

SPECTRUM PHARMACEUTICALS INC

Form 10-K/A

December 06, 2013

Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K/A

Amendment No. 1

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

For the fiscal year ended December 31, 2012

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

Commission File Number: 001-35006

SPECTRUM PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware **93-0979187**
(State or other jurisdiction of **(I.R.S. Employer**
incorporation or organization) **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

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

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

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

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

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

Large accelerated filer Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company
Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

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

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

DOCUMENTS INCORPORATED BY REFERENCE

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

Table of Contents

Explanatory Note

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

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

- (A) Amendments to Part I, Item 1 Business, to restate presented research and development expense detail for the 2012, 2011, and 2010 annual periods, as described below in (C) (ii).
- (B) Amendments to Part I, Item 1A Risk Factors, to add an additional risk factor regarding our internal controls over financial reporting as a result of the identification of a material weakness in our financial reporting.
- (C) Amendments to Part II, Item 6 Selected Financial Data, to revise our 2008 through 2012 annual financial results, and as of each fiscal year-end date, to reflect: (i) \$2.1 million of intangible asset amortization in the year ended December 31, 2012; (ii) a reduction in operating expenses related to certain accounts payable and other accrued obligations accounts which had the effect of overstating our consolidated operating expenses by \$3.0 million, \$1.4 million, \$1.8 million, \$0.7 million, and \$0.2 million for the years ended 2012, 2011, 2010, 2009, and 2008, respectively; and (iii) the impact on our intangible assets, goodwill, and income tax accounts for the effects of above items (i) and/or (ii) within our balance sheet as of December 31, 2012, 2011, 2010, 2009, and 2008.
- (D) Amendments to Part II, Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations, to reflect the revision of our financial results, described in (C) above.
- (E) Amendments to Part II, Item 8 Financial Statements and Supplementary Data, to revise our 2010 through 2012 annual financial results, and as of December 31, 2012 and 2011, to reflect the revision of our financial results, described in (C) above, as well as revising our statements of comprehensive income (loss), stockholders' equity, and cash flows for the years ended December 31, 2012, 2011, and 2010 for the items noted within (C) above, specifically for (i), (ii), and (iii).
- (F) Amendments to Part II, Item 9A Controls and Procedures, to (i) describe changes in our disclosure controls and procedures and its internal controls over financial reporting to address a material weakness, (ii) a modification to management's opinion of the effectiveness of our internal controls over financial reporting as of December 31, 2012, and (iii) a modification of the Report of our Independent Registered Public Accounting Firm for its opinion of the effectiveness of our internal controls over

financial reporting as of December 31, 2012.

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

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

Table of Contents

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

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

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

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

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

Table of Contents**TABLE OF CONTENTS**

	Page
<u>PART I</u>	
Item 1. <u>Business (As Amended)</u>	3
Item 1A. <u>Risk Factors (As Amended)</u>	29
Item 1B. <u>Unresolved Staff Comments</u>	50
Item 2. <u>Properties</u>	50
Item 3. <u>Legal Proceedings</u>	50
Item 4. <u>Mine Safety Disclosures</u>	51
<u>PART II</u>	
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	51
Item 6. <u>Selected Financial Data (As Restated)</u>	54
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations (As Restated)</u>	56
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	71
Item 8. <u>Financial Statements and Supplementary Data (As Restated)</u>	71
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	71
Item 9A. <u>Controls and Procedures (As Amended)</u>	72
Item 9B. <u>Other Information</u>	76
<u>PART III</u>	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	76
Item 11. <u>Executive Compensation</u>	76
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	76
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	76
Item 14. <u>Principal Accountant Fees and Services</u>	76
<u>PART IV</u>	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	76
<u>Signatures</u>	82

Table of Contents**FORWARD-LOOKING STATEMENTS**

Spectrum Pharmaceuticals, Inc.'s Annual Report on Form 10-K contains certain forward-looking statements. These forward-looking statements involve a number of risks and uncertainties. These forward-looking statements can generally be identified as such because the context of the statement will include certain words, including but not limited to, believes, may, will, expects, intends, estimates, anticipates, plans, seeks, continues, predicts, potential, likely, or opportunity, and also contains predictions, estimates and other forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and in reliance upon the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are based on the current beliefs of the Company's management, as well as assumptions made by and information currently available to the Company's management. Readers of this Annual Report on Form 10-K should not put undue reliance on these forward-looking statements, which speak only as of the time this Annual Report on Form 10-K was filed with the Securities and Exchange Commission, or SEC. Reference is made in particular to forward-looking statements regarding the success, safety and efficacy of our drug products, product approvals, product sales, revenues, development timelines, product acquisitions, liquidity and capital resources and trends. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. Spectrum Pharmaceuticals, Inc.'s actual results may differ materially from the results projected in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this Report, including the Risk Factors in Item 1A Risk Factors, and in Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations included in Part II. In addition, past financial or operating performance is not necessarily a reliable indicator of future performance, and you should not use our historical performance to anticipate results or future period trends. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our results of operations and financial condition. Except as required by law, we do not undertake to update any such forward-looking statements and expressly disclaim any duty to update the information contained in this Annual Report on Form 10-K.

