SPECTRUM PHARMACEUTICALS INC
Form 10-Q
May 10, 2010

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2010

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

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 during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes o No 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 definition 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	Smaller reporting company o

(Do not check if a 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 o No þ

Indicate the number of shares outstanding of each of the issuer s classes of Common Stock as of the latest practicable date:

Class	**Outstanding at May 3, 2010**
Common Stock, $.001 par value	49,497,839

TABLE OF CONTENTS

Table of Contents

SPECTRUM PHARMACEUTICALS, INC.
FORM 10-Q
For the Three-month Period ended March 31, 2010
(Unaudited)

PART I FINANCIAL INFORMATION

ITEM 1. Consolidated Financial Statements

Statement Regarding Financial Information

The accompanying unaudited condensed consolidated financial statements of Spectrum Pharmaceuticals, Inc. included herein have been prepared by management pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). Certain information normally included in the consolidated financial statements prepared in accordance with Generally Accepted Accounting Principles in the United States (GAAP), has been condensed or omitted pursuant to such rules and regulations. However, we believe that the disclosures are adequate to make the information presented not misleading. The results of operations for the three month period ended March 31, 2010 are not necessarily indicative of the results to be expected for the year ending December 31, 2010 or any other period(s).

We recommend that you read the unaudited condensed consolidated financial statements included herein in conjunction with the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2009, filed with the SEC on April 5, 2010. The consolidated financial statements contained therein included restatements of previously reported financial statements and related disclosures for each of the quarterly condensed consolidated financial statements on Form 10-Q for the periods ended March 31, 2009 through September 30, 2009 to record common stock warrants as a liability based on a reassessment of the applicable accounting and classification. All financial information contained herein, related to such prior restated quarterly periods, are as restated .

Table of Contents

SPECTRUM PHARMACEUTICALS, INC.
Condensed Consolidated Balance Sheets
(Unaudited)
(In Thousands, Except Share and Per Share Data)

	March 31, 2010	December 31, 2009
Assets		
Current Assets:		
Cash and cash equivalents	$ 35,637	$ 82,336
Marketable securities	49,482	31,005
Accounts receivable, net	6,259	8,658
Inventories, net	2,848	3,230
Prepaid expenses and other current assets	993	1,028
Total Current Assets	95,219	126,257
Bank certificates of deposit & treasuries	13,344	11,438
Property and equipment, net	2,090	1,928
ZEVALIN related intangible assets, net	32,395	33,325
Other assets	178	185
Total Assets	$ 143,226	$ 173,133
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable and other accrued obligations	$ 14,538	$ 16,606
Accrued compensation	1,588	3,360
Current portion of deferred revenue	12,300	8,300
Common stock warrant liability	5,060	6,635
Accrued drug development costs	3,717	4,598
Total Current Liabilities	37,203	39,499
Capital lease obligations, net of current portion	62	69
Deferred revenue and other credits, net of current portion	33,890	24,943
ZEVALIN related contingent obligations	298	298
Total Liabilities	71,453	64,809
Commitments and contingencies		
Stockholders Equity:		
Preferred Stock, par value $0.001 per share, 5,000,000 shares authorized:		
Series B Junior participating preferred stock, 1,000,000 shares authorized, no shares issued and outstanding		
Series E Convertible voting preferred stock, 2,000 shares authorized, stated value $10,000 per share, $0.8 million aggregate liquidation value, issued and outstanding, 68 shares at March 31, 2010 and December 31, 2009	419	419
Common stock, par value $0.001 per share, 100,000,000 shares authorized; issued and outstanding, 49,187,073 and 48,926,314 shares at March 31, 2010	49	49

and December 31, 2009		
Additional paid-in capital	371,977	369,482
Accumulated other comprehensive loss	(102)	(70)
Accumulated deficit	(300,570)	(261,556)
Total Stockholders Equity	71,773	108,324
Total Liabilities and Stockholders Equity	$ 143,226	$ 173,133

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these statements.

Table of Contents

SPECTRUM PHARMACEUTICALS, INC.
Condensed Consolidated Statements of Operations
(Unaudited)
(In Thousands, Except Share and Per Share Data)

	Three Months Ended	
	March 31, 2010	**March 31, 2009**
Revenues:		
Product sales, net	$ 7,122	$ 12,038
License and contract revenue	3,967	2,125
Total revenues	$ 11,089	$ 14,163
Operating expenses:		
Cost of product sales (excludes amortization of purchased intangibles shown below)	$ 3,245	$ 1,834
Selling, general and administrative	10,862	6,351
Research and development	36,544	5,654
Amortization of purchased intangibles	930	950
Total operating expenses	51,581	14,789
Loss from operations	(40,492)	(626)
Change in fair value of common stock warrant liability	1,575	(509)
Other (loss) / income, net	(97)	104
Pre-tax net loss	(39,014)	(1,031)
Income tax expense		
Net income attributable to non-controlling interest		1,146
Net (loss) income attributable to Spectrum Pharmaceuticals, Inc. stockholders	$ (39,014)	$ 115
Net (loss) income per share		
Basic	$ (0.80)	$ 0.00
Diluted	$ (0.80)	$ 0.00
Weighted average common shares outstanding		
Basic	48,667,653	31,952,523
Diluted	48,667,653	32,157,425

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these statements.

