SPECTRUM PHARMACEUTICALS INC
Form 10-Q
November 12, 2009

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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, 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

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 o	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

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 6, 2009**

Common Stock, $.001 par value	48,798,364

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SPECTRUM PHARMACEUTICALS, INC.
FORM 10-Q
For the Three-month and Nine-month Periods ended September 30, 2009
(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 Standards Codification (ASC) No. 105, Generally Accepted Accounting Principles, 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, 2008, filed with the SEC on March 31, 2009.

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

	September 30, 2009	December 31, 2008
	(In Thousands, Except Share and Per Share Data)	
Assets		
Current Assets:		
Cash and cash equivalents	$ 9,686	$ 9,860
Marketable securities	133,785	68,226
Cash, cash equivalents and marketable securities	143,471	78,086
Accounts receivable-trade, net	4,441	5,002
Inventory	2,160	1,841
Prepaid expenses and other current assets	472	693
Total current assets	150,544	85,622
Property and equipment, net	1,771	1,782
ZEVALIN related intangible assets, net	35,941	37,042
Other assets	193	289
Total assets	$ 188,449	$ 124,735
Liabilities and Stockholders Equity		
Current Liabilities:		
Accounts payable and accrued obligations	$ 21,460	$ 5,627
Accrued compensation	2,476	2,956
Note payable in connection with ZEVALIN Acquisition		7,500
Current portion of deferred revenue and other credits	8,500	8,500
Accrued drug development costs	3,779	3,449
Total current liabilities	36,215	28,032
Capital lease obligations, net of current portion	102	95
Deferred revenue and other credits, net of current portion	27,512	33,929
ZEVALIN related contingent obligations		8,798
Total liabilities	63,829	70,854
Commitments and contingencies (Note 5)		
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	419	419

September 30, 2009 and December 31, 2008		
Common stock, par value $0.001 per share, 100,000,000 shares authorized;		
Issued and outstanding, 48,741,009 and 32,166,316 shares at September 30, 2009 and December 31, 2008	49	32
Additional paid-in capital	398,967	296,531
Non-controlling interest in consolidated entity		14,262
Accumulated other comprehensive loss	(136)	(146)
Accumulated deficit	(274,679)	(257,217)
Total stockholders equity	124,620	53,881
Total liabilities and stockholders equity	$ 188,449	$ 124,735

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

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SPECTRUM PHARMACEUTICALS, INC.
Condensed Consolidated Statements of Operations
(Unaudited)

	Three-months Ended September 30, 2009	Three-months Ended September 30, 2008	Nine-months Ended September 30, 2009	Nine-months Ended September 30, 2008
	(In Thousands, Except Share and Per Share Data)			
Revenues				
Product sales	$ 4,976	$	$ 23,031	
License and contract revenue	2,125		6,375	$ 20,676
Total revenues	$ 7,101	$	$ 29,406	$ 20,676
Operating expenses:				
Cost of product sold (excludes amortization of purchased intangibles shown below)	$ 2,429	$	$ 5,700	$
Amortization of purchased intangibles	950		2,850	
Research and development	5,488	5,960	17,534	19,089
Selling, general and administrative	6,995	3,132	22,540	8,947
Total operating expenses	15,862	9,092	48,624	28,036
Loss from operations	(8,761)	(9,092)	(19,218)	(7,360)
Other income, net	372	276	601	556
Consolidated Loss	(8,389)	(8,816)	(18,617)	(6,804)
Less: Net loss attributable to non-controlling interest			1,146	
Net loss attributable to Spectrum stockholders	$ (8,389)	$ (8,816)	$ (17,471)	$ (6,804)
Basic and diluted net loss per share	$ (0.20)	$ (0.28)	$ (0.48)	$ (0.22)
Basic and diluted weighted average common shares outstanding	42,762,048	31,538,023	36,632,549	31,424,358

