SPECTRUM PHARMACEUTICALS INC
Form 10-K
April 05, 2010

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

Form 10-K

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2009

Or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission File Number: 000-28782

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.)*
157 Technology Drive Irvine, California	**92618**
(Address of principal executive offices)	*(Zip Code)*

Registrant s telephone number, including area code:
(949) 788-6700
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
Common Stock Purchase Warrants	
Rights to Purchase Series B Junior Participating Preferred Stock	

Securities registered pursuant to Section 12(g) of the Act:
None

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

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 o No þ

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 þ No o

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 o No þ

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 o

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 o	Accelerated filer þ	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller Reporting company þ

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2009 was $310,033,876 based on the closing sale price of such common equity on such date.

As of March 29, 2010 there were 49,170,969 shares of the registrant s common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the Registrant s 2010 Annual Meeting of Stockholders, to be filed on or before April 30, 2010, are incorporated by reference into Part III of this Form 10-K.

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FORWARD-LOOKING STATEMENTS

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

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

Spectrum Pharmaceuticals, Inc.®, Fusilev®, Zevalin® and RenaZorb® are registered trademarks of Spectrum Pharmaceuticals, Inc. and its subsidiaries. Belinostat, Turning Insights Into Hope™, RIT Oncology, LLC™, RIT™, and our logos are trademarks owned by Spectrum Pharmaceuticals, Inc. and its subsidiaries. EOquin® is a registered trademark of Allergan, Inc. All other trademarks and trade names are the property of their respective owners.

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PART I

Item 1. *Business*

Overview

We are a commercial stage biopharmaceutical company committed to developing and commercializing innovative therapies with a primary focus in the areas of hematology-oncology and urology. We have a fully developed commercial infrastructure that markets and sells two drugs in the United States, Zevalin® and Fusilev®. We have several drug candidates in development, the most advanced of which are apaziquone (EOquin®), which is presently being studied in two large Phase 3 clinical trials for non-muscle invasive bladder cancer (NMIBC) under a strategic collaboration with Allergan; and belinostat, a drug we recently partnered with TopoTarget A/S to jointly develop. Belinostat is being studied in multiple indications, including a Phase 2 registrational trial for relapsed or refractory Peripheral T-Cell Lymphoma (PTCL).

Our business strategy is comprised of the following initiatives:

> *Maximizing the growth potential of our marketed drugs, Zevalin* and *Fusilev*. Our near-term outlook largely depends on sales and marketing successes for our two marketed drugs. For Zevalin, our initial goal was to stabilize sales, which we believe we accomplished in 2009. With the approval by the U.S. Food and Drug Administration (FDA) for a significantly larger indication in non-Hodgkin s lymphoma (NHL) in late 2009 and our success in addressing historical hurdles associated with the uptake of this drug, we believe we can grow sales in 2010 and beyond. For Fusilev, which we launched in August 2008, we were able to benefit from broad utilization in community clinics and hospitals through mid-2009. Our focus now is to obtain approval for Fusilev in advanced metastatic colorectal cancer, which could potentially increase the patient pool substantially. As part of its review of our supplemental new drug application (sNDA) the FDA has requested additional data which we expect to submit in the third quarter of 2010.

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

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

We have assembled a drug development infrastructure that is comprised of highly experienced and motivated MDs, PhDs, medical science liaisons and a complement of other support personnel to rapidly develop these drugs. During 2009, this team achieved our goal of completing enrollment in the two Phase 3 apaziquone trials (with more than 1,600 patients enrolled). We expect to continue to maximize the value of apaziquone through further developmental efforts and initiation of additional trials, which we aim to begin in 2010. In addition, this team will focus its efforts in rapidly advancing the development of belinostat by expediting the patient enrollment in the registrational trial for

PTCL and initiating additional studies in other indications in 2010.

