SPECTRUM PHARMACEUTICALS INC
Form 10-Q
November 07, 2008

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 September 30, 2008

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 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 November 5, 2008**
Common Stock, $.001 par value	31,806,876

SPECTRUM PHARMACEUTICALS, INC.
TABLE OF CONTENTS

Table of Contents

SPECTRUM PHARMACEUTICALS, INC.
FORM 10-Q
For the Three-month and nine-month periods ended September 30, 2008
(Unaudited)

PART I FINANCIAL INFORMATION

ITEM 1. Financial Statements

Statement Regarding Financial Information

The 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 accounting principles generally accepted in the United States 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.

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, 2007, filed with the SEC on March 14, 2008.

Table of Contents

SPECTRUM PHARMACEUTICALS, INC.
Condensed Consolidated Balance Sheets
(Unaudited)

	September 30, 2008	December 31, 2007
	(In Thousands, Except Share and Per Share Data)	
Assets		
Current Assets:		
Cash and cash equivalents	$ 4,679	$ 1,141
Marketable securities	46,957	54,518
Accounts receivable, net of allowance for doubtful accounts	186	191
Inventory	1,446	
Prepaid expenses and other current assets	254	762
Total current assets	53,522	56,612
Property and equipment, net	1,633	716
Other assets	143	212
Total assets	$ 55,298	$ 57,540
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable and other accrued liabilities	$ 3,217	$ 1,598
Accrued compensation	1,145	1,111
Accrued drug development costs	3,572	5,090
Total current liabilities	7,934	7,799
Deferred revenue and other credits	1,026	992
Total liabilities	8,960	8,791
Commitments and Contingencies (Note 3)		
Stockholders Equity:		
Preferred stock, par value $0.001 per share, 5,000,000 shares authorized:		
Series E Convertible Voting Preferred Stock, 2,000 shares authorized, stated value $10,000 per share, $2.0 million aggregate liquidation value, issued and outstanding, 68 and 170 shares at September 30, 2008 and December 31, 2007, respectively	419	1,048
Common stock, par value $0.001 per share, 100,000,000 shares authorized:		

Issued and outstanding, 31,771,876 and 31,233,798 shares at September 30, 2008 and December 31, 2007, respectively	32	31
Additional paid-in capital	294,051	288,927
Accumulated other comprehensive income	390	493
Accumulated deficit	(248,554)	(241,750)
Total stockholders equity	46,338	48,749
Total liabilities and stockholders equity	$ 55,298	$ 57,540

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)

	Three Months Ended September 30, 2008	Three Months Ended September 30, 2007	Nine Months Ended September 30, 2008	Nine Months Ended September 30, 2007
	(In Thousands, Except Share and Per Share Data)			
Revenues				
Licensing and milestone revenues	$	$ 3,250	$ 20,676	$ 7,625
Total Revenues	$	$ 3,250	$ 20,676	$ 7,625
Operating expenses:				
Research and development	$ 5,960	$ 8,532	$ 19,089	$ 22,025
Selling, general and administrative	3,132	3,027	8,947	9,411
Total operating expenses	9,092	11,559	28,036	31,436
Loss from operations	(9,092)	(8,309)	(7,360)	(23,811)
Other income, net	276	927	556	2,259
Net loss	$ (8,816)	$ (7,382)	$ (6,804)	$ (21,532)
Basic and diluted net loss per share	$ (0.28)	$ (0.24)	(0.22)	$ (0.76)
Basic and diluted weighted average common shares outstanding	31,538,023	31,034,241	31,424,358	28,276,992

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 Cash Flows
(Unaudited)

	Nine Months Ended September 30, 2008	Nine Months Ended September 30, 2007
	(In Thousands, Except Share and Per Share Data)	
Cash Flows From Operating Activities:		
Net loss	$ (6,804)	$ (21,532)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	146	187
Share-based compensation	4,207	4,096
Fair value of common stock issued in connection with drug license	305	520
Minority interest in subsidiary		(20)
Changes in operating assets and liabilities:		
Decrease <increase> in accounts receivable	5	(194)
Increase in inventory	(1,446)	
Decrease <increase> in prepaids and other assets	686	(54)
Increase in accounts payable and accrued expenses	101	1,673
Increase <decrease> in accrued compensation and related taxes	34	(78)
Increase <decrease> in deferred revenue and other credits	17	(30)
Net cash used in operating activities	(2,749)	(15,432)
Cash Flows From Investing Activities:		
Sales <Purchases> of marketable securities	7,351	(12,425)
Purchases of property and equipment	(1,064)	(334)
Net cash provided by <used in> investing activities	6,287	(12,759)
Cash Flows From Financing Activities:		
Proceeds from issuance of common stock and warrants, net of related offering costs and expenses		30,041
Proceeds from exercise of warrants		519
Proceeds from exercise of stock options		120
Net cash provided by financing activities		30,680
Net increase in cash and cash equivalents	3,538	2,489
Cash and cash equivalents, beginning of period	1,141	519
Cash and cash equivalents, end of period	$ 4,679	$ 3,008

