a function of the working capital drivers of (i) decreased revenue and related collections and (ii) increased payments to our vendors to reduce trade payables between these periods.

For the years ended December 31, 2013 and 2012, our cash collections from customers totaled $239.7 million and $301.9 million, respectively, representing 154% and 113% of reported net revenue for the same years.

For the years ended December 31, 2013 and 2012, cash payments to our employees and vendors for products, services, and rebates totaled $249.7 million and $231.3 million, respectively.

Net Cash (Used In) Investing Activities

Net cash used in investing activities of $14.3 million in 2013 was due to (i) our acquisition of Talon for $11.2 million (see *Note 10(a)* to the accompanying Consolidated Financial Statements), (ii) our $3.0 million purchase of C-E MELPHALAN rights (see *Note 10(b)*), and (iii) $0.2 million in purchases of property and equipment.

Net Cash Provided By Financing Activities

Net cash provided by financing activities of $35.3 million in 2013 is due to (i) $115.4 million in net proceeds from our 2018 Convertible Notes (see below) issuance in December 2013, (ii) proceeds of $7.0 million from Mundipharma towards our continued development of FOLOTYN (see *Note 13*), and (iii) $3.6 million in proceeds from the exercise of employee stock options.

These cash proceeds are partially offset by (i) $75.0 million net repayment of our terminated credit facility, (ii) $13.1 million of net costs for derivative instrument purchases to hedge the conversion feature of our 2018 Convertible Notes, and (iii) $1.7 million purchase of treasury stock, which was subsequently retired.

Convertible Senior Notes Due 2018

On December 17, 2013, we entered into an agreement for the sale of $120.0 million aggregate principal amount of 2.75% Convertible Senior Notes due December 2018 (the 2018 Convertible Notes). The 2018 Convertible Notes are convertible into shares of our common stock at a conversion rate of 95 shares per $1,000 principal amount of the 2018 Convertible Notes, totaling 11.4 million common shares if fully converted. The in-the-money conversion price is equivalent to $10.53 per common share. The conversion rate and conversion price are subject to adjustment under certain limited circumstances. Initially, we may only settle conversions of the 2018 Convertible Notes by delivering shares of our common stock. However, if we obtain stockholder approval in accordance with applicable NASDAQ rules (which is expected at our Annual Meeting of Shareholders in June 2014), we may then settle conversions of the 2018 Convertible Notes by paying or delivering, as the case may be, cash, shares of our common stock, or a combination of cash and shares, at our election.

The 2018 Convertible Notes bear interest at a rate of 2.75% per year, payable semiannually in arrears on June 15 and December 15 of each year, beginning on June 15, 2014. The 2018 Convertible Notes will mature and become payable on December 15, 2018, subject to earlier conversion into common stock at the holders option.

Our December 23, 2013 net proceeds were $115.4 million from the sale of the 2018 Convertible Notes, after deducting banker and professional fees of $4.6 million. We used a portion of these proceeds to simultaneously enter into bought call and sold warrant transactions with Royal Bank of Canada (collectively, the Note Hedge). We recorded the Note Hedge on a net cost basis of $13.1 million, as a reduction to additional paid-in capital in our accompanying Consolidated Balance Sheets. Under applicable GAAP, the Note Hedge transaction is not expected to be marked-to-market through earnings or comprehensive income in future reporting periods.

Retired Credit Facility

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, as amended July 16, 2013 (the Credit Agreement). The Credit Agreement provided us with a committed $50.0 million revolving line of credit facility (the Credit Facility). The Credit Facility was to expire on September 5, 2014, but was repaid in full and cancelled by us on December 20, 2013.

The Credit Facility bore interest, at our election, at a rate equal to the London Interbank Offer Rate (LIBOR), plus an applicable margin (2.75% to 4.25%, dependent on a defined liquidity ratio).

Future Capital Requirements

We believe that the future growth of our business will depend on our ability to successfully develop and acquire new drugs for the treatment of cancer and successfully bring these drugs to market.

The timing and amount of our future capital requirements will depend on many factors, including:

- the need for additional capital to fund future development programs;
- the need for additional capital to fund strategic acquisitions;
- the need for additional capital to fund licensing arrangements;
- our requirement for additional information technology infrastructure and systems; and
- adverse outcomes from potential litigation and the cost to defend such litigation.

We believe that our $159.8 million in aggregate cash and equivalents, and marketable securities as of December 31, 2013, will allow us to fund our current and 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.

Contractual Obligations

The following table summarizes our contractual and other commitments, including obligations under facility and equipment leases, as of December 31, 2013:

	Total	Less than 1 Year	2-3 Years	4-5 Years	After 5 Years
			(in thousands)		
Operating lease obligations (1)	$ 4,693	$ 849	$ 1,842	$ 1,711	$ 291
Purchase obligations (2)	42,925	37,404	4,295	1,226	
Contingent milestone obligations (3)	428,438	35,630	21,295	25,729	345,784
Drug development liability (4)	17,742	3,119	2,413	2,267	9,943

Debt obligations (5)	136,666	3,273	6,701	126,692	
Total	$ 630,464	$ 80,275	$ 36,546	$ 157,625	$ 356,018

(1) The operating lease obligations are primarily related to the facility lease for our corporate headquarters in Henderson, Nevada, expiring April 30, 2014; and our research and development and administrative facility in Irvine, California, expiring May 31, 2019.

(2) 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, 2013.

(3) Milestone obligations are payable contingent upon successfully reaching certain development and regulatory milestones (see *Note 14* to the accompanying Consolidated Financial Statements). 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.

(4) Research and development services under the Mundipharma Collaboration Agreement (see *Note 13* to the accompanying Consolidated Financial Statements) over the period required to complete the jointly agreed-upon clinical development activities.

(5) Debt obligations represent amount due under our 2018 Convertible Notes issued in December 2013, inclusive of interest payments over its full term (see *Note 12* to the accompanying Consolidated Financial Statements).

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements (except for operating leases) that provide financing, liquidity, market or credit risk support, or involve derivatives. In addition, we have no arrangements that may expose us to liability that are not expressly reflected in the accompanying Consolidated Financial Statements.

As of December 31, 2013, we did not have any relationships with unconsolidated entities or financial partnerships, often referred to as structured finance or special purpose entities, established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As such, we are not subject to any material financing, liquidity, market or credit risk that could arise if we had engaged in such relationships.

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. 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, 2013, any decline in the fair value of our investments would not be material in the context of our accompanying 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.