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

Expanding commercial bandwidth through licensing and business development. It is our goal to identify new strategic opportunities that will create strong synergies with our currently marketed drugs and identify and pursue partnerships for out-licensing certain of our drugs in development. To this end, we will continue

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to explore strategic collaborations as these relate to drugs that are either in advanced clinical trials or are currently on the market. We believe that such opportunistic collaborations will provide synergies with respect to how we deploy our internal resources. In this regard, we intend to identify and secure drugs that have significant growth potential either through enhanced marketing and sales efforts or through pursuit of additional clinical development. We believe our recent in-licensing of belinostat, a novel histone deacetylase (HDAC) inhibitor, is demonstrative of such licensing and business development efforts outlined above.

Managing our financial resources effectively. We remain committed to fiscal discipline, a policy which has allowed us to become well capitalized among our peers, despite a very challenging capital markets environment in 2009. This policy includes the pursuit of non-dilutive funding options, prudent expense management, and the achievement of critical synergies within our operations in order to maintain a reasonable burn rate. Even with the continued build-up in operational infrastructure to facilitate the marketing of our two commercial drugs, we intend to be fiscally prudent in any expansion we undertake. In terms of revenue generation, we plan to become more reliant on sales from currently marketed drugs and intend to pursue out-licensing of select pipeline drugs in select territories, as discussed above. When appropriate, we may pursue other sources of financing, including non-dilutive financing alternatives. While we are currently focused on advancing our key drug development programs, we anticipate that we will make regular determinations as to which other programs, if any, to pursue and how much funding to direct to each program on an ongoing basis, based on clinical success and commercial potential, including termination of our existing development programs, especially if we do not expect value being driven from continued development. Our raising of over $100 million in equity financing in 2009 in a difficult financing environment, and our recent termination of the development of ozarelix in benign prostate hypertrophy (BPH), which resulted in planned development expense reduction, are recent examples of this strategy.

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 recently 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.

Restatement of Previously Issued Consolidated Financial Statements

In this Annual Report on Form 10-K, we have restated our previously issued consolidated financial statements and related disclosures for fiscal years ended December 31, 2007 and 2008, and each of the quarterly condensed consolidated financial statements on Form 10-Q for the periods ended March 31, 2008 through September 30, 2009 to reclassify warrant contracts based on a reassessment of the applicable accounting and classification.

The Company has historically accounted for warrants as equity instruments, pursuant to its, and Kelly & Company s (Kelly & Co.), the predecessor independent registered public accounting firm, interpretation and evaluation of applicable accounting guidance contained in Accounting Standards Codification (ASC) Topic 815 Derivatives and Hedging Contracts in Entity s Own Equity (ASC 815) (formerly known as Emerging Issues Task Force Issue 00-19, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock). Accordingly, in connection with warrants issued in registered offerings during 2005 and 2009, the Company classified the warrants as equity. In connection with the audit for the fiscal year 2009, the Company, in consultation with Ernst & Young LLP (Ernst & Young), the Company s current independent registered public accounting firm, reassessed the accounting classification of the warrants payment to ASC 815 based on certain terms of the warrants. The warrants provide that in the event the Company is unable to issue registered shares upon exercise, the warrant holders are entitled, under securities laws, to receive freely tradable shares pursuant to a cashless exercise provision.

However, based on interpretation of ASC 815, there is a required presumption of net cash settlement, as it is not within the control of the Company to provide registered shares, no matter how remote the probability. After several extensive discussions among the Company s management, Ernst & Young and the Company s outside legal advisors, as well as informal discussions with Staff of the Securities and Exchange Commission by the Company s management, it appears that the interpretation and applicability of this particular accounting pronouncement is complex and must be applied based on a strict reading of the authoritative

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literature without respect to probability. The Company s Audit Committee, together with management, in consultation with the Company s outside legal advisors, determined on March 30, 2010 that, notwithstanding the highly remote theoretical nature of the possibility of net cash settlement, the warrants should have originally been recorded as liabilities, measured at fair value, with changes in the fair values being recognized in the statement of operations. In this regard, the Company reassessed the accounting classification of the warrants issued in September 2005 pursuant to ASC 815, and in consultation with its predecessor auditor, Kelly & Co., determined that there should be consistent treatment of the warrants issued in September 2005 with the warrants issued in 2009, and concluded that such 2005 warrants should also be reclassified as a liability.