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

Spectrum Pharmaceuticals, Inc.[®], FUSILEV[®], FOLOTYN[®], ZEVALIN[®] and RenaZorb[®] are registered trademarks of Spectrum Pharmaceuticals, Inc. and its subsidiaries. Redefining Cancer Care[™], Turning Insights Into Hope[™], RIT Oncology, LLC[™], RIT[™], RRZ[™], and our logos are trademarks owned by Spectrum Pharmaceuticals, Inc. and its subsidiaries. EOquin[®] is a registered trademark of Allergan, Inc. that is in the process of being assigned to Spectrum. All other trademarks and trade names are the property of their respective owners.

PART I**Item 1. Business****Overview**

We are a biotechnology company with fully integrated commercial and drug development operations with a primary focus in hematology and oncology. Our strategy is comprised of acquiring, developing and commercializing a broad and diverse pipeline of late-stage clinical and commercial products. In the United States, or the U.S., we market three oncology drugs, FUSILEV[®], FOLOTYN[®] and ZEVALIN[®] and also market ZEVALIN outside of the U.S. We have

two drugs, apaziquone and belinostat, in late stage development along with a diversified pipeline of novel drug candidates.

We have assembled an integrated in-house scientific team, including formulation development, clinical development, medical affairs, regulatory affairs, biostatistics and data management, and have established a commercial infrastructure for the marketing of our drug products. We also leverage the expertise of our worldwide partners to assist in the execution of our strategy. Apaziquone has been studied in two large Phase 3 clinical trials for non-muscle invasive bladder cancer, or NMIBC, and is under strategic collaborations with Nippon Kayaku Co. Ltd., or Nippon Kayaku, and Handok Pharmaceuticals Co. Ltd., or Handok. Belinostat, is being studied in multiple indications including a Phase 2 registrational trial for relapsed or refractory peripheral T-cell lymphoma, or PTCL, under a strategic collaboration with TopoTarget A/S, or TopoTarget. FOLOTYN is being further developed under a collaboration agreement with Mundipharma International Corporation Limited, or Mundipharma.

Table of Contents

Our business strategy is comprised of the following initiatives:

Maximizing the growth potential of our marketed drugs, FUSILEV, FOLOTYN and ZEVALIN. Our near-term outlook largely depends on sales and marketing successes for our three marketed drugs. For FUSILEV, we are working to expand usage in colorectal cancer. We launched FUSILEV in August 2008 and we were able to benefit from broad utilization in community clinics and hospitals and recognized a dramatic increase in sales beginning in the second half of 2010 due to a shortage of generic leucovorin. While generic leucovorin supplies and utilization have been negatively impacted by this shortage, we cannot predict how long the shortage may continue or the extent of the impact the shortage may ultimately have on FUSILEV utilization. In April of 2011, we received two FDA approvals for FUSILEV. The first FDA approval was for the use of FUSILEV in combination with 5-fluorouracil in the palliative treatment of patients with advanced metastatic colorectal cancer. The second FDA approval was for a Ready-To-Use formulation, or RTU, of FUSILEV. We are now actively engaged in marketing FUSILEV for use in advanced metastatic colorectal cancer.

We added FOLOTYN to our commercial drug portfolio with the acquisition of Allos Therapeutics, Inc. or Allos in September 2012. FOLOTYN is a folate analogue metabolic inhibitor designed to accumulate preferentially in cancer cells. FOLOTYN targets the inhibition of dihydrofolate reductase, or DHFR, an enzyme critical in the folate pathway, thereby interfering with DNA and RNA synthesis and triggering cancer cell death. FOLOTYN can be delivered as a single agent, for which we currently have approval in the United States for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma, or PTCL, and has the potential to be used in combination therapy regimens. We believe that FOLOTYN's unique mechanism of action offers us the ability to target the drug for development in a variety of hematological malignancies and solid tumor indications and for autoimmune diseases as well. FOLOTYN has been available for commercial sale in the United States since October 2009.