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.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Spectrum Pharmaceuticals, Inc.

By: /s/ Rajesh C. Shrotriya, M.D.
Rajesh C. Shrotriya, M.D.

Chief Executive Officer and President

Date: March 12, 2014

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, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each attorney-in-fact, or his substitute, may do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ Rajesh C. Shrotriya, M.D.	Chairman of the Board, Chief Executive	March 12, 2014
Rajesh C. Shrotriya, M.D.	Officer, and President	
	(Principal Executive Officer)	
/s/ Kurt A. Gustafson	Executive Vice President and Chief	March 12, 2014
Kurt A. Gustafson	Financial Officer	
	(Principal Financial and Accounting Officer)	
/s/ Dolotrai M. Vyas, Ph.D.	Director	March 12, 2014
Dolatrai M. Vyas, Ph.D.		
/s/ Luigi Lenaz, M.D.	Director	March 12, 2014
Luigi Lenaz, M.D.		
/s/ Stuart M. Krassner, Sc.D., Psy.D.	Director	March 12, 2014
Stuart M. Krassner, Sc.D., Psy.D.		
/s/ Anthony E. Maida, Iii, M.A., M.B.A., Ph.D.	Director	March 12, 2014
Anthony E. Maida, III, M.A., M.B.A., Ph.D.		

/s/ Raymond W. Cohen	Director	March 12, 2014
Raymond W. Cohen		
/s/ Gilles Gagnon	Director	March 12, 2014
Gilles Gagnon, M.Sc., M.B.A		

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

SPECTRUM PHARMACEUTICALS, INC.

FORM 10-K ANNUAL REPORT

For the Fiscal Year Ended December 31, 2013

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders

Spectrum Pharmaceuticals, Inc.

We have audited Spectrum Pharmaceuticals, Inc. s internal control over financial reporting as of December 31, 2013, 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. s 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 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.

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, (i) ineffective design of controls over the process of estimating the required period-end accruals for services performed under open purchase orders, which resulted in overstated operating expenses and accrued liabilities in multiple reporting periods in, and prior to, 2013; and (ii) the ineffective design and operating effectiveness of controls over the process for identifying and recording liabilities for vendor invoices received subsequent to year end that related to 2013 activities, which would have resulted in understated operating expenses and accrued liabilities, if left uncorrected.

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. as of December 31, 2013 and 2012, and the related consolidated statements of operations, comprehensive income (loss), stockholders equity, and cash flows for each of the three years in the period ended December 31, 2013. 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 March 12, 2014, 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. has not maintained effective internal control over financial reporting as of December 31, 2013, based on the COSO criteria.

/s/ Ernst & Young LLP

Irvine, California
March 12, 2014

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders

Spectrum Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Spectrum Pharmaceuticals, Inc. as of December 31, 2013 and 2012, and the related consolidated statements of operations, comprehensive income (loss), stockholders equity, and cash flows for each of the three years in the period ended December 31, 2013. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Spectrum Pharmaceuticals, Inc. at December 31, 2013 and 2012, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2013, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Spectrum Pharmaceuticals, Inc. s internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 framework) and our report dated March 12, 2014 expressed an adverse opinion thereon.

/s/ Ernst & Young LLP

Irvine, California
March 12, 2014

SPECTRUM PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and par value amounts)

	December 31, 2013	2012
ASSETS		
Current assets:		
Cash and equivalents	$ 156,306	$ 139,698
Marketable securities	3,471	3,310
Accounts receivable, net of allowance for doubtful accounts of $206 and $228, respectively	49,483	92,169
Other receivables	7,539	
Inventories	13,519	14,478
Prepaid expenses and other current assets	3,213	2,745
Deferred tax assets	1,659	12,473
Total current assets	235,190	264,873
Property and equipment, net	1,535	2,548
Intangible assets, net	231,352	200,234
Goodwill	18,501	7,279
Deferred tax assets		23,276
Other assets	12,577	6,745
Total assets	$ 499,155	$ 504,955
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 79,837	$ 105,252
Accrued payroll and related expenses	6,872	4,835
Deferred revenue	156	12,300
Drug development liability	3,119	856
Total current liabilities	89,984	123,243
Drug development liability, less current portion	14,623	11,377
Deferred payment contingency		2,287
Acquisition-related contingent obligations	8,329	
Deferred tax liability	7,168	
Other long-term liabilities	5,965	4,367
Revolving line of credit		75,000
Convertible senior notes	91,480	
Total liabilities	217,549	216,274
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized		
Series B Junior Participating Preferred Stock, $0.001 par value; 1,500,000 shares authorized: no shares issued and outstanding		
Series E Convertible Voting Preferred Stock, $0.001 par value and $10,000 stated value; 2,000 shares authorized; 20 shares issued and outstanding at December 31, 2013 and 2012, respectively (convertible into 40,000 shares of common stock, with aggregate liquidation value of $240)	123	123
Common stock, $0.001 par value; 175,000,000 shares authorized; 64,104,173 and 60,026,675 issued and outstanding at December 31, 2013 and 2012, respectively	64	60
Additional paid-in capital	518,144	463,710
Accumulated other comprehensive income	894	273

Accumulated deficit	(237,619)	(175,485)
Total stockholders equity	281,606	288,681
Total liabilities and stockholders equity	$ 499,155	$ 504,955

See accompanying notes to these consolidated financial statements.

SPECTRUM PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share amounts)

	Year Ended December 31,		
	2013	**2012**	**2011**
Revenues:			
Product sales, net	$ 143,475	$ 254,992	$ 180,663
License fees and service revenue	12,379	12,715	12,300
Total revenues	$ 155,854	$ 267,707	$ 192,963
Operating costs and expenses:			
Cost of product sales (excludes amortization of purchased intangible assets)	28,580	46,633	33,838
Selling, general and administrative	99,315	89,922	72,197
Research and development	46,670	41,560	26,662
Amortization and impairment of intangible assets	20,074	8,818	3,720
Total costs and operating expenses	194,639	186,933	136,417
(Loss) income from operations	(38,785)	80,774	56,546
Other income (expense):			
Interest expense, net	(2,192)	(485)	297
Change in fair value of contingent consideration related to acquisition	2,871		
Change in fair value of common stock warrant liability			(3,488)
Other income (expense), net	1,470	(359)	280
Total other income (expense)	2,149	(844)	(2,911)
(Loss) income before income taxes	(36,636)	79,930	53,635
(Provision) benefit for income taxes	(25,498)	14,271	(3,704)
Net (loss) income	$ (62,134)	$ 94,201	$ 49,931
Net (loss) income per share:			
Basic	$ (1.02)	$ 1.61	$ 0.94
Diluted	$ (1.02)	$ 1.46	$ 0.86
Weighted average shares outstanding:			
Basic	60,729,128	58,588,916	53,272,767
Diluted	60,729,128	64,637,256	57,959,714

See accompanying notes to these consolidated financial statements.