Supplemental Cash Flow Information:

Interest paid	$		$	
Income taxes paid	$		$	

Schedule of Non-Cash Investing and Financing Activities:

Fair value of common stock issued in connection with drug license	$	305	$	520
Fair value of restricted stock granted employees and directors	$	275	$	1,308
Fair value of stock issued to match employee 401k contributions	$	208	$	129
Fair value of warrants issued to consultants and placement agents	$	69	$	

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
September 30, 2008
(Unaudited)

1. Business and Basis of Presentation

Business

Spectrum Pharmaceuticals, Inc. (the Company, we, our, or us) is a biopharmaceutical company with a focus oncology, urology and other critical health challenges for which there are few other treatment options.

The following is a brief update of the most advanced products under development as of September 30, 2008:

Fusilev (levoleucovorin) for injection (FUSILEV): On August 15, 2008, we commercially launched our proprietary oncology drug FUSILEV, which New Drug Application (NDA) was approved by the U.S. Food and Drug Administration (FDA) in March 2008. Shipments of FUSILEV for the period ended September 30, 2008 were approximately $140,000. Based on our revenue recognition policy, we have deferred the recognition of this revenue and related cost of goods sold until such time as we have a basis to reliably determine the amount of potential returns and other credits likely to offset the gross revenues.

FUSILEV rescue is indicated after high-dose methotrexate therapy in patients with osteosarcoma, the most common form of bone cancer, and is also indicated to diminish the toxicity and counteract the effects of impaired methotrexate elimination or inadvertent overdose of folic acid antagonists. Based on the current approved indication for osteosarcoma and the size of the market, we anticipate the uptake of FUSILEV will continue to remain slow until such time we get an approval for the use of FUSILEV in colorectal cancer, which is a significantly larger market. We filed a supplemental NDA for its use in colorectal cancer in 5-fluorouracil containing regimens with the FDA at the end of October 2008. Also, in June 2008, we filed an NDA amendment for a tablet formulation.

Apaziquone (EOquin® in bladder cancer): Pursuant to a special protocol assessment procedure, in 2007, we initiated two Phase 3 clinical studies in the United States and Canada for Apaziquone in non-muscle invasive bladder cancer. We have received scientific advice from the European Medicines Agency (EMEA), the European equivalent to the FDA, whereby the EMEA agreed that the two Phase 3 studies being conducted at this time should be sufficient for a regulatory decision regarding European registration. We continue to enroll patients into the two trials at sites in the United States and Canada and expect enrollment in both trials to be completed by the end of 2009. As described in note 5, on October 28, 2008, we entered into a strategic collaboration with Allergan, Inc. for the future development and commercialization of Apaziquone in bladder cancer.

Ozarelix (in benign prostatic hypertrophy): In April 2008, we announced the completion of a 9-month, randomized, double-blind, placebo-controlled, Phase 2b study of the safety and efficacy of ozarelix, the Company s drug candidate for the treatment of benign prostatic hypertrophy (BPH). Based on the results of that study, we have designed and submitted to the FDA the protocol for the next study of ozarelix in BPH and are currently in the process of patient enrollment.

Sumatriptan and other generic injectibles (non-dilutive funding): During the nine-month period ended September 30, 2008 , we entered into an agreement with Par Pharmaceutical, Inc. (Par), our marketing partner for sumatriptan injection, pursuant to which we received a non-refundable $20 million cash payment from Par for the sale of our share of the profits from the commercialization of sumatriptan injection. Also, during the nine-month period ended September 30, 2008, we entered into an agreement with Sagent Pharmaceuticals, Inc. (Sagent) to sell to Sagent rights to certain of our abbreviated new drug applications (ANDAs) for $660,000. These payments were recorded as revenues when received, since we had no remaining future obligations related to such transfer of rights.

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, 2007.

Table of Contents

SPECTRUM PHARMACEUTICALS, INC.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements are prepared on a consistent basis in accordance with accounting principles generally accepted 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 have been included. Operating results for the three-month and nine- month periods ended September 30, 2008 are not necessarily indicative of the results that may be expected for the year ending December 31, 2008. The balance sheet at December 31, 2007 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by GAAP 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, 2007.

2. Summary of Significant Accounting Policies and Estimates

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and of its wholly-owned and majority-owned subsidiaries. As of September 30, 2008, we had one subsidiary: Spectrum Pharmaceuticals GmbH, a wholly-owned inactive subsidiary incorporated in Switzerland in April 1997. In June 2008, we dissolved NeoJB, LLC, an 80% owned inactive subsidiary that was organized in Delaware in April 2002. We have eliminated all significant intercompany accounts and transactions.