For ZEVALIN, we continue to work on growing the ZEVALIN brand and are working to expand indications for use beyond follicular non-Hodgkin's lymphoma through additional trials. Effective April 2, 2012, with the acquisition of licensing rights from Bayer Pharma AG, we began the sales of ZEVALIN outside of the U.S. We have initiated and continue to build appropriate infrastructure and additional initiatives to facilitate broad customer reach and to address other market requirements, as appropriate, to expand utilization. We have formed a dedicated commercial organization comprised of highly experienced and motivated sales representatives, account managers, and a complement of other support marketing personnel to manage the sales and marketing of our drugs. In addition our scientific department supports field activities through various MDs, PhDs and other medical science liaison personnel.

Optimizing our development portfolio and maximizing the asset values of its components. While over the recent few years, we have evolved from a development-stage to a commercial-stage pharmaceutical company, we have maintained a highly focused development portfolio. Our strategy with regard to our development portfolio is to focus on late-stage drugs and to develop them safely and expeditiously to the point of regulatory approval. We plan to develop some of these drugs ourselves or with our subsidiaries and affiliates, or secure collaborations with third parties such that we are able to suitably monetize these assets. We have assembled a drug development infrastructure that is comprised of highly experienced and motivated MDs, PhDs, clinical research associates and a complement of other support personnel to develop these drugs. In April 2012, we announced that the single instillation Phase 3 clinical trials for apaziquone did not meet their primary endpoint however the pooled data from the studies did show a statistically significant treatment effect. A meeting with the FDA was held in December 2012 to discuss the results from these

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

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

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

Table of Contents

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

Managing our financial resources effectively. We remain committed to fiscal discipline, a policy which has allowed us to become well capitalized among our peers, despite a very challenging capital markets environment beginning in 2009 and continuing through 2012. This policy includes the pursuit of dilutive and non-dilutive funding options, prudent expense management, and the achievement of critical synergies within our operations in order to maintain a reasonable burn rate. Even with the continued build-up in operational infrastructure to facilitate the marketing of our three commercial drugs, we intend to be fiscally prudent in any expansion we undertake.

In terms of revenue generation, we rely on sales from currently marketed drugs and intend to pursue out-licensing of select pipeline drugs in select territories, as discussed above. When appropriate, we may pursue other sources of financing, including dilutive and non-dilutive financing alternatives. While we are currently focused on advancing our key drug development programs, we anticipate that we will make regular determinations as to which other programs, if any, to pursue and how much funding to direct to each program on an ongoing basis, based on clinical success and commercial potential, including termination of our existing development programs, especially if we do not expect value to be realized from continued development.

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

Recent Developments

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

In late January 2012, we entered into a co-development and commercialization agreement with Hanmi Pharmaceutical Company for SPI-2012 (formerly known as LAPS-GCSF), a drug for the treatment of chemotherapy induced neutropenia based on Hanmi's proprietary LAPSCOVERY Technology. We expect to initiate Phase 2 trials in collaboration with Hanmi in 2013. If SPI-2012 is ultimately commercialized, we will have worldwide rights except for Korea, China and Japan.

On April 1, 2012, through a subsidiary, Spectrum Pharmaceuticals Cayman, L.P., we completed the acquisition of the licensing rights to market ZEVALIN, outside of the U.S., from Bayer Pharma AG. ZEVALIN is currently approved for sale in more than 40 countries for the treatment of B-cell non-Hodgkin lymphoma, including countries in Europe, Latin America and Asia. Under the agreement, Spectrum acquired marketing rights, patents, and access to existing

inventory of ZEVALIN from Bayer. Spectrum intends to utilize a combination of company resources and partnerships to support the product outside the U.S.

In July 2012, we initiated an international, randomized, placebo-controlled Phase 2 study evaluating lucanthone in primary therapy for Glioblastoma Multiforme. An orally administered small molecule, lucanthone inhibits topoisomerase II and AP endonuclease and has been shown to sensitize tumor cells to radiation and chemotherapy by inhibiting DNA repair.

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

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

Table of Contents

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

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

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

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

Through the above-referenced agreements and our continued efforts, we continue to build a global pharmaceutical organization in 2013. For two of our non-U.S. business entities, Spectrum Pharma Canada, Inc., a Canadian affiliate headquartered in the Province of Quebec, Canada, and OncoRx Pharma Private Ltd., a wholly-owned Indian subsidiary headquartered in Mumbai, India, we continue to grow these entities in an effort to facilitate the opening of clinical trials sites in these countries to advance the clinical development of our products at a reduced cost. In connection with our acquisition of the ZEVALIN rights outside of the U.S. we have formed entities in the Cayman Islands, Netherlands and Japan.

Product Portfolio

We have a product portfolio consisting of both commercial stage and development stage products. While we are committed to growing the sales of our marketed products, we strive to maintain a robust pipeline of products under development to bring to market.