SPECTRUM PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(In thousands)

	Year Ended December 31,		
	2013	**2012**	**2011**
Net (loss) income	$ (62,134)	$ 94,201	$ 49,931
Other comprehensive (loss) income, net of tax:			
Unrealized gain (loss) on available-for-sale securities	1,110	797	(135)
Income tax on unrealized gain on available-for-sale securities	(420)	(213)	
Foreign currency translation adjustments	(69)	(84)	
Other comprehensive income (loss), net	621	500	(135)
Total comprehensive (loss) income	$ (61,513)	$ 94,701	$ 49,796

See accompanying notes to these consolidated financial statements.

SPECTRUM PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

(In thousands, except share data)

	Preferred Stock		Common Stock		Additional	Accumulated Other Comprehensive	Accumulated	Treasury Stock		Total Stockholders
	Shares	Amount	Shares	Amount	Paid-In Capital	Income (Loss)	Deficit	Shares	Amount	Equity
Balance at December 31, 2010	26	$ 160	51,459,284	$ 51	$ 384,757	$ (92)	$ (307,635)		$	$ 77,241
Net income							49,931			49,931
Other comprehensive income, net						(135)				(135)
Conversion of Series E preferred stock to common stock	(6)	(37)	12,000		37					
Issuance of common stock to 401(k) plan			65,889		593					593
Issuance of common stock for ESPP			100,386		655					655
Adjustments resulting from change in value of warrants recognized in equity					7,392					7,392
Issuance of common stock upon exercise of stock options			1,126,257	1	5,136					5,137
Issuance of common stock upon exercise of warrants			3,747,312	4	24,804					24,808
Share-based compensation expense and common stock issued (net of forfeitures)			998,711	1	21,643					21,644
Purchase of treasury stock								363,055	(2,926)	(2,926)
Issuance of restricted stock for management incentive plan, net of shares repurchased/retired for employee tax withholding			426,562	1	(4,033)					(4,032)
Fair value of common stock issued to Targent for milestone			1,311,082	1	11,777					11,778
Balance at December 31, 2011	20	$ 123	59,247,483	$ 59	$ 452,761	$ (227)	$ (257,704)	363,055	$ (2,926)	$ 192,086
Net income							94,201			94,201
Other comprehensive income, net						500				500
Issuance of common stock to 401(k) plan			56,254		691					691
Issuance of common stock for ESPP			54,521		606					606
Issuance of common stock upon exercise of stock options			1,287,430	2	5,815					5,817
Issuance of common stock upon exercise of warrant			50,000		89					89
Share-based compensation expense and common stock issued (net of forfeitures)			554,239		14,193					14,193
Repurchase of shares to satisfy employee tax			(120,197)		(1,434)					(1,434)

withholding										
Dividends paid					(9,011)					(9,011)
Purchase of treasury stock								740,000	(9,057)	(9,057)
Retirement of treasury stock			(1,103,055)	(1)			(11,982)	(1,103,055)	11,983	
Balance at December 31, 2012	20	$ 123	60,026,675	$ 60	$ 463,710	$ 273	$ (175,485)		$	$ 288,681
Net loss							(62,134)			(62,134)
Other comprehensive loss, net						621				621
Issuance of common stock to 401(k) plan			99,359		860					860
Issuance of common stock for ESPP			74,925		495					495
Issuance of common stock upon exercise of stock options			825,884	1	3,576					3,577
Share-based compensation expense and common stock issued (net of forfeitures)			471,875		11,913					11,913
Repurchase of shares to satisfy employee tax withholding			(159,545)		(1,509)					(1,509)
Purchase of treasury stock								235,000	(1,651)	(1,651)
Retirement of treasury stock			(235,000)		(1,651)			(235,000)	1,651	
Issuance of common stock for Talon acquisition			3,000,000	3	26,307					26,310
Issuance of 2018 Convertible Notes					14,443					14,443
Balance at December 31, 2013	20	$ 123	64,104,173	$ 64	$ 518,144	$ 894	$ (237,619)		$	$ 281,606

See accompanying notes to these consolidated financial statements.

SPECTRUM PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,		
	2013	**2012**	**2011**
Cash Flows From Operating Activities:			
Net (loss) income	$ (62,134)	$ 94,201	$ 49,931
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:			
Amortization of deferred service revenue	(12,400)	(12,300)	(12,300)
Depreciation and amortization	22,096	12,243	5,650
Stock-based compensation	12,423	14,884	22,237
Change in fair value of common stock warrants issued to non-employees	356		3,488
Accretion of debt discount to interest expense on 2018 Convertible Notes	43		
Amortization of deferred financing costs to interest expense on 2018 Convertible Notes	101		
Bad debt expense (recovery)	127	(128)	245
Loss on disposal of fixed assets		132	38
Non-cash foreign currency exchange loss	1,222	107	
Impairment of FOLOTYN distribution rights	1,023		
Change in fair value of contingent consideration related to acquisition	(2,871)	20	
Change in fair value of Allos deferred development costs and deferred payment contingency	(2,869)		
Changes in operating assets and liabilities:			
Accounts receivable	42,559	(33,504)	(30,897)
Inventories	1,570	3,530	(6,528)
Prepaid expenses and other current assets	(359)	9,483	(7,115)
Deferred tax assets	33,252	(34,605)	
Other assets	(8,989)		
Accounts payable and other accrued obligations	(23,897)	24,038	15,711
Accrued payroll and related expenses	425	(9,726)	(1,525)
Drug development liability	(5,917)	2,376	3,519
Other long-term liabilities	2,153	1,208	834
Net cash (used in) provided by operating activities	(2,086)	71,959	43,288
Cash Flows From Investing Activities:			
Sales and maturities of marketable securities		72,463	18,255
Purchases of marketable securities		(26,430)	(17,027)
Purchases of property and equipment	(161)	(312)	(475)
Purchases of available-for-sale securities		(1,712)	(164)
Proceeds from sale of available-for-sale securities			157
Purchase of ZEVALIN Ex-U.S. rights		(25,435)	
Purchase of C-E MELPHALAN rights	(3,000)		
Acquisition of Talon, net of cash acquired	(11,169)		
Acquisition of Allos, net of cash acquired		(133,264)	
Net cash (used in) provided by investing activities	(14,330)	(114,690)	746
Cash Flows From Financing Activities:			
Proceeds from Mundipharma for FOLOTYN development	7,000		
Proceeds from exercise of stock options	3,576	5,817	5,137
Proceeds from exercise of common stock warrants		89	24,808
Proceeds from sale of common stock under employee stock purchase plan	495	606	655
Payments to acquire treasury stock	(1,651)	(9,057)	(2,926)
Repurchase of restricted stock to satisfy employee tax withholdings at vesting	(1,509)	(1,434)	(4,032)
Payment of stock dividend		(9,011)	