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

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

	Nine-Months Ended September 30, 2009	Nine-Months Ended September 30, 2008
	(In Thousands, Except Share and Per Share Data)	
Cash Flows From Operating Activities:		
Net loss attributable to Spectrum stockholders	$ (17,471)	$ (6,804)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Amortization of deferred revenue	(6,375)	
Depreciation and amortization	3,248	146
Share-based compensation expense	6,013	4,207
Fair value of common stock issued in connection with drug license	935	305
Non-controlling interest in consolidated entities	(1,146)	
Changes in operating assets and liabilities:		
Accounts receivable	561	5
Inventory	(319)	(1,446)
Prepaid expenses and other assets	314	686
Accounts payable and accrued obligations	7,663	101
Accrued compensation and related taxes	(480)	34
Deferred revenue and other credits	(35)	17
Net cash used for operating activities	(7,092)	(2,749)
Cash Flows From Investing Activities:		
Net purchases of marketable securities	(65,538)	7,351
Investment in ZEVALIN acquisition	(22,687)	
Purchases of property and equipment	(388)	(1,064)
Net cash used in investing activities	(88,613)	6,287
Cash Flows From Financing Activities:		
Proceeds from issuance of common stock and warrants, net of related offering costs and expenses	95,810	
Proceeds from sale of common stock to employees shelf takedown	1,167	
Repurchase of warrants	(71)	
Proceeds from exercise of stock options	1,145	
Repurchase of stock options pursuant to tender offer	(2,520)	
Net cash provided by financing activities	95,531	
Net increase in cash and cash equivalents	(174)	3,538
Cash and cash equivalents, beginning of period	9,860	1,141

Cash and cash equivalents, end of period	$	9,686	$	4,679
Supplemental Cash Flow Information:				
Interest paid	$	10	$	
Income taxes paid	$	45	$	
Schedule of Non-Cash Investing and Financing Activities:				
Fair value of common stock issued in connection with drug license	$	935	$	305
Fair value of restricted stock granted employees and directors	$	226	$	275
Fair value of stock issued to match employee 401(k) contributions	$	342	$	208
Fair value of equity awarded to consultants and placement agents	$	111	$	69

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

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SPECTRUM PHARMACEUTICALS, INC.
Notes to Condensed Consolidated Financial Statements
September 30, 2009
(Unaudited)

1. Business and Basis of Presentation

Business

Spectrum Pharmaceuticals, Inc. (the Company, we, Spectrum , our, or us) is a commercial stage biopharmaceutic company committed to developing and commercializing innovative therapies with a focus primarily in the areas of hematology-oncology and urology. We have a fully developed commercial infrastructure that is responsible for the sales and marketing of two drugs in the United States, ZEVALIN® and FUSILEV®. Our lead developmental drug is Apaziquone, which is presently being studied in two large Phase 3 registrational trials for non-muscle invasive bladder cancer under a strategic collaboration with Allergan, Inc. (Allergan).

The following is a brief update of our most advanced products as of September 30, 2009:

ZEVALIN®: ([90Y]-ibritumomab tiuxetan) (ZEVALIN): For the three-months and nine-months ended September 30, 2009, we recorded net revenues of approximately $4.7 million and $10.6 million from sales of ZEVALIN. In December 2008, we partnered with Cell Therapeutics, Inc. (CTI) to form a 50-50 owned joint venture, RIT Oncology, LLC (RIT) to commercialize and develop ZEVALIN, a CD20-directed radiotherapeutic antibody, in the United States. Pursuant to provisions of the 2008 joint-venture agreement, in March 2009, we acquired the remaining 50% ownership of RIT for $16.5 million, resulting in RIT becoming our wholly-owned subsidiary. In April 2009, we disputed payment of an installment of $3.5 million of the $16.5 million, on the grounds that CTI s unpaid liabilities pertaining to ZEVALIN, and CTI s share of joint venture expenses equaled or exceeded the installment amount. In May 2009, we received an arbitration award of approximately $4.3 million. The entire $3.5 million was released to us and CTI additionally paid us approximately $0.8 million. The award was final, binding and non-appealable by either party.