Table of Contents

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

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

Overview of Cancer

According to the American Cancer Society's publication *Cancer Facts & Figures 2012*, cancer is the second leading cause of death in the U.S., accounting for approximately 25% of all deaths. In the U.S., approximately 1.64 million new cancer cases were expected to be diagnosed in 2012 and over 577,000 persons were expected to die from the disease in 2012. Accordingly, there is significant demand for improved and novel cancer treatments.

Cancer develops when cells in a part of the body begin to grow out of control. Although there are many kinds of cancer, they all start because of out-of-control growth of abnormal cells, or travel of these cells to sites outside of their normal environment. Normal body cells grow, divide, and die in an orderly fashion. During the early years of a person's life, normal cells divide more rapidly until the person becomes an adult. After that, cells in most parts of the body divide only to replace worn-out or dying cells and to repair injuries. Because cancer cells continue to grow and divide, they are different from normal cells. Instead of dying, they outlive normal cells and continue to form new abnormal cells in their typical environment or migrate to other sites in the body.

Cancer cells may develop because of damage to DNA. Most of the time, when DNA becomes damaged, the body is able to repair it. In cancer cells, the damaged DNA is not repaired. People can inherit damaged DNA, which accounts for inherited cancers. More often, however, a person's DNA becomes damaged by exposure to something in the environment, such as smoking or a virus.

Table of Contents

Cancer usually forms as a tumor. Some cancers, like leukemia, do not typically form tumor masses. Instead, these cancer cells involve the blood and blood-forming organs and circulate through other tissues where they may grow. Often, cancer cells travel to other parts of the body where they begin to grow and replace normal tissue. This process is called metastasis. Regardless of where a cancer may spread, however, it is always named for the place it began. For instance, breast cancer that spreads to the liver is still called breast cancer, not liver cancer.

Different types of cancer can behave very differently. For example, lung cancer and breast cancer are very different diseases. They grow at different rates and respond to different treatments. That is why people with cancer need treatment that is aimed at their particular kind of cancer. In the more recent era, certain similar or identical molecular abnormalities may be found in histologically different kinds of cancers, with treatment designed to resolve the molecular abnormality. Cancer is currently treated by surgery, chemotherapy, radiation therapy, hormonal therapy, biological therapy and immunotherapy. Cancer is referred to as refractory when it has not responded, or is no longer responding, to a treatment.

We are seeking novel drugs that address cancer or cancer related indications with significant unmet medical need, that:

are already approved for sale or have demonstrated initial safety and efficacy in clinical trials and/or we believe have a higher probability of regulatory approval than that of a typical compound at a similar stage of development;

target cancer indications with significant unmet medical need, where current treatments either do not exist or are not deemed to be effective; and

we believe we can acquire at a fair value based on our judgment of clinical success and commercial potential.

Development of Our Drug Products

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

FUSILEV is a novel folate analog formulation and the pharmacologically active isomer (the *levo*-isomer) of the racemic compound, calcium leucovorin. Isomers are compounds with the same molecular formula, but mirror image atomic structures. Leucovorin is a mixture of equal parts of both isomers: the pharmacologically active *levo*-isomer and the inactive *dextro*-isomer. Preclinical studies have demonstrated that the inactive *dextro*-isomer may compete with the active *levo*-isomer for uptake at the cellular level. By removing the inactive *dextro* form, the dosage of FUSILEV is one-half that of leucovorin and patients are spared the administration of an inactive substance.

FUSILEV rescue is indicated after high-dose methotrexate therapy in patients with osteosarcoma, and to diminish the toxicity and counteract the effects of impaired methotrexate elimination or inadvertent overdose of folic acid antagonists. FUSILEV has been designated as an orphan drug for its approved indications. Methotrexate is a widely

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

The American Cancer Society estimated that the 2012 incidence of colorectal cancer in the U. S. would be approximately 143,460 and is the third most common cancer in both men and women. Leucovorin is currently a standard combination agent with 5-FU in various colorectal cancer treatment regimens. Leucovorin potentiates the effects of 5-FU and its derivatives by stabilizing the binding of the drug's metabolite to its target enzyme, thus prolonging drug activity. There are peer-reviewed publications wherein FUSILEV is used in place of the leucovorin in combination with 5-FU containing regimens for adjuvant and advanced colorectal cancer and in combination with oxaliplatin and/or irinotecan for advanced disease. The National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology™ in colon cancer and rectal cancer have been updated to reflect that FUSILEV is available in the U.S. Additionally, in the fourth quarter of 2008, FUSILEV was listed and continues to be listed in the NCCN Drugs and Biologic Compendium for use in combination with high-dose methotrexate for the treatment of bone cancer (osteosarcoma and de-differentiated chondrosarcoma). The NCCN Drugs and Biologics Compendium is an important reference that has been recognized by United HealthCare as a formal guidance for coverage policy. In addition, Centers for Medicare & Medicaid Services, or CMS, announced in June 2008 that it would recognize the NCCN Drugs & Biologics Compendium as a source of information to determine which drugs may be covered under Medicare Part B.