During meetings held on March 30, 2010, the Audit Committee, together with management, in consultation with Kelly & Co., the Company s independent registered public accounting firm during the years ended December 31, 2008 and 2007, concluded that the Company s previously filed consolidated financial statements for the fiscal years ended December 31, 2005, 2006, 2007 and 2008 on Form 10-K, each of the quarterly condensed consolidated financial statements on Form 10-Q for the periods ended March 31, 2008 through September 30, 2009, and the independent registered public accounting firm s reports on the financial statements and the effectiveness of internal control over financial reporting for the fiscal years ended December 31, 2007 and 2008, and all related earnings releases and similar communications issued by the Company, should no longer be relied upon.

The restatements reflect the reclassification of the warrants from equity to a liability in the following amounts, which represents the fair value of the warrants, as of the issuance dates, calculated using the Black-Scholes option pricing model.

Issuance Date	Number of Warrants Issued	Exercise Price	Expiration of Warrants	Fair Value of Warrants at Issuance Date (In thousands)
September 14, 2005	4,000,000	$ 6.62	September 14, 2011	$ 15,472
May 27, 2009	1,956,947	$ 5.11	February 25, 2010	$ 2,881
June 15, 2009	857,633	$ 5.83	March 15, 2010	$ 1,847
June 30, 2009	1,468,020	$ 7.10	March 30, 2010	$ 4,117
September 18, 2009	2,649,007	$ 7.55	June 20, 2010	$ 5,170

The revaluation of the warrants at each subsequent balance sheet date to fair value, results in a change in the carrying value of the liability, which change is recorded as Change in fair value of common stock warrant liability in the consolidated statement of operations. The net effect of these changes for fiscal years ended December 31, 2008 and 2007, and for each of the quarterly condensed consolidated financial statements on Form 10-Q for the periods ended March 31, 2008 through September 30, 2009 are as follows:

	Income (Loss) Resulting

Reporting Period		from Change in Fair Value of Common Stock Warrant Liability (In thousands)
Annual		
Year ended December 31, 2007	$	12,055
Year ended December 31, 2008	$	1,271
Interim (unaudited)		
Quarter ended March 31, 2008	$	520
Quarter ended June 30, 2008	$	916
Quarter ended September 30, 2008	$	45
Quarter ended December 31, 2008	$	(210)
Quarter ended March 31, 2009	$	(509)

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Reporting Period	Income (Loss) Resulting from Change in Fair Value of Common Stock Warrant Liability (In thousands)
Quarter ended June 30, 2009	$ (20,113)
Quarter ended September 30, 2009	$ 8,863

We have not amended our previously filed Annual Reports on Form 10-K for the fiscal years ended December 31, 2005, 2006, 2007 and 2008, or the Quarterly Reports on Form 10-Q for the periods ended September 30, 2005 through September 30, 2009 to reflect the restatements described in this Annual Report on Form 10-K, and thus the financial statements and related financial statement information contained in those reports should no longer be relied upon. Throughout this Annual Report on Form 10-K, all amounts presented from prior periods and prior period comparisons that have been revised are labeled as restated and reflect the balances and amounts on a restated basis.

Recent Developments

In 2009 and early 2010, we have executed on our business strategy that we described above. We discuss below the key developments during that period.

We recorded approximately $28.2 million in sales of our products for the year 2009. We successfully increased Zevalin sales to approximately $15.7 million in 2009 as compared to approximately $11 million by the predecessor owner of the product in 2008. We recorded approximately $0.3 million in Zevalin sales since we acquired the rights to fifty percent of the product in December 2008. We also recorded Fusilev sales of $12.5 million in 2009, compared to approximately $7.7 million in 2008. We believe that in 2010 and beyond, revenues from these products have the potential to significantly grow.