Repayment of capital leases		(9)	(31)
Proceeds from revolving line of credit	100,000	125,000	
Repayment of revolving line of credit	(175,000)	(50,000)	
Proceeds from 2018 Convertible Notes	120,000		
Deferred financing costs	(4,573)		
Proceeds from sale of common stock warrants related to 2018 Convertible Notes issuance	12,612		
Payment of debt issuance costs		(976)	
Purchase of common stock call options related to 2018 Convertible Notes issuance	(25,692)		
Net cash provided by financing activities	35,258	61,025	23,611
Effect of exchange rates on cash and equivalents	(2,235)	202	
Net increase (decrease) in cash and equivalents	16,608	18,496	67,645
Cash and equivalents beginning of year	139,698	121,202	53,557
Cash and equivalents end of year	$ 156,306	$ 139,698	$ 121,202
Supplemental Disclosure of Cash Flow Information:			
Cash paid for income taxes	$	$ 17,157	$ 2,042
Cash paid for interest	$ 1,200	$ 495	$ 14
Retirement of treasury shares	$ 1,652	$ 11,983	$
Inventory liability assumed in acquisitions	$	$ 580	$
Inventory included in accounts payable	$	$ 5,000	$
Conversion of preferred stock to common stock	$	$	$ 37
Common stock issued for Targent milestones	$	$	$ 11,778
Common stock issued for Talon acquisition	$ 26,310		

See accompanying notes to consolidated financial statements.

SPECTRUM PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(all tabular amounts presented in thousands, except percentages, share and per share data, and number of years)

1. DESCRIPTION OF BUSINESS, BASIS OF PRESENTATION, AND OPERATING SEGMENT

(a) Description of Business

Spectrum Pharmaceuticals, Inc. and its wholly-owned subsidiaries (Spectrum , the Company , we , our , or us), is a biotechnology company wi fully integrated commercial and drug development operations, with a primary focus in oncology and hematology. Our strategy is comprised of acquiring, developing, and marketing a diverse pipeline of late-stage clinical and commercial products.

We currently market four drugs:

- FUSILEV injection for patients in the U.S. with advanced metastatic colorectal cancer and to counteract certain effects of methotrexate therapy;
- ZEVALIN injection for patients in the U.S. and various international markets with follicular non-Hodgkin s lymphoma;
- FOLOTYN injection for patients in the U.S. with relapsed or refractory peripheral T-cell lymphoma; and
- MARQIBO injection for patients in the U.S. with Philadelphia chromosome negative acute lymphoblastic leukemia.

We also have a pipeline of product candidates in advanced-stage Phase 2 and Phase 3 studies. 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 business strategies.

(b) Basis of Presentation

Principles of Consolidation

The accompanying Consolidated Financial Statements in this Annual Report on Form 10-K have been prepared in accordance with generally accepted accounting principles in the United States of America (GAAP) and with the rules and regulations of the U.S. Securities and Exchange Commission (SEC). These financial statements include the financial position, results of operations, and cash flows of Spectrum and its subsidiaries, all of which are wholly-owned. All inter-company accounts and transactions among the consolidated entities have been eliminated in consolidation.

On April 1, 2012, we acquired the licensing rights outside of the U.S. to market ZEVALIN (the ZEVALIN Rights); on September 5, 2012, we acquired Allos Therapeutics, Inc. (Allos); and on July 17, 2013, we acquired Talon Therapeutics, Inc. (Talon). Our accompanying Consolidated Financial Statements include the assets acquired and liabilities assumed in connection with these acquisitions, in addition to the operating results and cash flows, beginning with the corresponding acquisition date for each acquisition.

Variable Interest Entity

We own fifty-percent of Spectrum Pharma Canada (a variable interest entity, as defined under applicable GAAP), which was organized in Quebec, Canada in January 2008. Certain of our drug clinical studies are conducted through this entity. We are obligated to fund all costs of this entity and have the sole rights to any revenue derived from its operations. Since we carry the full risks and rewards of this entity, we meet the applicable GAAP criteria as its primary beneficiary . As the primary beneficiary of this variable interest entity, Spectrum Pharma Canada s

balance sheets and statements of operations are included in our Consolidated Financial Statements as if it were a wholly-owned subsidiary for all periods presented.

(c) Operating Segment

We operate in one reportable operating segment that is focused exclusively on developing and commercializing oncology and hematology drug products. For the years ended December 31, 2013, 2012, and 2011, all of our revenue and related expenses were solely attributable to these activities. Substantially all of our long-lived assets are located in the U.S.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND USE OF ESTIMATES

The preparation of financial statements in conformity with GAAP requires our management to make informed estimates and assumptions that affect the reported amounts of assets and liabilities, revenues and expenses, and related disclosure of contingent liabilities. On an on-going basis, our management evaluates its estimates, including those related to (i) revenue adjustments; (ii) the collectability of customer accounts; (iii) whether the cost of inventories can be recovered; (iv) the value of goodwill and intangible assets; (v) the realization of tax assets and estimates of tax liabilities; (vi) the likelihood of payment and value of contingent liabilities; (vii) the fair value of investments; (viii) assumptions used in reporting stock-based compensation; and (ix) the potential outcome of litigation.