In December 2008, the United States Food and Drug Administration (FDA) had accepted for filing and review, and granted priority review status for a supplemental Biologics License Application (sBLA) for the use of ZEVALIN as part of a first-line therapy for patients with previously untreated follicular non-Hodgkin s lymphoma (NHL). The sBLA application was approved by the FDA on September 3, 2009, which now allows the use of ZEVALIN for a substantially larger patient population. ZEVALIN is now FDA approved and marketed by Spectrum for treatment of patients with previously untreated follicular NHL who achieve a partial or complete response to chemotherapy and with relapsed or refractory, low-grade or follicular B-cell NHL, including patients who have rituximab-refractory follicular NHL. In connection with the FDA approval, we became obligated to pay $8.5 million in milestone payments. Such amount was included in accrued liabilities as of September 30, 2009 and paid in October 2009. In November 2009, the Centers for Medicare & Medicaid Services (CMS) finalized a policy to allow reimbursement for ZEVALIN®, in the Hospital Outpatient Prospective Payment System, based on the Average Sales Price (ASP) methodology applicable to other injectable drugs and biologicals. This reimbursement methodology will go into effect on January 1, 2010.

FUSILEV®: (levoleucovorin) for injection (FUSILEV): We commercially launched FUSILEV in August 2008 and recorded net revenues of approximately $0.3 million and $12.4 million from FUSILEV sales for the three-months and nine-months ended September 30, 2009. FUSILEV is the only commercially available drug containing only the pure active L-isomer of racemic (L and R forms) leucovorin. FUSILEV is currently 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. On October 8, 2009, we received a Complete Response letter from the FDA regarding our October 2008 supplemental New Drug Application (sNDA) filing for advanced metastatic colorectal cancer. The FDA stated in the Complete Response letter that the submission did not demonstrate that FUSILEV is non-inferior to leucovorin; and recommended that we meet with the FDA to discuss options for continuing to seek approval of FUSILEV in advanced metastatic colorectal cancer. However, the FDA did not request any changes to the currently approved indications and package insert. We plan to meet with the FDA in January 2010 to discuss options for FUSILEV in this indication.

Apaziquone: 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 expenses commencing January 1, 2009. As such, during the three month and nine month periods ended September 30, 2009, Allergan reimbursed us approximately $2.7 and $8.0 million of research and development costs. In addition, during the three-months and nine-months ended September 30, 2009, we recorded approximately $2.1 million and $6.4 million of licensing revenue from the amortization of the upfront $41.5 million fee that we received from Allergan in October 2008.
We continue to recruit sites and enroll patients in these two studies and expect to complete enrollment for both Phase 3 clinical trials, as targeted, by year-end 2009.

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RenaZorb: In August 2009, we acquired 100% of the rights to RenaZorb® and RENALAN®, lanthanum-based nanotechnology compounds with potent and selective phosphate binding properties, for all uses pursuant to an amended and restated agreement that we entered into with Altair Nanomaterials, Inc. and Altair Nanotechnologies (Altair). In 2005, the Company had acquired the worldwide license from Altair to develop and commercialize Altair s lanthanum-based nanotechnology compounds and related technology or all human therapeutic uses. The August 2009 acquisition expanded the worldwide, exclusive license to include all uses. In conjunction with the expanded license, Altair assigned all intellectual property associated with RenaZorb® (associated with human uses), RENALAN® (associated with animal or veterinarian use), its lanthanum-based nanotechnology and all of its other life sciences research and development to us. In consideration, we issued 113,809 shares of our common stock, with a then fair value of approximately $750,000. Moving forward, we are responsible for all development, commercialization and intellectual property costs that accrue after the August 2009 execution date for the amended and restated agreement.

Ozarelix: We have initiated a multi-center, randomized, double-blind, placebo-controlled Phase 2b study to evaluate the efficacy of Ozarelix compared to placebo in the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia in men as assessed by the international prostate symptom score at Week 14. We are currently enrolling patients in the study in North America, and intend to expand the study to enroll patients in India.

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, 2008.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements are prepared on a consistent basis, in accordance with ASC No. 105, Generally Accepted Accounting Principles , for interim financial information and with the instructions to Form 10-Q and Article 8 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by ASC No. 105 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, 2009 are not necessarily indicative of the results that may be expected for the year ending December 31, 2009. The balance sheet at December 31, 2008 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by ASC No. 105 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, 2008.