Table of Contents

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

In April 2006, we acquired all of the oncology drug product assets of Targent, Inc. or Targent. Pursuant to the agreement, as of the end of 2011, Targent has received all payments provided for under the agreement based on the achievement of certain regulatory and sales milestones. We made such payments in a combination of our common stock and cash.

In May 2006, we amended and restated a license agreement with Merck & Cie AG, a Swiss corporation, which we assumed in connection with the acquisition of the assets of Targent. Pursuant to the license agreement with Merck & Cie, we obtained the exclusive license to use regulatory filings related to FUSILEV and a non-exclusive license under certain patents and know-how related to FUSILEV to develop, make, and have made, use, sell and have sold FUSILEV in the field of oncology in North America. In addition, we have the right of first opportunity to negotiate an exclusive license to manufacture, have manufactured, use and sell FUSILEV products outside the field of oncology in North America. Also, under the terms of the license agreement, we paid Merck & Cie \$100,000 for the achievement of FDA approval of FUSILEV. Merck & Cie is also eligible to receive a \$200,000 payment upon achievement of FDA approval of an oral form of FUSILEV, in addition to royalties in the mid-single digits based on a percentage of net sales. The term of the license agreement is determined on a product-by-product and country-by-country basis until royalties are no longer owed under the license agreement. The license agreement expires in its entirety after the date that we no longer owe any royalties to Merck & Cie. We have the unilateral right to terminate the license agreement, in its entirety or on a product-by-product or country-by-country basis, at any time for any reason and either party may terminate the license agreement due to material breach of the terms of the license agreement by or insolvency of the other party.

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

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

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

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

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

ZEVALIN (ibritumomab tiuxetan) Injection for intravenous use: In December 2008, we acquired rights to commercialize and develop ZEVALIN in the U.S., as the result of a transaction with Cell Therapeutics, Inc., or CTI as further described below. In April 2012, we acquired licensing rights to market ZEVALIN outside of the U.S from Bayer Pharma AG, or Bayer, as further described below.

Table of Contents

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

ZEVALIN was approved by the FDA in February of 2002 for the treatment of follicular non-Hodgkin's lymphoma, or NHL. ZEVALIN was approved as part of a ZEVALIN therapeutic regimen for treatment of relapsed or refractory, low-grade or follicular B-cell NHL, including patients with rituximab-refractory follicular NHL. For reference, the term "refractory" refers to lymphoma that does not respond to a particular therapy. The term "relapsed" refers to lymphoma that returns after initially responding to therapy. The terms "low-grade" and "follicular" refer to types of lymphoma tumors as determined by laboratory and microscopy tests, which have an indolent (slow growing) clinical course. Rituximab is a monoclonal antibody that specifically recognizes a particular part of a B-cell also called the CD 20 antigen, and is used as monotherapy or in combination with other agents for the treatment of B-cell NHL.

NHL is caused by the abnormal proliferation of white blood cells and normally spreads through the lymphatic system, a system of vessels that drains lymphatic fluid from the peripheral tissues and returns lymphatic fluid to circulation. There are many different types of NHL which can be divided into aggressive NHL, a more rapidly spreading and refractory form of the disease, and indolent NHL, which progresses more slowly. NHL can be classified as either B-cell or T-cell NHL. According to the National Cancer Institute's SEER database there were nearly 400,000 people in the U.S. with NHL in 2004. The American Cancer Society estimated that in the U. S. 70,130 people were expected to be newly diagnosed with NHL in 2012. Additionally, approximately 18,940 were expected to die from this disease in 2012.

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

The sBLA was based upon data from the multinational, randomized Phase 3 First-line Indolent Trial, or FIT, which evaluated the efficacy and safety of a single infusion of ZEVALIN in 414 patients with CD20-positive follicular NHL who had achieved a partial response or a complete response after receiving one of the standard first-line chemotherapy regimens. The FIT trial demonstrated that when used as a first-line consolidation therapy for patients with follicular NHL, ZEVALIN significantly improved the median progression-free survival time from 18 months (control arm) to 38 months (ZEVALIN arm) ($p < 0.0001$).

The primary investigators of the study concluded that ZEVALIN consolidation of first remission in advanced stage follicular NHL is highly effective, resulting in a total complete response (CR + CRu) rate of 87 percent and prolongation of median progression-free survival by almost two years, with a toxicity profile comparable to that seen with ZEVALIN's use in relapsed or refractory indications. In September 2009, we received FDA approval for the sBLA.