In September 2009, Zevalin received FDA approval for an expanded label for the treatment of patients with previously untreated follicular NHL who achieve a partial or complete response to first-line chemotherapy. This new and expanded indication supplements the 2002 FDA approval of Zevalin as treatment for patients with relapsed or refractory, low-grade or follicular B-cell NHL. Additionally, in November 2009, the Centers for Medicare and Medicaid Services (CMS) decided that Zevalin should be reimbursed under an Average Sales Price (ASP) methodology in the Hospital Outpatient Prospective Payment System (HOPPS) and issued a corresponding proposed rule, which became effective on January 1, 2010. The ASP methodology is widely used for injectable chemotherapy drugs and creates a consistent reimbursement standard in the hospital setting.

In October 2009, the FDA issued a Complete Response letter regarding the sNDA for Fusilev. In the Complete Response letter, the FDA recommended that we meet with them to discuss options for continuing to seek approval of Fusilev in advanced metastatic colorectal cancer. We promptly requested such a meeting, which occurred in January 2010. In that meeting, the FDA requested additional data which we expect to submit in the third quarter of 2010.

As for apaziquone, in November 2009, we entered into a collaboration agreement with Nippon Kayaku Co. Ltd. for the development and commercialization of apaziquone in Asia, with the exception of North and South Korea. In exchange, Nippon Kayaku paid Spectrum an up-front payment of $15 million and agreed to make additional payments of up to $136.0 million based on the achievement of certain regulatory and commercialization milestones contained in

the collaboration agreement, as well as royalties on net sales. Nippon Kayaku received exclusive rights to apaziquone for the treatment of NMIBC in Asia, including Japan and China. Under the terms of the Nippon Kayaku collaboration agreement, Nippon Kayaku will conduct the apaziquone clinical trials pursuant to a development plan, and will be responsible for all expenses relating to the development and commercialization of apaziquone in the Nippon Kayaku territory. As for South Korea, or the Republic of Korea, and North Korea, or the Democratic People s Republic of Korea, (collectively, Korea), we entered into a collaboration agreement with Handok Pharmaceuticals Co. Ltd. for the development and commercialization of apaziquone for the treatment of NMIBC. Under the terms of the Handok collaboration agreement, Handok paid us an up-front payment of

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$1.0 million and there are potential milestone payments of approximately $19 million, as well as royalties on net sales. The potential milestones will be based on the achievement of certain regulatory and commercialization milestones. Additionally, Handok will conduct the apaziquone clinical trials pursuant to a development plan and will be responsible for all expenses relating to the development and commercialization of apaziquone in North and South Korea.

In addition, in the fourth quarter of 2009, we completed enrollment of two Phase 3 pivotal clinical trials for apaziquone. The two trials enrolled more than 1,600 patients with non-muscle invasive bladder cancer. We received a $1.5 million milestone payment in January 2010 from Allergan for the completion of these clinical trials, per the terms of the collaboration agreement, which we entered into with Allergan on October 28, 2008.

In February 2010, we entered into a licensing and collaboration agreement with TopoTarget, for the development and commercialization of belinostat, a drug being studied in multiple indications, including a Phase 2 registrational trial for patients with PTCL. The licensing and collaboration agreement provides that we have the exclusive right to make, develop and commercialize belinostat in North America and India, with an option for China. In consideration for the rights granted under the licensing and collaboration agreement, we paid TopoTarget an up-front fee of $30 million. In addition, we will pay up to $313 million and one million shares of Spectrum common stock based on the achievement of certain development, regulatory and sales milestones, as well as double-digit royalties on net sales of belinostat.

In 2009, we raised net proceeds of approximately $95.8 million from the sale of 15,187,715 shares of our common stock, despite adverse global financial market conditions. We believe these funds, as well as the funds generated through the sales of our products and other non-dilutive funding in 2008, have resulted in our being well capitalized. At the end of 2009, we had approximately $125.0 million in cash, cash equivalents and marketable securities, which we believe will be sufficient to finance our anticipated capital and operating requirements for the next twelve months and beyond.