5

Table of Contents

SPECTRUM PHARMACEUTICALS, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In Thousands)

	Three Months Ended	
	March 31, 2010	March 31, 2009
Cash Flows From Operating Activities:		
Net (loss) income	$ (39,014)	$ 115
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:		
Amortization of deferred revenue	(3,967)	(2,125)
Depreciation and amortization	1,064	136
Share-based compensation expense	2,475	968
Fair value adjustments of common stock warrants	(1,575)	509
Fair value of common stock issued in connection with drug license		185
Non-controlling interest in consolidated entities		(1,146)
Changes in operating assets and liabilities:		
Accounts receivable	2,399	(1,304)
Inventories	382	(53)
Prepaid expenses and other current assets	35	148
Other assets		
Accounts payable and other accrued obligations	(2,075)	3,942
Accrued compensation	(1,772)	(1,035)
Accrued drug development cost	(881)	
Deferred revenue and other credits	16,915	(25)
Net cash (used in) provided by operating activities	(26,014)	315
Cash Flows From Investing Activities:		
Net (purchases) sales of marketable securities	(20,408)	18,112
Investment in ZEVALIN acquisition		(24,050)
Purchases of property and equipment	(296)	(172)
Net cash used in investing activities	(20,704)	(6,110)
Cash Flows From Financing Activities:		
Proceeds from exercise of stock options	19	
Net cash provided by financing activities	19	
Net decrease in cash and cash equivalents	(46,699)	(5,795)
Cash and cash equivalents, beginning of period	82,336	9,860
Cash and cash equivalents, end of period	$ 35,637	$ 4,065
Supplemental Cash Flow Information:		
Interest paid	$ 18	$ 7

Income taxes paid	$	148	$	45
Schedule of Non-Cash Investing and Financing Activities:				
Fair value of common stock issued in connection with drug license	$		$	185
Fair value of restricted stock granted to employees and directors	$	977	$	182
Fair value of stock issued to match employee 401k contributions	$	168	$	108
Fair value of equity awarded to consultants	$	219	$	111

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these statements.

Table of Contents

SPECTRUM PHARMACEUTICALS, INC.
Notes to Condensed Consolidated Financial Statements
March 31, 2010
(Unaudited)

1. Business and Basis of Presentation

Business

Spectrum Pharmaceuticals, Inc. (Spectrum, the Company, we, our, or us) is a commercial stage biopharmac 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 proprietary products 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 strategic collaborations with Allergan, Inc. (Allergan), Nippon Kayaku Co. Ltd. (Nippon Kayaku), and Handok Pharmaceuticals Co. Ltd. (Handok), and Belinostat, a drug being co-developed with TopoTarget A/S (TopoTarget), and which is being studied in multiple indications including a Phase 2 registrational trial for relapsed or refractory peripheral T-cell lymphoma (PTCL).

The following is a brief update of our most advanced products as of March 31, 2010. For a more detailed description of these and our other drugs in development, refer to our Annual Report on Form 10-K for the year ended December 31, 2009 filed with the SEC on April 5, 2010.

ZEVALIN®: ([90Y]-ibritumomab tiuxetan) (ZEVALIN): For the three-month periods ended March 31, 2010 and 2009, we recorded net revenues of approximately $6.5 million and $2.6 million, respectively, from sales of ZEVALIN.

On September 3, 2009, the United States Food and Drug Administration (FDA) approved our supplemental Biologics License Application, which allows the use of ZEVALIN as part of a first line therapy for treatment of patients with previously untreated follicular non-Hodgkin s lymphoma (NHL) who achieve a partial or complete response to chemotherapy, a substantially larger patient population with follicular NHL. Previously, ZEVALIN was approved by the FDA and marketed by us for patients with relapsed or refractory, low-grade or follicular B-cell NHL, including patients who have rituximab-refractory follicular NHL. In November 2009, the Centers for Medicare & Medicaid Services finalized a policy to allow reimbursement for ZEVALIN®, in the Hospital Outpatient Prospective Payment System, based on the Average Sales Price methodology applicable to other injectable drugs and biologicals. This reimbursement methodology went into effect on January 1, 2010.