Such estimates are based on our management s judgment which takes into account historical experience and various assumptions. Nonetheless, actual results may materially differ from management s estimates. In our judgment, the accounting policies, estimates, and assumptions described below have the potential to significantly impact our preparation of the accompanying Consolidated Financial Statements:

(i) Revenue Recognition

(a) Product Sales: We sell our products to wholesalers and distributors. Our wholesalers and distributors purchase our products and sell the products directly to end-users, such as clinics, hospitals, and private oncology-based practices. Revenue from product sales is recognized upon shipment of product when title and risk of loss have transferred to our customer, and the following additional criteria are met:

(1) appropriate evidence of a binding arrangement exists with our customer;

(2) price is substantially fixed and determinable;

(3) collection from our customer is reasonably assured;

(4) our customer s obligation to pay us is not contingent on resale of the product;

(5) we do not have significant obligations for future performance to directly bring about the resale of our product; and

(6) we have a reasonable basis to estimate returns.

Our gross revenue is reduced by our gross-to-net (GTN) estimates, resulting in our reported Product sales, net in the accompanying Consolidated Statements of Operations. We defer revenue recognition in full if/when these estimates are not reasonably determinable at the time of sale.

Our GTN estimates reduce revenue in the same period that the related sale is recorded and include the following major categories:

Product Returns Allowances: Our FUSILEV customers are typically permitted to return products within six months after its expiration date, subject to certain restocking fees and preauthorization requirements. We estimate potential returns, based on several factors, including historical rates of return, customer and end-user ordering patterns, inventory held by distributors, and sell through data of distributor sales to end users. In general, returned product is not resold.

Government Chargebacks: Our products are subject to certain pricing limits under federal government programs. Qualifying entities purchase products through our distributors at the discounted price. Our distributors charge the difference between the list price and discounted price back

to us, for which there may be significant lag time. Due to estimates and assumptions inherent in determining the amount and extent of government chargebacks we will incur, which take in account our estimates of which sales will be subject to government chargebacks and the amount of such chargebacks, the actual amount of government chargeback claims may be materially different from our estimates.

Discounts: Discounts (generally prompt payment discounts) are estimated at each reporting period. We review the terms of the contracts, specifically price and discount structures, and applicable payment terms to estimate its value.

Rebates: Rebates are estimated based on the customer s actual purchase level during the rebate purchase period, and the corresponding contractual rebate tier we expect the customer to achieve.

SPECTRUM PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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Medicaid Rebates: Our products are subject to state government-managed Medicaid programs whereby discounts and rebates are provided to participating state governments. 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 forecasting techniques, 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. Due to estimates and assumptions inherent in determining the amount of our product sales subject to Medicaid rebates, and the time lag to receive these rebate notices (generally several months after the sale is made), the actual amount of these claims may be materially different from our estimates. As a result, adjustments may be recorded over several periods after the initial sale is recorded.

Distribution and Data Fees: Distribution and data fees are paid to authorized wholesalers and specialty distributors of FUSILEV and FOLOTYN as a percentage of products sold. The services provided include contract administration, inventory management, product sales reporting by customer, returns processing. We estimate these fees based on a percentage of FUSILEV and FOLOTYN revenues that are governed by distribution agreements.

(b) License Fees: We recognize license fees based on the terms of each contractual agreement. In general, this results in periodic revenue recognition as the third-party licensee has sales for which we are entitled to a royalty, or in certain cases, a lump-sum license fee in which revenue is recognized in that period.

(c) Service Revenue: We receive fees under certain arrangements for our research and development services. These services are generally undertaken in connection with a collaboration agreement with another pharmaceutical company. Payment may be triggered by the successful completion of a phase of development, results from a clinical trial, acceptance of an NDA or an equivalent filing, and/or regulatory approval. We recognize revenue when the corresponding milestone is achieved, or the revenue is otherwise earned through our on-going activities.

(ii) Cash and Equivalents

Cash and equivalents consist of highly liquid investments with original maturities of three months or less from the original purchase date.

(iii) Marketable Securities

Marketable securities are equity securities. These are classified as available-for-sale, with any unrealized change in value reflected in unrealized gain (loss) on securities on the accompanying Consolidated Statements of Comprehensive Income (Loss).

(iv) Accounts Receivable

Accounts receivable are recorded at the invoiced amount, and do not bear interest. The allowance for doubtful accounts is management s best estimate of the amount of probable credit losses in existing accounts receivable. Account balances are charged off against the allowance after appropriate collection efforts are exhausted.

(v) Inventories

We value inventory at the lower of the actual cost to purchase or manufacture the inventory, or the market value for such inventory (i.e., net realizable value). Cost is determined on the first-in, first-out method (FIFO). We regularly review inventory quantities in process and on hand, and when appropriate, record a provision for obsolete and excess inventory to reduce it to its net realizable value.

(vi) Property and Equipment

Property and equipment are stated at cost and depreciated on a straight-line basis over its estimated useful lives. In the case of leasehold improvements, depreciation is over the shorter of the estimated useful life or remaining term of the lease. We evaluate the recoverability of long-lived assets (which includes property and equipment) whenever events or changes in circumstances in our business indicate that the asset s

carrying amount may not be recoverable through on-going operations.

SPECTRUM PHARMACEUTICALS, INC.

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(vii) Goodwill and Intangible Assets

Goodwill represents the excess of acquisition cost over the fair value of the net assets of the acquired businesses. Goodwill has an indefinite useful life and is not amortized, but instead tested for impairment annually unless there are interim impairment indicators. We perform our annual evaluation as of October 1 each year.

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

(a) a significant decrease in the market value of an asset;

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

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

(viii) Stock-Based Compensation

We recognize stock-based compensation expense for employees and directors over the equity award vesting period, based on its fair value at the date of grant. The fair value of equity awards that are expected to vest is amortized on a straight-line basis over the requisite service period. Stock-based compensation expense recognized is net of an estimated forfeiture rate, which is updated as appropriate.

We use the Black-Scholes option pricing model to determine the fair value of stock option grants with service conditions for vesting and the Monte Carlo valuation model to value certain equity awards with market conditions and service conditions for vesting. These models require the use of highly subjective assumptions, including the probability of the achievement of certain market capitalization levels.

(ix) Foreign Currency Translation

We translate the assets and liabilities of our foreign subsidiaries stated in local functional currencies to U.S. dollars at the rates of exchange in effect at the end of the period. Revenues and expenses are translated using rates of exchange in effect during the period. Gains and losses from the translation of financial statements denominated in foreign currencies are included as a separate component of accumulated other comprehensive income (loss) in the statement of comprehensive income (loss).

We record foreign currency transactions at the exchange rate prevailing at the date of the transaction with resultant gains and losses being included in results of operations. Foreign currency transaction gains and losses have not been significant for any period presented.