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 subsidiaries. As of September 30, 2009, we had three consolidated subsidiaries: RIT Oncology, LLC (RIT), which became 100% owned effective March 15, 2009, and was organized in Delaware in 2008; OncoRx Pharma Private Limited (OncoRx), a wholly-owned subsidiary, organized in Mumbai, India in 2008 and Spectrum Pharmaceuticals GmbH, a wholly-owned inactive subsidiary, incorporated in Switzerland in April 1997; and one consolidated joint venture: Spectrum Pharma Canada, Inc., organized in Quebec, Canada in January 2008. We have eliminated all significant intercompany accounts and transactions.

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Use of Estimates

The preparation of financial statements in conformity with ASC No. 105 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.

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 ASC No. 320, Investments-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.

We have adopted ASC No. 820, Fair Value Measurements and Disclosures, and utilize the market approach to measure fair value of 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.

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 carrying values of our cash, cash equivalents, marketable securities, and financing proceeds receivables carried at fair value as of September 30, 2009, are classified in the table below in one of the three categories described above:

	Fair Value Measurements at September 30, 2009			
	Level 1	Level 2	Level 3	Total
Cash & equivalents	$ 9,686			$ 9,686
U.S. Treasury T-Bills	3,505			3,505
Money Market Currency Funds	5,872			5,872
FDIC insured Bank CDs	17,552			17,552
Medium Term Corporate Notes	4,708			4,708
U.S. Treasury Backed Securities	102,148			102,148
Cash, cash equivalents, marketable securities	143,471			143,471
Other Securities	44			44
	$ 143,515			$ 143,515

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As of September 30, 2009, 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 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.

Certain Risks and Concentrations

Our cash, cash equivalents and marketable security investments are subject to concentration of credit risk. We manage such risk by diversification of the investment portfolio and by the purchase of investment-grade securities.

Our product sales are concentrated in a limited number of customers. For the nine months ended September 30, 2009, approximately 54% of our product sales were derived from distributors and Group Purchasing Organizations (GPOs) of oncology products, 26% from radio pharmacies and approximately 20% from end use customers. Due to changes in market dynamics, these ratios are not indicative of future concentrations. We do not require collateral or other security to support credit sales, but provide an allowance for bad debts when warranted.

We are dependent on single source suppliers for raw materials, and the manufacturing of finished product of ZEVALIN and FUSILEV. A disruption in supply could materially affect our sales. Similarly, we have single source suppliers for the manufacturing of our development drug product candidates. If we are unable to obtain sufficient quantities of such product, our research and development activities may be adversely affected.

Inventory

Inventory is stated at the lower of cost (first-in, first-out method) or market. 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.

Intangible Assets

In December 2008, we partnered with CTI to form a 50/50 owned joint venture, RIT, to commercialize and develop ZEVALIN in the U.S. Pursuant to provisions of the 2008 joint-venture agreement, in March 2009, CTI sold to us its remaining 50% ownership in RIT, resulting in RIT becoming a wholly-owned subsidiary of Spectrum. The assets contributed by CTI to RIT were all of its interests in the ZEVALIN business.

Based on the provisions of ASC No. 805, Business Combinations, the purchase price for the acquisition of ZEVALIN rights was allocated to identifiable intangible assets acquired and liabilities assumed based on their estimated fair values at the acquisition date, as determined by an independent third-party valuation firm. Such a valuation requires significant estimates and assumptions including but not limited to: determining the timing and expected costs to complete the in-process projects, projecting regulatory approvals, estimating future cash flows from product sales resulting from in-process projects, and developing appropriate discount rates and probability rates by project. We believe the fair values assigned to the assets acquired and liabilities assumed are based on reasonable assumptions. However, these assumptions may be inaccurate, and unanticipated events and circumstances may occur.

We recorded intangible assets in connection with the acquisition of ZEVALIN and related amortization as follows:

	September 30, 2009		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount

Developed technology	$ 23,100	$ (1,793)	$ 21,307
Core technology	14,100	(1,213)	12,887
Goodwill	1,747		1,747
Acquired in-process research and development	4,700	(4,700)	
Total intangible assets	$ 43,647	$ (7,706)	$ 35,941

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Identifiable intangible assets with definite lives are amortized on a straight-line basis over their estimated useful lives. The developed and core technology assets are being amortized over 10 years, or approximately $3.7 million annually through 2018. Included in the intangible assets was an amount of $4.7 million of in process research and development for a medical indication still awaiting approval by the FDA. Such amount was completely written off during the year ended December 31, 2008.