Reclassification of Accounts

Certain reclassifications have been made to prior-year comparative financial statements to conform to the current year presentation. These reclassifications had no effect on previously reported results of operations or financial position.

Use of Estimates

The preparation of financial statements in conformity with GAAP 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. Our most significant assumptions are employed in estimates used in determining values of financial instruments and accrued obligations, as well as in estimates used in applying the revenue recognition policy and estimating share-based compensation. 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.

Fair Value of Financial Instruments

Effective January 1, 2008, we adopted Statement of Financial Accounting Standards No. 157, *Fair Value Measurements*, or FAS 157. In February 2008, the Financial Accounting Standards Board (FASB) issued FASB Staff Position No. FAS 157-2, Effective Date of FASB Statement No. 157, which provides a one year deferral of the effective date of FAS 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually. Therefore, we adopted the provisions of FAS 157 with respect to our financial assets and liabilities only. FAS 157 defines fair value, establishes a framework for measuring fair value under GAAP and enhances disclosures about fair value measurements. Fair value is defined under FAS 157 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value under FAS 157 must maximize the use of observable inputs and minimize the use of unobservable inputs.

We utilize the market approach to measure fair value for our financial assets and liabilities. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets or liabilities. The standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

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.

Table of Contents

SPECTRUM PHARMACEUTICALS, INC.

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 considers counterparty credit risk in its assessment of fair value.

The adoption of this statement did not have a material impact on our consolidated results of operations and financial condition. The carrying values of our cash, cash equivalents and marketable securities, carried at fair value as of September 30, 2008, are classified in the table below in one of the three categories described above:

	Fair Value Measurements at September 30, 2008			
	Level 1	Level 2	Level 3	Total
Cash & Equivalents	$ 4,679	0	$ 0	$ 4,679
U.S. Treasury T-Bills	23,814	0	0	23,814
Money Market Currency Funds	0	0	0	0
Medium Term Corporate Notes	0	$ 2,000	0	2,000
U.S. Treasury Backed Securities	0	21,142	0	21,142
	$ 28,493	$ 23,142	$ 0	$ 51,635

Cash, Cash Equivalents and Marketable Securities

Cash, 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, in accordance with the provisions of FASB Statement (SFAS) No. 115, *Accounting for Certain Investments in Debt and Equity Securities* . Investments that lack immediate liquidity, or which we intend to hold for more than one year are classified as long-term investments, and included in other assets. As of September 30, 2008, substantially all of our marketable securities were held in short-term US treasury bills or US treasury backed mutual funds.

Concentrations of Credit Risk

All of our cash, cash equivalents and marketable securities are invested at major financial institutions. These institutions are required to invest our cash in accordance with our investment policy with the principal objectives 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 as have existed since late 2007. We manage such risks on our portfolio by matching scheduled investment maturities with our cash requirements and investing in highly rated instruments. As of September 30, 2008, substantially all of our marketable securities were held in short-term US treasury bills or US treasury backed mutual funds.

We believe the financial institutions through which we have invested our funds are strong, well capitalized and our instruments are held in accounts segregated from the assets of the institutions. However, due to the current extremely volatile financial and credit markets and liquidity crunch faced by most banking institutions, the financial viability of these institutions, and the safety and liquidity of our funds is being constantly monitored.

9

Table of Contents

SPECTRUM PHARMACEUTICALS, INC.

Inventory

Inventory is stated at the lower of cost (first-in, first-out method) or market. As of September 30, 2008, inventory consisted of finished product of FUSILEV. The lower of cost or market is determined based on net estimated realizable value after appropriate consideration is given to obsolescence, excessive levels, deterioration, and other factors.

Patents and Licenses

We own or license all the intellectual property that forms the basis of our business model. We expense all licensing and patent application costs as they are incurred.

Revenue Recognition

We follow the provisions as set forth by current accounting rules, which primarily include Staff Accounting Bulletin (SAB) 104, *Revenue Recognition* , and Emerging Issues Task Force (EITF) No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*. Generally, revenue is recognized when evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed and determinable, and collectibility is reasonably assured.

Upfront monies representing non-refundable fees received upon the execution of licensing or other agreements are recognized as revenue upon execution of the agreements where we have no significant future performance obligations and collectibility of the fees is reasonably assured. Milestone payments, which are generally based on developmental or regulatory events, are recognized as revenue when the milestones are achieved, collectibility is reasonably assured, and we have no significant future performance obligations in connection with the milestone. In those instances where we have collected upfront fees or milestone payments but have significant future performance obligations related to the development of the drug product, we record deferred revenue and recognize it over the period of our future obligations.