In August 2009, we acquired 100% of the rights to RenaZorb (a family of compounds represented by SP-014, also known as RZB-014), a lanthanum-based nanotechnology compound with potent and selective phosphate binding capabilities from Altair Nanotechnologies. Our acquisition of RenaZorb expands upon our 2005 license agreement with Altair, pursuant to which Altair granted us worldwide rights to Renazorb, but only for human uses. The August 2009 acquisition provides us with access to all uses of and intellectual property for the asset. In consideration for the acquisition, we paid Altair a total of $750,000 in restricted shares of common stock.

In January 2010, based upon the mixed results of our earlier Phase 2 study of ozarelix for the treatment of BPH and the recently announced failure of Aeterna Zentaris s large, Phase 3, registrational trial of cetrorelix (another LHRH antagonist), we discontinued development of ozarelix in BPH. We estimate that this discontinuation will result in a substantial reduction in future clinical development expenses. We will continue to look for alternative indications for the development of ozarelix.

We continued our efforts to build a global pharmaceutical organization in 2009. For two of our non-US business entities, Spectrum Pharma Canada, Inc., a Canadian affiliate headquartered in the Province of Quebec, Canada, and OncoRx Pharma Private Ltd., a wholly-owned Indian subsidiary headquartered in Mumbai, India, we continued to grow and establish these entities in an effort to facilitate the opening of clinical trials sites in these countries to continue the clinical development of our products at a reduced cost.

Product Portfolio

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

development to bring to the market.

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

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

Overview of Cancer

According to the American Cancer Society s publication *Cancer Facts & Figures 2009*, cancer is the second leading cause of death in the United States, accounting for approximately 25% of all deaths. In the United States, approximately 1.5 million new cancer cases were expected to be diagnosed in 2009 and over 562,000 persons were expected to die from the disease in 2009. Accordingly, there is significant demand for improved and novel cancer treatments.

Cancer develops when cells in a part of the body begin to grow out of control. Although there are many kinds of cancer, they all start because of out-of-control growth of abnormal cells. Normal body cells grow, divide, and die in an orderly fashion. During the early years of a person s life, normal cells divide more rapidly until the person becomes an adult. After that, cells in most parts of the body divide only to replace worn-out or dying cells and to

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repair injuries. Because cancer cells continue to grow and divide, they are different from normal cells. Instead of dying, they outlive normal cells and continue to form new abnormal cells.

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

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

Different types of cancer can behave very differently. For example, lung cancer and breast cancer are very different diseases. They grow at different rates and respond to different treatments. That is why people with cancer need treatment that is aimed at their particular kind of cancer. Cancer is currently treated by surgery, chemotherapy, radiation therapy, hormonal therapy, biological therapy and immunotherapy. Cancer is referred to as refractory when it has not responded, or is no longer responding, to a treatment.

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

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

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

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

Our drug products

Zevalin ([90Y]-ibritumomab tiuxetan): In December 2008, we acquired rights to commercialize and develop Zevalin in the United States, as the result of a transaction with Cell Therapeutics, Inc., (CTI) further described below.

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

The current Zevalin therapeutic regimen also requires a bioscan (also known as an imaging study) of the prospective patient prior to treatment with Y-90 Zevalin. For the bioscan, the patient is infused with In-111 Zevalin, the In-111 radioisotope combined with the CD20 MAB. In-111 Zevalin produces a kind of radiation called gamma emission,

which is very similar to the kind of radiation used to produce x-rays. Once infused with In-111, the prospective patient goes through a bioscan. The bioscan allows a physician to follow In-111 Zevalin as it travels within the prospective patient s body. Based upon the distribution of In-111 Zevalin (whether the In-111 Zevalin goes to certain unintended areas of the body), the physician may elect to not infuse the patient with Y-90 Zevalin. Many healthcare providers throughout the world who provide Zevalin therapy do not believe that the In-111 bioscan is a necessary part of the Zevalin therapeutic regimen. In the EU, most countries do not perform the In-111 bioscan prior to the Y-90 Zevalin infusion. Currently, we are working with the FDA to remove this bioscan requirement.