Additionally, in November 2009, the Centers for Medicaid & Medicare Services or the CMS decided that ZEVALIN should be reimbursed under an Average Sales Price, or ASP, methodology in the Hospital Outpatient Prospective Payment System, or HOPPS, and issued a corresponding proposed rule, which went into effect on January 1, 2010. The ASP methodology is widely used for injectable chemotherapy drugs and creates a consistent reimbursement

standard in the hospital setting.

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

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

On December 15, 2008, we closed a transaction to form a 50/50 owned joint venture in an entity called RIT Oncology, LLC or RIT, with CTI. CTI previously acquired the U.S. rights to develop, market and sell ZEVALIN from Biogen Idec, Inc., or Biogen on December 21, 2007.

Table of Contents

Upon entering into the joint venture arrangement, CTI contributed the ZEVALIN product assets to RIT in exchange for a 50% membership interest in RIT and the cash payments to CTI noted below. CTI received an initial cash payment of \$7.5 million at the closing of the joint venture transaction on December 15, 2008, and received an additional \$7.5 million cash payment in early January 2009. CTI also had the option to sell its remaining 50% membership interest in RIT to us, subject to adjustment for any amounts owed between RIT and CTI at the time of sale. CTI exercised this Put option in February 2009. On March 15, 2009, we entered into an agreement with CTI to complete such sale for an aggregate amount of \$16.5 million subject to certain adjustments for, among other things, payables determined to be owed between CTI and RIT. CTI disputed the adjustments, but in a May 2009 arbitration proceeding, we were awarded approximately \$4.3 million. As a result of the sale, we own 100% of RIT and are its sole member and therefore, we have, through licenses, all of the U.S. rights to ZEVALIN.

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

an amendment to the original asset purchase agreement between CTI and Biogen, referred to as the CTI/Biogen Agreement, modifying future milestone payments. Pursuant to the terms of the agreement, as amended, (i) upon the achievement of the specified FDA approval milestone, which was achieved in 2009, RIT (as successor to CTI) paid Biogen an additional amount of \$5.5 million, (ii) RIT may be required to make an additional \$10.0 million milestone payment upon the achievement of an additional FDA approval milestone, and (iii) RIT is required to make yearly royalty payments determined as a mid-single to mid-teen digits percentage of yearly net sales for the preceding year, increasing with the passage of time, with specific rates subject to confidential treatment pursuant to an order by the SEC. The agreement has an indefinite term and is no longer subject to termination; provided, however, that the royalty obligations automatically terminate upon the latest to occur of expiration of the subject patents, the sale by a third party of a biosimilar product in the U.S. or December 31, 2015. CTI's rights and obligations, including its payment obligations to Biogen, including royalties on net sales of ZEVALIN and an additional regulatory milestone payment, under both the CTI/Biogen Agreement and the amendment were assigned to and assumed by RIT in connection with the closing of the joint venture transaction.

an amendment to the original supply agreement between Biogen and CTI, referred to as the CTI/Biogen Supply Agreement, modifying certain of the pricing and manufacturing technology transfer terms contained in the CTI/Biogen Supply Agreement and also providing that the term of the agreement may be shortened in some instances in the event of a mid-term manufacturing technology transfer. Pursuant to the terms of this agreement, as amended, we are required to purchase from Biogen certain kits to make single doses as part of one treatment to a patient, of either (i) Indium-111 Ibritumomab Tiuxetan (In-111 ZEVALIN) or (ii) Yttrium-90 Ibritumomab Tiuxetan (Y-90 ZEVALIN) or packages containing one dose of each for sale to end-users in the U.S. at a cost plus manufacturing price, with specific rates subject to confidential treatment pursuant to an order by the SEC. There are no milestone or royalty payments required pursuant to this agreement. The term of the agreement is until a manufacturing technology transfer occurs. Either party may generally terminate this agreement due to a bankruptcy of the other party or due to such other party's material noncompliance with the agreement or certain other related agreements. CTI's rights and obligations, including its payment obligations to Biogen, under both the CTI/Biogen Supply Agreement and the amendment were