(x) Comprehensive Income (Loss)

Comprehensive income (loss) is calculated in accordance with authoritative guidance which requires the disclosure of all components of comprehensive income, including net income (loss) and changes in equity during a period from transactions and other events and circumstances generated from non-owner sources.

(xi) Basic and Diluted Net (Loss) Income per Share

We calculate basic and diluted net (loss) income per share using the weighted average number of common shares outstanding during the periods presented. In periods of a net loss, basic and diluted loss per share are the same. For the diluted earnings per share calculation, we adjust the weighted average number of common shares outstanding to include only dilutive stock options, warrants, and other common stock equivalents outstanding during the period.

(xii) Income Taxes

Deferred tax assets and liabilities are recorded based on the estimated future tax effects of temporary differences between the tax basis of assets and liabilities and amounts reported in the financial statements, as well as operating losses and tax credit carry forwards using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain.

We have recorded a valuation allowance to reduce our net deferred tax assets, because we believe that, based upon a weighting of positive and negative factors, it is more likely than not that these deferred tax assets will not be realized. If we were to determine that we would be able to realize our deferred tax assets in the future, an adjustment to the valuation allowance of our deferred tax

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assets would increase net income in the period such determination was made. In the event that we were assessed interest and/or penalties from taxing authorities, such amounts would be included in income tax expense within the Consolidated Statements of Operations and Comprehensive Income (Loss) in the period the notice was received.

(xiii) Research and Development Costs

Research and development costs are expensed as incurred.

(xiv) Fair Value Measurements

We measure fair value based on the prices that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. We utilize valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. Fair value measurements are based on a three-tier hierarchy that prioritizes the inputs used to measure fair value. These tiers include the following:

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

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data. These inputs include quoted prices for similar assets or liabilities; quoted market prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

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

Cash and equivalents within our accompanying Consolidated Balance Sheets include certificates of deposit and money market funds that are valued utilizing Level 2 inputs. Marketable securities consist of publicly-traded equity instruments that are valued utilizing Level 1 inputs.

The fair value of our drug development liability and our deferred payment contingency within our accompanying Consolidated Balance Sheets was valued using a model commonly referred to as the discounted income approach model. The unobservable inputs (i.e., Level 3 inputs) in this valuation model that have the most significant effect on these liabilities include (i) internal estimates of research and development personnel costs needed to perform the research and development services, (ii) estimates of expected cash outflows to third parties for services and supplies over the expected period that the services will be performed, and (iii) an appropriate discount rate for these expenditures. These inputs are reviewed for reasonableness by management on at least on a quarterly basis.

Acquisition-related contingent obligations within our accompanying Consolidated Balance Sheets represent future amounts we may be required to pay in conjunction with various business combinations. See *Note 10(a)* for a discussion of CVRs granted as part of our acquisition of Talon, and *Note 10(b)* for the fair value of the liability associated with FDA approval of C-E MELPHALAN. These liabilities are valued using Level 3 inputs and include probabilities and assumptions related to the timing and likelihood of achievement of regulatory and sales milestones.

3. BALANCE SHEET ACCOUNT DETAIL

(a) Cash and Equivalents and Marketable Securities

As of December 31, 2013, we held substantially all of our cash and equivalents, and marketable securities at major financial institutions.

Our investment policy requires that investments in marketable securities be in only highly-rated instruments, which are primarily U.S. treasury bills or U.S. treasury-backed securities, with limitations on investing in securities of any single issuer. We maintain cash balances in excess of federally insured limits with reputable financial institutions. To a limited degree, the Federal Deposit Insurance Corporation (FDIC) and other third parties insure these investments. However, these investments are not insured against the possibility of a complete loss of earnings or principal and are inherently subject to the credit risk related to the continued credit worthiness of the underlying issuer and general credit market risks. We manage such risks on our portfolio by investing in highly liquid, highly rated instruments and do not invest in long-term maturity instruments.

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Cash and equivalents and marketable securities, including long term bank certificates of deposits, and investments totaled $159.8 million and $143.0 million as of December 31, 2013 and 2012, respectively. The carrying amount of our money market funds and bank certificate of deposits (Bank CDs) approximates its fair value (utilizing Level 2 inputs see *Note 2(x)*) because of our ability to immediately convert these instruments into cash with minimal change in value.

The following is a summary of our cash and equivalents and marketable securities:

	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated fair Value	Cash and equivalents	Marketable Securities Current	Marketable Securities Long Term
December 31, 2013							
Bank deposits	$ 55,911	$	$	$ 55,911	$ 55,911	$	$
Money market funds	100,395			100,395	100,395		
Bank CDs	410			410		410	
Mutual funds	3,061			3,061		3,061	
Total cash and equivalents and marketable securities	$ 159,777	$	$	$ 159,777	$ 156,306	$ 3,471	$
December 31, 2012							
Bank deposits	$ 128,000	$	$	$ 128,000	$ 128,000	$	$
Money market funds	11,698			11,698	11,698		
Bank CDs	987			987		987	
Mutual funds	2,323			2,323		2,323	
Total cash and equivalents and marketable securities	$ 143,008	$	$	$ 143,008	$ 139,698	$ 3,310	$

As of December 31, 2013, none of these securities had been in a continuous unrealized loss position longer than one year.

(b) Property and Equipment

Property and equipment consist of the following:

	December 31, 2013	December 31, 2012
Computers and software	$ 5,154	$ 4,540
Lab and media equipment	1,063	886
Office furniture and equipment	1,575	1,492
Leasehold improvements	2,813	2,799
Assets held under capital lease obligations		146
Property and equipment, at cost	10,605	9,863
(Less): accumulated depreciation and amortization	(9,070)	(7,315)
Property and equipment, net	$ 1,535	$ 2,548

Depreciation and amortization expense for property and equipment (including leasehold improvements) for the years ended December 31, 2013, 2012, and 2011 was $1.2 million, $1.2 million, and $0.9 million, respectively.