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

NHL is caused by the abnormal proliferation of white blood cells and normally spreads through the lymphatic system, a system of vessels that drains fluid from the body. There are many different types of NHL which can be divided into aggressive NHL, a rapidly spreading acute form of the disease, and indolent NHL, which progresses more slowly, and can be classified as either B-cell or T-cell NHL. According to the National Cancer Institute s SEER database there were nearly 400,000 people in the U.S. with NHL in 2004. The American Cancer Society estimated that in the United States 65,980 people were expected to be newly diagnosed with NHL in 2009. Additionally, approximately 19,500 were expected to die from this disease in 2009.

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

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

The primary investigators of the study concluded that Zevalin consolidation of first remission in advanced stage follicular NHL is highly effective, resulting in a total complete response (CR + CRu) rate of 87 percent and prolongation of median progression-free survival by almost two years, with a toxicity profile comparable to that seen with Zevalin s use in relapsed or refractory indications. Zevalin-treated patients had reversible and manageable Grade 3 or 4 hematologic side effects including neutropenia in 41 percent, thrombocytopenia in 51 percent, and anemia in 5 percent of patients. Non-hematologic toxicities were 24 percent Grade 3, 5 percent Grade 4, and Grade 3 4 infections were 8 percent.

In September 2009, we received FDA approval for the sBLA.

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

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

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

Upon entering into the joint venture arrangement, CTI contributed the Zevalin product assets to RIT in exchange for a 50% membership interest in RIT and the cash payments to CTI noted below. CTI received an initial cash payment of $7.5 million at the closing of the joint venture transaction on December 15, 2008, and received an additional $7.5 million cash payment in early January 2009. CTI also had the option to sell its remaining 50% membership interest in RIT to us, subject to adjustment for any amounts owed between RIT and CTI at the time of sale. CTI exercised this Put option in February 2009. On March 15, 2009, we entered into an agreement with CTI to complete such sale for an aggregate amount of $16.5 million subject to certain adjustments for, among other things, payables determined to be owed between CTI and RIT. CTI

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disputed the adjustments, but in a May 2009 arbitration proceeding, we were awarded approximately $4.3 million. As a result of the sale, we own 100% of RIT and are its sole member and therefore, we have, through licenses, all of the U.S. rights to Zevalin.

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

an amendment to the original asset purchase agreement between CTI and Biogen (CTI/Biogen Agreement), modifying future milestone payments, to provide that (i) concurrently with the execution of the amendment CTI was required to pay Biogen $0.2 million (which was reimbursed to CTI by RIT from the initial capital contributions made by CTI and us), (ii) upon the December 2008 closing of the joint venture transaction, CTI was required to pay Biogen an additional $2.0 million (which was paid by RIT as successor to CTI under the amendment), (iii) upon the achievement of the specified FDA approval milestone, RIT (as successor to CTI) was required to pay Biogen an additional amount of $5.5 million if the milestone event occurred in 2009 (provided that RIT may elect to defer any such payment until January 1, 2010, but upon such election the required payment will increase to $6.0 million), $7.0 million if the milestone event occurs in 2010, $9.0 million if the milestone event occurs in 2011, or $10.0 million if the milestone event occurs in 2012 or later. As disclosed above, we received FDA approval for the treatment of patients with previously untreated follicular NHL who achieve a partial or complete response to first-line chemotherapy and in accordance with the amendment, we paid Biogen $5.5 million. No other material terms of the CTI/Biogen Agreement were modified. CTI s rights and obligations, including its payment obligations to Biogen, including royalties on net sales of Zevalin and an additional regulatory milestone payment, under both the CTI/Biogen Agreement and the amendment were assigned to and assumed by RIT in connection with the closing of the joint venture transaction.

an amendment to the original supply agreement between Biogen and CTI (CTI/Biogen Supply Agreement), modifying certain of the pricing and manufacturing technology transfer terms contained in the CTI/Biogen Supply Agreement and also providing that the term of the agreement may be shortened in some instances in the event of a mid-term manufacturing technology transfer. CTI s rights and obligations, including its payment obligations to Biogen, under both the CTI/Biogen Supply Agreement and the amendment were assigned to and assumed by RIT in connection with the closing of the joint venture transaction.