Revenue from sales of product is recognized upon shipment of product, when title and risk of loss have transferred to the customer, and provisions for estimates, including promotional adjustments, price adjustments, returns, and other potential adjustments are reasonably determinable. Such revenue is recorded, net of such estimated provisions, at the minimum amount of the customer s obligation to us. We state the related accounts receivable at net realizable value, with any allowance for doubtful accounts charged to general operating expenses. If revenue from sales is not reasonably determinable due to provisions for estimates, promotional adjustments, price adjustments, returns or any other potential adjustments, we defer the revenue and recognize revenue when the estimates are reasonably determinable, even if the monies for the gross sales have been received.

Research and Development

Research and development expenses are comprised of the following types of costs incurred in performing research and development activities: personnel expenses, facility costs, contract services, license fees and milestone payments, costs of clinical trials, laboratory supplies and drug products, and allocations of corporate costs. We expense all research and development activity costs in the period incurred. We review and accrue drug development expenses based on factors such as estimates of work performed, patient enrollment, completion of patient studies and other events. Accrued clinical study costs are subject to revisions as trials progress to completion. Revisions are recorded in the period in which the facts that give rise to the revision become known.

Basic and Diluted Net Income (Loss) per Share

In accordance with FASB Statement No. 128, *Earnings Per Share,* we calculate basic net income (loss) per share by using the weighted average number of common shares outstanding during the periods presented. Diluted net income (loss) per share is calculated by using the weighted average number of common shares outstanding during the periods presented, increased to include all additional dilutive common shares issuable pursuant to outstanding common stock equivalents, determined using the treasury-stock method.

Table of Contents

SPECTRUM PHARMACEUTICALS, INC.

Potentially dilutive common stock equivalents include the common stock issuable upon the conversion of preferred stock and the exercise of warrants and stock options. These are included in the calculation of diluted net income (loss) per share only when their effect is dilutive. We incurred a net loss in each period presented, and as such, did not include the effect of potentially dilutive common stock equivalents in the diluted net loss per share calculation, as their effect would be anti-dilutive for all periods. Dilutive common stock equivalents would include the common stock issuable upon the conversion of preferred stock and the exercise of warrants and stock options that have conversion or exercise prices below the market value of our common stock at the measurement date.

The following table presents the data used in the calculations of basic and diluted net loss per share for the three-month and nine-month periods ended September 30, 2008 and 2007.

	Three-Months Ended September 30, 2008	Three-Months Ended September 30, 2007	Nine-Months Ended September 30, 2008	Nine-Months Ended September 30, 2007
	(In Thousands, Except Share and Per Share Data)			
Net income (loss)	$ (8,816)	$ (7,382)	$ (6,804)	$ (21,532)
Less:				
Preferred dividends paid in cash or stock	0	(10)	0	(12)
Income (loss) attributable to common stockholders	$ (8,816)	$ (7,392)	$ (6,804)	$ (21,544)
Weighted average shares outstanding	31,538,023	31,034,241	31,424,358	28,276,992
Basic and diluted net loss per share	$ (0.28)	$ (0.24)	$ (0.22)	$ (0.76)

Accounting for Share-Based Employee Compensation

Effective January 1, 2006, we adopted SFAS No. 123(R), *Share-Based Payment.* We measure compensation cost for all share-based awards at fair value on the date of grant and recognize compensation expense in our consolidated statements of operations over the service period that the awards are expected to vest. As permitted under SFAS No. 123(R), we have elected to recognize compensation cost for all options with graded vesting on a straight-line basis over the vesting period of the entire option.

In estimating the fair value of share-based compensation, we use the closing market price of our common stock for stock awards, and the Black-Scholes Option Pricing Model for stock options and warrants. We estimate future volatility based on past volatility of our common stock, and we estimate the expected length of options based on several criteria, including the vesting period of the grant and the expected volatility.

We recorded share-based compensation expense during the three-month and nine-month periods ended September 30, 2008 and 2007, as follows:

	Three-Months Ended September 30, 2008	Three-Months Ended September 30, 2007	Nine-Months Ended September 30, 2008	Nine-Months Ended September 30, 2007

	(In Thousands)			
Research and development	$ 630	$ 1,215	$ 2,630	$ 2,532
General and administrative	461	654	1,577	1,565
Total share based charges	$ 1,091	$ 1,869	$ 4,207	$ 4,097

Table of Contents

SPECTRUM PHARMACEUTICALS, INC.

Income Taxes

We recorded no tax provision for the three-month and nine-month periods ended September 30, 2008, based on an anticipated operating loss for the full calendar year.

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on the deferred tax assets and liabilities of