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(c) Inventories

Inventories, net consist of the following:

	December 31, 2013	2012
Raw materials	$ 1,794	$ 887
Work in process	3,312	7,302
Finished goods	8,413	6,289
Inventories	$ 13,519	$ 14,478

(d) Intangible Assets and Goodwill

Intangible assets consist of the following:

	December 31, 2013						
	Historical Cost	Accumulated Amortization	Foreign Currency Translation	Impairment	Net Amount	Full Amortization Period (years)	Remaining Amortization Period (years)
MARQIBO IPR&D	$ 17,600	$	$	$	$ 17,600	n/a	n/a
MELPHALAN IPR&D	7,700				7,700	n/a	n/a
MARQIBO developed technology	26,900	(1,107)			25,793	11	11
ZEVALIN marketing rights U.S.	41,900	(23,455)			18,445	10	5
ZEVALIN marketing rights Ex-U.S.	23,490	(5,343)	682		18,829	8	6
FUSILEV developed technology	16,778	(4,821)			11,957	11	8
FOLOTYN distribution rights*	27,900	(3,662)		(1,023)	23,215	10	9
FOLOTYN developed technology	118,400	(10,587)			107,813	13	12
Total intangible assets	$ 280,668	$ (48,975)	$ 682	$ (1,023)	$ 231,352		

* On May 29, 2013, we amended our collaboration agreement with Mundipharma in order to modify the scope of their licensed territories and the respective development obligations. As a result of the amendment, Europe and Turkey were excluded from Mundipharma s commercialization territory, and royalty and milestone rates were modified. The modification of our associated royalty and milestone rights constituted a change in the contractual provisions under which we measured our original acquired intangible asset (i.e., the FOLOTYN distribution rights). We determined that an impairment of the FOLOTYN distribution rights of $1.0 million resulted from the amendment and is recorded in the amortization and impairment of intangible assets in the accompanying Consolidated Statement of Operations for the year ended December 31, 2013.

December 31, 2012

		Historical Cost	Accumulated Amortization	Foreign Currency Translation	Net Amount
ZEVALIN marketing rights	U.S.	$ 41,900	$ (19,735)	$	$ 22,165
ZEVALIN marketing rights	Ex-U.S.	23,490	(2,192)	(355)	20,943
FUSILEV developed technology		16,778	(2,980)		13,798
FOLOTYN distribution rights		27,900	(895)		27,005
FOLOTYN developed technology		118,400	(2,077)		116,323
Total intangible assets		$ 228,468	$ (27,879)	$ (355)	$ 200,234

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Intangible asset amortization expense recognized in 2013, and 2012, and 2011 was $21.2 million, $8.8 million, and $4.7 million, respectively. Estimated intangible asset amortization expense (excluding incremental amortization from the reclassification of IPR&D to developed technology) for the five succeeding years and thereafter is as follows:

Years Ending December 31	
2014	$ 22,468
2015	22,468
2016	22,468
2017	22,468
2018	22,313
2019 and thereafter	93,867
	$ 206,052

Goodwill is comprised of the following (by source):

	December 31, 2013	**December 31, 2012**
Acquisition of Talon	$ 10,526	
Acquisition of ZEVALIN Rights	2,525	$ 2,525
Acquisition of Allos	5,346	4,791
Foreign exchange translation effects	104	(37)
	$ 18,501	$ 7,279

(e) Other assets

Other assets are comprised of the following:

	December 31, 2013	**December 31, 2012**
Investments in equity securities	$ 3,593	$ 2,476
Deposits	190	304
Debt issuance cost	3,432	814
Life insurance cash surrender value	5,361	2,881
	$ 12,576	$ 6,475

(f) Accounts payable and other accrued obligations

Accounts payable and other accrued obligations are comprised of the following:

	December 31,	
	2013	2012
Trade payables	$ 12,796	$ 30,814
Accrued rebates	28,893	11,023
Accrued product royalty	9,498	12,275
Allowance for returns	2,900	5,056
Accrued data and distribution fees	2,430	8,449
Accrued GPO administrative fees	2,327	2,650
Inventory management fee	616	3,050
Accrued income taxes	3	2,522
Allowance for chargebacks	5,074	15,153
Accrued drug development costs	6,433	11,441
Other accrued obligations	8,867	2,819
	$ 79,837	$ 105,252

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Amounts presented within accounts payable and other accrued obligations in the accompanying Consolidated Balance Sheets for GTN estimates (see *Note 2(i)*) were as follows:

Description	Rebates and Chargebacks	Data and Distribution, GPO Fees, and Inventory Management Fees	Prompt Pay Discount	Returns
Balance as of December 31, 2011	$ 9,064	$ 9,808	$ 992	$ 4,000
Allos accruals assumed	2,371	182		941
Add: provisions (recovery)	91,059	32,793	4,814	159
Less: credits or actual allowances	(76,318)	(28,634)	(4,355)	(44)
Balance as of December 31, 2012	26,176	14,149	1,451	5,056
Add: provisions (recovery)	63,609	19,067	183	(2,034)
Less: credits or actual allowances	(55,818)	(27,843)	(1,317)	(122)
Balance as of December 31, 2013	$ 33,967	$ 5,373	$ 317	$ 2,900

(g) Other long-term liabilities

Other long-term liabilities are comprised of the following:

	December 31, 2013	2012
Accrued executive deferred compensation	$ 3,949	$ 2,366
Deferred rent (non-current portion)	366	571
Business acquisition liability	298	298
Other tax liabilities	1,352	1,132
	$ 5,965	$ 4,367

4. GROSS-TO-NET PRODUCT SALES

The below table presents a GTN product sales reconciliation for the accompanying Consolidated Statement of Operations:

	2013	2012	2011
Gross product sales	$ 224,301	$ 383,817	$ 220,670
Rebates and government chargebacks	(63,610)	(91,059)	(22,190)
Distribution and data fees and group purchasing organizations fees	(19,067)	(32,793)	(11,637)

Prompt pay discounts	(183)	(4,814)	(4,086)
Product returns allowance	2,034	(159)	(2,094)
Product sales, net	$ 143,475	$ 254,992	$ 180,663

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5. PRODUCT SALES, NET BY GEOGRAPHIC REGION AND PRODUCT LINE

The below table presents product sales, net by geography for the years ended December 31, 2013, 2012, and 2011:

	Year Ended December 31,					
	2013		2012		2011	
United States	$ 133,462	93.0%	$ 245,697	96.4%	$ 180,663	%
International:						
Europe	3,953	2.8%	3,113	1.2%		%
Asia Pacific	6,060	4.2%	6,182	2.4%		%
Total International	10,013	7.0%	9,295	3.6%		%
Product sales, net	$ 143,475	100.0%	$ 254,992	100.0%	$ 180,663	100.0%

The below table presents product sales, net by product line for the years ended December 31, 2013, 2012, and 2011:

	Year Ended December 31,					
	2013		2012		2011	
FUSILEV	$ 68,397	47.7%	$ 204,253	80.1%	$ 153,110	84.7%
FOLOTYN	44,370	30.9%	20,412	8.0%		%
ZEVALIN	29,393	20.5%	30,327	11.9%	27,553	
MARQIBO	1,315	0.9%		%		%
Product sales, net	$ 143,475	100.0%	$ 254,992	100.0%	$ 180,663	15.3%

6. STOCK-BASED COMPENSATION

2009 Stock Incentive Plan

We have one active stockholder-approved stock-based compensation plan, the 2009 Incentive Award Plan (the 2009 Plan), which replaced our former stockholder-approved plans. We may grant incentive stock options, non-qualified options, restricted stock awards, and stock appreciation rights under the 2009 Plan.