FUSILEV®: (levoleucovorin) for injection (FUSILEV): For the three-month periods ended March 31, 2010 and 2009, we recorded net revenues of $0.6 million and $9.4 million, respectively, from sales of FUSILEV.

FUSILEV is the only commercially available drug containing only the pure active L-isomer of racemic (L and R forms) leucovorin. In October 2008, we filed a supplemental New Drug Application (sNDA) for advanced metastatic colorectal cancer. In October 8, 2009, we received a Complete Response letter from the FDA regarding our sNDA. We met with the FDA in January 2010. During that meeting, the FDA requested additional data which we expect to submit before the end of 2010.

Apaziquone: During the three-months ended March 31, 2010, we recorded approximately $2.1 million of licensing revenue from the amortization of the upfront $41.5 million fee that we received from Allergan in October 2008. Further, pursuant to our 2009 collaboration agreement with Nippon Kayaku and Handok Pharmaceuticals, we received $16 million in upfront milestone payments. In light of our obligations under these agreements, including procurement, manufacture and the supply of materials for clinical studies, ongoing development and regulatory guidance, we have deferred the recognition as revenue of the $16 million and we are amortizing the $16 million over a period of 4 years. We recorded approximately $1.0 million of licensing revenue from the amortization of the upfront $16 million fee that we received from Nippon Kayaku and Handok.

Pursuant to our October 2008 strategic collaboration agreement with Allergan to co-develop and co-market Apaziquone for bladder cancer, we continue to conduct the two Phase 3 registrational trials pursuant to a joint development plan, with Allergan bearing 65% of these development costs. As such, during each of the three months ended March 31, 2010 and 2009, Allergan reimbursed us approximately $2.7 million of research and development

costs.

Belinostat: In February 2010, we entered into a licensing and collaboration agreement with TopoTarget, for the development of Belinostat, a drug being studied in multiple indications, including in 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, which we expensed as a research and development cost for the three-month period ended March 31, 2010. In addition, the terms of the agreement include potential future development, regulatory and sales milestones to TopoTarget of up to $313 million in cash, one million shares of our common stock and royalties on net sales of Belinostat.

Table of Contents

Ozarelix: In January 2010, based upon the results of our earlier Phase 2 study of Ozarelix for the treatment of benign prostatic hypertrophy (BPH) and the recently announced mixed results of Aeterna Zentaris s large Phase 3 registrational trial of cetrorelix (another LHRH antagonist), we discontinued development of Ozarelix in BPH. Currently, we are considering the future development of Ozarelix for other indications. In January 2007, we had received approximately $0.9 million, representing our 50% share of an economic interest that Aeterna Zentaris had from an arrangement with Nippon Kayaku for certain rights to Ozarelix in Japan and recognized the amount as deferred revenue. During the three month period ended March 31, 2010, we reevaluated the basis for deferral having determined that there are no further ongoing obligations and recorded the approximately $0.9 million as license revenue.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements are prepared on a consistent basis, in accordance with Generally Accepted Accounting Principles in the United States (GAAP), for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals and consolidation and elimination entries) considered necessary for a fair presentation of these interim unaudited condensed consolidated financial statements have been included herein. As permitted, certain footnotes or other financial information that are normally required by GAAP, can be condensed or omitted. Operating results for the three-months ended March 31, 2010 are not necessarily indicative of the results that may be expected for the year ending December 31, 2010. The balance sheet at December 31, 2009 has been derived from the audited consolidated financial statements at that date but does not include all of the information and footnotes required for complete financial statements. For further information, refer to the consolidated financial statements and footnotes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2009 filed with the SEC on April 5, 2010.

2. Summary of Significant Accounting Policies

Principles of Consolidation and Basis of Presentation

The consolidated financial statements include the accounts of the Company, our wholly-owned subsidiaries, and joint venture partners which we control, or of which we are the primary beneficiary. We evaluate the need to consolidate joint ventures as variable interest entities. Investments by outside parties in our consolidated entities are recorded as non-controlling interest in consolidated entities in our consolidated financial statements, and stated net after allocation of income and losses in the entity.

As of March 31, 2010 and 2009, we had three consolidated subsidiaries: OncoRx Pharma Private Limited, an entity organized in Mumbai, India in May 2008; Spectrum Pharmaceuticals GmbH, an inactive entity incorporated in Switzerland in April 1997; and RIT Oncology, LLC (RIT), a wholly-owned entity since March 2009, organized in Delaware in October 2008; and one consolidated joint venture, Spectrum Pharma Canada, organized in Quebec, Canada in January 2008. We have eliminated all significant intercompany accounts and transactions from the condensed consolidated financial statements.