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

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

pursuant to the transfer of Zevalin assets from CTI to RIT in December 2008, RIT assumed certain license and sublicense agreements with various third parties related to Zevalin intellectual property under which RIT is required to make certain payment obligations including milestone payments and royalties.

Fusilev® (levoleucovorin) for injection: On March 7, 2008, our new drug application (NDA) for our proprietary drug Fusilev was approved by the FDA. We commercially launched Fusilev in August 2008, with an in-house sales force and commercialization team. Subsequent to the launch, in November 2008, we received a unique J-code for Fusilev

from CMS, which went into effect on January 1, 2009. The J-code is a unique, product-specific billing code that assists providers (*e.g.*, physicians that prescribe Fusilev) in obtaining reimbursement for Fusilev.

Fusilev is a novel folate analog formulation and the pharmacologically active isomer (the *levo*-isomer) of the racemic compound, calcium leucovorin. Isomers are compounds with the same molecular formula, but mirror image atomic structures. Leucovorin is a mixture of equal parts of both isomers: the pharmacologically active *levo*-isomer and the inactive *dextro*-isomer. Preclinical studies have demonstrated that the inactive *dextro*-isomer may

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compete with the active *levo*-isomer for uptake at the cellular level. By removing the inactive *dextro* form, the dosage of Fusilev is one-half that of leucovorin and patients are spared the administration of an inactive substance.

Fusilev rescue is indicated after high-dose methotrexate therapy in patients with osteosarcoma, and to diminish the toxicity and counteract the effects of impaired methotrexate elimination or inadvertent overdose of folic acid antagonists. Fusilev has been designated as an orphan drug for its approved indications. Methotrexate is a widely used anti-cancer drug. It is a therapeutic option in the treatment of solid tumors and hematological malignancies, such as NHL. In addition, methotrexate is also used to treat autoimmune diseases such as rheumatoid arthritis, psoriasis and some rare opportunistic infections.

In mid-year 2008, we filed an NDA amendment for Fusilev tablets. Following the tablet submission, in October 2008, we filed a sNDA for Fusilev (levoleucovorin) for injection in combination with 5-FU-containing regimens in the treatment of colorectal cancer. In October 2009, the FDA issued a Complete Response letter regarding the sNDA for Fusilev. In the Complete Response letter, the FDA recommended that we meet with them to discuss options for continuing to seek approval of Fusilev in advanced metastatic colorectal cancer. We promptly requested such a meeting, which occurred in January 2010. In that meeting, the FDA requested additional data which we expect to submit in the third quarter of 2010.

Leucovorin is currently a standard combination agent with 5-FU in various colorectal cancer treatment regimens. Leucovorin potentiates the effects of 5-FU and its derivatives by stabilizing the binding of the drug s metabolite to its target enzyme, thus prolonging drug activity. There are peer-reviewed publications wherein Fusilev is used in place of the leucovorin in combination with 5-FU containing regimens for adjuvant and advanced colorectal cancer and in combination with oxaliplatin and/or irinotecan for advanced disease. The National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology™ in colon cancer and rectal cancer have been updated to reflect that Fusilev is available in the United States. Additionally, in the fourth quarter of 2008, Fusilev was listed and continues to be listed in the NCCN Drugs and Biologic Compendium for use in combination with high-dose methotrexate for the treatment of bone cancer (osteosarcoma and de-differentiated chrondrosarcoma). The NCCN Drugs and Biologics Compendium is an important reference that has been recognized by United HealthCare as a formal guidance for coverage policy. In addition, CMS announced in June 2008 that it would recog