The maximum number of our common stock available for issuance under the 2009 Plan is 10.0 million shares. Beginning on January 1, 2010, and each January 1st thereafter, the number of shares of common stock available for issuance under the 2009 Plan increases by the greater of (i) 2.5 million shares or (ii) a number of shares such that the total number of shares of common stock available for issuance under the 2009 Plan shall equal 30% of the then number of shares of common stock issued and outstanding. As of December 31, 2013, 5.7 million shares were available for grant. It is our policy that before stock is issued through the exercise of stock options, we must first receive all required cash payment for such shares (whether through an upfront cash exercise or net-settlement exercise).

Stock-based awards are governed by agreements between us and the recipients. Incentive stock options and nonqualified stock options may be granted under the 2009 Plan at an exercise price of not less than 100% of the closing fair market value of our common stock on the respective

date of grant. The grant date is generally the date the award is approved by the Compensation Committee of the Board of Directors, though for aggregate awards of 50,000 or less in each quarter, the grant date is the date the award is approved by our Chief Executive Officer.

Stock-based awards generally vest 25% on the first anniversary of the date of grant, or for new hires, the first anniversary of their initial date of employment. Awards vest monthly thereafter on a straight-line basis over three years. Stock options must be exercised, if at all, no later than 10 years from the date of grant. Upon termination of employment, vested stock options may be exercised within 90 days from the last date of employment. In the event of an optionee s death, disability, or retirement, the exercise period is 365 days from the last date of employment.

Employee Stock Purchase Plan

Under the terms of our 2009 Employee Stock Purchase Plan (the ESPP), eligible employees can purchase common stock through payroll deductions. The purchase price is equal to the closing price of our common stock on the first or last day of the offering period (whichever is less), minus a 15% discount. We use the Black-Scholes option-pricing model, in combination with the

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discounted employee price, in determining the value of ESPP expense to be recognized during each offering period. A participant may purchase a maximum of 50,000 shares of common stock during a six-month offering period, not to exceed $25,000 worth of stock on the offering date during each plan year.

A total of 5.0 million shares of common stock are authorized for issuance under the ESPP. Beginning on January 1, 2010, and each January 1st thereafter, the number of shares of common stock available for issuance under the ESPP shall increase by an amount equal to the lesser of (i) 1 million shares or (ii) an amount determined by the ESPP administrator. However, in no event shall the number of shares of common stock available for future sale under the ESPP exceed 10.0 million shares, subject to capitalization adjustments occurring due to dividends, splits, dissolution, liquidation, mergers, or changes in control.

Stock-Based Compensation Expense Summary

We classify our stock-based compensation expense (inclusive of our 2009 Plan, ESPP, and 401(k) matching) in the accompanying Consolidated Statements of Operations, based on the department to which the recipient belongs. Stock-based compensation expense included within operating expenses for years ended December 31, 2013, 2012, and 2011 was as follows:

	Year Ended December 31,		
	2013	2012	2011
Selling, general and administrative	$ 10,762	$ 13,041	$ 20,609
Research and development	2,017	1,843	1,628
Total	$ 12,779	$ 14,884	$ 22,237

Employee stock-based compensation expense for the years ended December 31, 2013, 2012, and 2011 was recognized (reduced for estimated forfeitures) on a straight-line basis over the vesting period. Forfeitures are estimated at the time of grant and prospectively revised if actual forfeitures differ from those estimates. We estimate forfeitures of stock options using the historical exercise behavior of our employees. For purposes of this estimate, we have applied an estimated forfeiture rate of 8%, 5%, and 5% for the years ended December 31, 2013, 2012, and 2011.

Valuation Assumptions Restricted Stock and Stock Options

The grant-date fair value per share for restricted stock awards was based upon the closing market price of our common stock on the award grant-date.

The fair value of stock options granted was estimated at the date of grant using the Black-Scholes option-pricing model. The following assumptions were used to determine fair value for the stock awards granted in the applicable year:

	Year Ended December 31,		
	2013	2012	2011
Expected option life (in years) (a)	4.95	4.50	4.93
Risk-free interest rate (b)	0.35% - 0.78%	0.34% - 0.51%	0.82% - 2.4%
Volatility (c)	58.3% - 71.5%	64.2% -73.6%	55.8%
Dividend yield (d)	0%	0%	0%
Weighted-average grant-date fair value per stock option	$4.66	$6.20	$2.65

(a) Determined by the historical stock option exercise behavior of our employees (maximum term is 10 years).
(b) Based upon the U.S. Treasury yields in effect during the period which the options were granted (for a period equaling the stock options expected term).
(c) Measured using our historical stock price for a period equal to stock options expected term.
(d) We do not expect to declare any cash dividends in the foreseeable future.

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Stock Option Activity

Stock option activity during the years ended December 31, 2013, 2012, and 2011 is as follows:

		Number of Shares	Weighted-Average Exercise Price/Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding	December 31, 2010	8,397,094	$ 4.17		
Granted		3,622,150	7.92		
Exercised		(1,126,257)	4.07		$ 8,255(1)
Forfeited		(547,479)	4.81		
Expired		(159,987)	5.17		
Outstanding	December 31, 2011	10,185,521	$ 5.46		
Granted		1,821,915	11.57		
Exercised		(1,287,430)	4.52		$ 11,500(1)
Forfeited		(316,825)	7.93		
Expired		(3,916)	7.69		
Outstanding	December 31, 2012	10,399,265	$ 6.57		
Granted		2,041,300	8.92		
Exercised		(825,884)	4.40		$ 3,435(1)
Forfeited		(202,882)	8.22		
Expired		(82,581)	8.91		
Outstanding	December 31, 2013	11,329,218	$ 7.10	7.0	$ 25,849(2)