Subsequent Events

In connection with the preparation of the interim unaudited condensed consolidated financial statements, we have evaluated subsequent events through the filing date of this Form 10-Q.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and disclosure of contingent obligations in the financial statements and accompanying notes. The estimation process requires assumptions to be made about future events and conditions, and as such, is inherently subjective and uncertain. Actual results could differ materially from our estimates.

Table of Contents

Cash, Cash Equivalents and Marketable Securities

Cash and cash equivalents and marketable securities primarily consist of bank checking deposits, short-term treasury securities, institutional money market funds, corporate debt and equity, municipal obligations, government agency notes, and certificates of deposit. We classify highly liquid short-term investments, with insignificant interest rate risk and maturities of 90 days or less at the time of acquisition, as cash and cash equivalents. Other investments, which do not meet the above definition of cash equivalents, are classified as either held-to-maturity or available-for-sale marketable securities. Investments that lack immediate liquidity, or which we intend to hold for more than one year are classified as long-term investments.

As of March 31, 2010, substantially all of our cash, cash equivalents and marketable securities were held at major financial institutions, which are required to invest our funds in accordance with our investment policy with the principal objectives of such policy being preservation of capital, fulfillment of liquidity needs and above market returns commensurate with preservation of capital. Our investment policy also requires that investments in marketable securities be in only highly rated instruments, which are primarily US treasury bills or US treasury backed securities, with limitations on investing in securities of any single issuer. To a limited degree, these investments are insured by the Federal Deposit Insurance Corporation and by third party insurance. However, these investments are not insured against the possibility of a complete loss of earnings or principal and are inherently subject to the credit risk related to the continued credit worthiness of the underlying issuer and general credit market risks. We manage such risks on our portfolio by matching scheduled investment maturities with our cash requirements and investing in highly rated instruments.

Cash and cash equivalents, and investments in marketable securities, including long term bank certificates of deposits, totaled $98.5 million and $124.8 million as of March 31, 2010 and December 31, 2009, respectively. The following is a summary of such investments (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash	Marketable Securities Current	Marketable Securities Long Term
March 31, 2010							
Cash, Cash Equivalents	$ 35,637	$	$	$ 35,637	$ 35,637	$	$
Bank Certificates of Deposit	26,364			26,364		15,782	10,582
U.S. Government securities	34,039			34,039		31,277	2,762
Corporate debt securities	2,423			2,423		2,423	
Other Securities (included in other assets)	34		7	27			27
Total investments	$ 98,497	$	$ 7	$ 98,490	$ 35,637	$ 49,482	$ 13,371
December 31, 2009							
Cash, Cash Equivalents	$ 82,336	$	$	$ 82,336	$ 82,336	$	$
Bank Certificates of Deposit	20,948			20,948		12,260	8,688
Money Market Currency Funds	4,800			4,800		4,800	
U.S. Government securities	16,542			16,542		13,792	2,750
Corporate debt securities	153			153		153	
Other Securities (included in other assets)	47		12	35			35
Total investments	$ 124,826	$	$ 12	$ 124,814	$ 82,336	$ 31,005	$ 11,473

Fair Value of Financial Instruments

We measure fair value based on the prices that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value measurements are based on a three-tier hierarchy that prioritizes the inputs used to measure fair value. These tiers include:

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

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

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

In determining fair value, we utilize valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible, as well as consider counterparty credit risk in the assessment of fair value.

The carrying values of our cash, cash equivalents, marketable securities, other securities and common stock warrants, carried at fair value as of March 31, 2010 are classified in the table below in one of the three categories described above:

	Fair Value Measurements at March 31, 2010			
	Level 1	**Level 2**	**Level 3**	**Total**
		($ in 000 s)		
Assets**:**				
Cash & equivalents	$ 35,637			$ 35,637
U.S. Treasury T-Bills	1,528			1,528
FDIC Insured Bank CDs	26,364			26,364
Medium Term Corporate Notes	2,423			2,423
U.S. Treasury Backed Securities	32,511			32,511
Cash, Cash Equivalents and Marketable Securities	98,463			98,463
Other Securities	27			27
	$ 98,490	$	$	$ 98,490
Liabilities:				
Common Stock Warrant Liability			5,060	5,060
	$	$	$ 5,060	$ 5,060

Table of Contents

The following summarizes the activity of Level 3 inputs measured on a recurring basis for the three months ended March 31, 2010:

	Fair Value Measurements of Common Stock Warrants Using Significant Unobservable Inputs (Level 3) ($ in 000 s)
Balance at December 31, 2009	$ 6,635