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

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

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

Table of Contents

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

On April 1, 2012, through a subsidiary, Spectrum Pharmaceuticals Cayman, L.P., we completed the acquisition of licensing rights to market ZEVALIN outside of the U.S., referred to as the ZEVALIN Ex-US Rights, from Bayer Pharma AG, or Bayer. Pursuant to the terms of the agreement, Spectrum acquired all rights including marketing, selling, intellectual property and access to existing inventory of ZEVALIN from Bayer. We currently market ZEVALIN in the U.S. and this agreement expands our commercial efforts to the rest of the world. ZEVALIN is currently approved in more than 40 countries outside the U.S. for the treatment of B-cell non-Hodgkin lymphoma, including countries in Europe, Latin America and Asia. In consideration for the rights granted under the agreement, concurrent with the closing, Spectrum paid Bayer a one-time fee of Euro 19 million or US \$25.4 million and will pay Bayer royalties based on a mid-teen digits percentage of net sales of the licensed products in all territories worldwide except the U.S., with specific rates subject to confidential treatment pursuant to an order by the SEC. Under the agreement, we also acquired access to existing inventory of ZEVALIN and concurrent with the closing, entered into certain ancillary agreements including but not limited to a transition services agreement to transition the business. Unless earlier terminated, the term of the agreement continues until the expiration of our royalty payment obligations which, in turn, run until the last-to-expire patent covering the sale of a licensed product in the relevant country or fifteen (15) years from the date of first commercial sale of the licensed product in such country, whichever is longer. This agreement may be terminated in the event of a material default, which is defined to include: (i) our failure to timely pay royalty payments under this agreement or payments under certain related agreements; (ii) our insolvency; and (iii) our breach and the resulting termination of an Amended and Restated License Agreement between Biogen and Bayer, dated as of January 16, 2012.

Apaziquone: Apaziquone is an anti-cancer agent that becomes activated by certain enzymes often present in higher amounts in cancer cells than in normal cells. It is currently being investigated for the treatment of NMIBC, which is a cancer that is only in the innermost layer of the bladder and has not spread to deeper layers of the bladder.

The American Cancer Society estimated that the 2012 incidence and prevalence of bladder cancer in the U.S. would be approximately 73,510 and over 500,000 respectively. According to Botteman et al., (PharmacoEconomics 2003), bladder cancer is the most expensive cancer to treat on a lifetime basis.

The initial treatment of this cancer is to attempt a complete surgical removal of the tumor. However, bladder cancer is a highly recurrent disease with approximately 75% of patients recurring within 5 years, and a majority of patients recurring within 2 years. This high recurrence rate is attributed to: (1) the highly implantable nature of cancer cells

that are dispersed during surgery, (2) incomplete tumor resection, and (3) tumors present in multiple locations in the bladder which may be missed or too small to visualize at the time of resection. Despite evidence in the published literature and guidance from the American and European Urology Associations, instillation of a chemotherapeutic agent immediately following surgery is not a standard clinical practice. Currently, there are no FDA approved drugs for this indication which may, in part, explain the difference between the literature and urology guidelines and actual clinical management of this disease. For more than 30 years, no new drugs have been introduced in the market for treatment of NMIBC. An immediate instillation of apaziquone may help by (1) reducing tumor recurrence by destroying dispersed cancer cells that would otherwise re-implant onto the inner lining of the bladder, (2) by destroying remaining cancer cells at the site of tumor resection (also known as chemo-resection), and (3) by destroying tumors not observed during resection (also known as chemo-ablation).

Table of Contents

Apaziquone is a bio-reductive alkylating indoloquinone that is enzymatically activated by enzymes that are over expressed by bladder tumors. Pharmacokinetic studies have verified that apaziquone is rarely detectable in the bloodstream of patients when it is administered either after surgical resection or as a part of a delayed multi-instillation protocol. Apaziquone is inactivated in the systemic circulation by the red blood cell fraction. The proposed dose therefore carries a minimal risk of systemic toxicity which could arise from absorption of a drug through the bladder wall into the bloodstream. Additionally, the current proposed dose is a fraction of the systemic toxic dose. These features of apaziquone are distinct from other intravesical agents currently in use for the treatment of recurrent bladder cancer.

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

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

In September 2005, we initiated an open label, multi-center clinical study in Europe in high-risk NMIBC in 53 patients. Patients with high-risk NMIBC usually have more aggressive bladder cancer with higher incidence of recurrence and/or progression to a more invasive stage, where the cancer invades the muscle wall of the bladder, which may require total surgical removal of the bladder. Apaziquone was well-tolerated over multiple instillations in this study of patients with high-risk superficial bladder cancer. At 18 months follow up 55% of the patients were recurrence free.

In 2006, we performed a 20 patient pilot safety study in low-grade NMIBC. In this study, apaziquone was found to be well tolerated when a single 4 mg dose is given to patients immediately following surgery. In addition, there was no adverse effect on wound healing and apaziquone was not detected in the bloodstream.

In March 2007, we received agreement from the FDA for the design of a Phase 3 study protocol for the treatment of non-invasive bladder cancer under a special protocol assessment procedure. The development plan for apaziquone is two randomized, double-blind, placebo-controlled Phase 3 clinical trials, each with 562 evaluable patients with TaG1-G2 (low-grade) NMIBC. Patients are being randomized in a one-to-one ratio to apaziquone or placebo. Under the protocol, the patients are given a single 4 mg dose following surgical removal of the tumors. The primary endpoint is a statistically significant difference ($p < 0.05$) in the rate of tumor recurrence at year two between the apaziquone patient group and the placebo group. The first study began during the second quarter of 2007, and the second very similar study began during the third quarter of 2007. In 2008, we received scientific advice from the European Medicines Agency, or the EMEA whereby the EMEA agreed that the two Phase 3 studies as designed should be sufficient for a regulatory decision regarding European registration. In December 2009, we achieved our goal of completing enrollment for both Phase 3 clinical trials. In April 2012, we announced that the single instillation Phase 3 clinical trials for apaziquone did not meet their primary endpoint however the pooled data from the studies did show a statistically significant treatment effect. A meeting with the FDA was held in December 2012 to discuss the results from these clinical trials. Based on the discussions with the FDA, we understand that the FDA can accept the NDA filing with the current Phase III data and will likely convene an Advisory Committee meeting. Further, based on

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

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

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

Table of Contents

In October, 2008, we entered into a license, development, supply and distribution agreement with Allergan pursuant to which we and Allergan agreed to collaboration for the development and commercialization of a formulation of apaziquone suitable for use in treating cancer or precancerous conditions via instillation. The agreement with Allergan also provided that Allergan had the exclusive right to make, develop and commercialize apaziquone for the treatment of bladder cancer, or pre-bladder cancer conditions worldwide except for Asia (as is defined in the agreement). We concurrently entered into a co-promotion agreement with Allergan providing for the joint commercialization of apaziquone in the U.S., whereby we and Allergan agreed to share equally all profits and commercialization expenses. Pursuant to the terms of the license, development, supply and distribution agreement, Allergan paid us an up-front non-refundable \$41.5 million at closing and was obligated to make additional payments based on the achievement of certain development, regulatory and commercialization milestones, of which \$1.5 million was achieved following completion of enrollment in clinical trials. In January 2013, we entered into an amendment to the license, development, supply and distribution agreement to restructure the collaboration with Allergan, with Spectrum buying back the rights it originally licensed to Allergan in the U.S., Europe and other territories in exchange for a tiered single digit royalty not to exceed mid-single digits on certain products containing apaziquone, and Allergan being relieved of its obligations for development, commercialization and other activities. The license, development, supply and distribution agreement, as amended, will continue until the expiration of the last royalty payment obligation in the last country in the Allergan territory (as defined in the agreement) with certain provisions surviving.

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

Also in November 2009, we entered into a collaboration agreement with Handok Pharmaceuticals for the development and commercialization of apaziquone in North and South Korea. Under the terms of the Handok collaboration agreement, Handok paid us an up-front payment of \$1.0 million and agreed to make additional milestone payments of up to \$18.6 million based on the achievement of certain regulatory and commercialization milestones. Handok received rights to apaziquone for the treatment of NMIBC in North and South Korea. Additionally, Handok will conduct the apaziquone clinical trials in North and South Korea pursuant to a development plan and will be responsible for all expenses relating to the development and

commercialization of apaziquone in North and South Korea.

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

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

Table of Contents

Based on the data from past and ongoing studies, we believe there are many potential attributes associated with belinostat that separate it from other currently marketed HDACs, including efficacy when used alone and in combination, less toxicities (when compared to other currently-marketed HDACs), including less bone marrow toxicity, and a lack of other severe side effects, such as mucositis, that may enable full dose combinations of this drug with several other cytotoxic agents. Hence, belinostat is currently being investigated in multiple indications, both as monotherapy and in combination with other treatment regimens. Numerous studies have been conducted, and are ongoing, through the National Cancer Institute, or the NCI, and other well-known oncologic academic institutions. Additionally, we plan on a comprehensive development program for belinostat, which includes both hematologic indications, such as PTCL, and solid tumor indications, such as ovarian cancer, colorectal cancer and non-small cell lung cancer. Based upon the foregoing, we believe belinostat potentially has broad applicability and hence, commercial potential beyond that of currently marketed HDACs.

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

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

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

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

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

commercial product.

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

Ozarelix: Ozarelix is a Luteinizing Hormone Releasing Hormone, or LHRH, antagonist (a substance that blocks the effects of a natural hormone found in the body). Mechanistically, LHRH antagonists exert rapid inhibition of luteinizing hormone and follicle stimulating hormone with an accompanying rapid decrease in sex hormones and would therefore be expected to be effective in a variety of hormonally dependent disease states including ovarian cancer, prostate cancer, benign prostatic hyperplasia, or BPH, infertility, uterine myoma and endometriosis.

Table of Contents

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

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