We evaluate the recoverability of intangible assets whenever events or changes in circumstances indicate that an intangible asset s carrying amount may not be recoverable. Such circumstances could include, but are not limited to the following:

i a significant decrease in the market value of an asset;

ii a significant adverse change in the extent or manner in which an asset is used; or

iii an accumulation of costs significantly in excess of the amount originally expected for the acquisition of an asset.

We measure the carrying amount of the asset against the estimated undiscounted future cash flows associated with it. Should the sum of the expected future net cash flows be less than the carrying value of the asset being evaluated, an impairment loss would be recognized. The impairment loss would be calculated as the amount by which the carrying value of the asset exceeds its fair value.

Industry Segment and Geographic Information

We operate in one business segment, that of acquiring, developing and commercializing prescription drug products. Accordingly, the accompanying financial statements are reported in the aggregate, including all of our activities in one segment. Our foreign operations were not significant for any of the periods presented herein.

Revenue Recognition

We follow the provisions as set forth by current accounting rules, which primarily include ASC No. 605-10, Revenue Recognition , and ASC No. 605-25, Revenue Recognition-Multiple-Element Arrangements.

Generally, revenue is recognized when all four of the following criteria are met:

(i) persuasive evidence that an arrangement exists;

(ii) delivery of the products has occurred, or services have been rendered;

(iii) the selling price is both fixed and determinable; and

(iv) collectibility is reasonably assured.

We sell our products to wholesalers and distributors of oncology products and directly to the end user, directly or through group purchasing organizations (GPOs) (e.g., certain hospitals or hospital systems and clinics with whom we have entered into a direct purchase agreement). Our wholesalers and distributors purchase our products and sell the products directly to the end users, which include, but are not limited to, hospitals, clinics, medical facilities, managed care facilities and private oncology based practices etc. Revenue from product sales is recognized upon shipment of product when title and risk of loss have transferred to the customer, and the following additional criteria specified by ASC No. 605-15, Revenue Recognition: Products are met:

(i) the price is substantially fixed and determinable;

(ii) our customer has economic substance apart from that provided by us;

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

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

(v) we have a reasonable basis to estimate future returns.

Provisions for estimated product returns, sales discounts, rebates and charge backs are established as a reduction of gross product sales at the time such revenues are recognized. Thus, revenue is recorded, net of such estimated provisions.

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Consistent with industry practice, our product return policy permits our customers to return products within 30 days after shipment, if incorrectly shipped or not ordered, and within a window of time 6 months before and 12 months after the expiration of product dating, subject to certain restocking fees and preauthorization requirements, as applicable. Currently, our returns policy does not allow for replacement of product. The returned product is destroyed if it is damaged, it s quality is compromised or it is past its expiration date. Based on our returns policy, we refund the sales price to the customer as a credit and record the credit against receivables. In general returned product is not resold. We generally reserve the right to decline granting a return and to decide on product destruction. As of each balance sheet date, we estimate potential returns, based on several factors, including: inventory held by distributors, sell through data of distributor sales to end users, customer and end-user ordering and re-ordering patterns, aging of accounts receivables, rates of returns for directly substitutable products and other pharmaceutical products for the treatment of therapeutic areas similar to indications served by our products, shelf life of our products and the extensive experience of our management with selling the same and similar oncology products. We record an allowance for future returns by debiting revenue, thereby reducing gross revenues and crediting a reserve for returns to reduce gross receivables. If allowances exceed the related accounts receivables, we reclassify such excess to accrued obligations. We also 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.

Up-front fees representing non-refundable payments 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 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. Pursuant to this policy, as of December 31, 2008, we had recorded all of the $41.5 million up-front fee we received from Allergan for the October 2008 co-development agreement as deferred revenue. We expect that we shall amortize such deferred revenue to income over the anticipated period of Apaziquone s development for bladder cancer. Accordingly, for the three-months and nine-months ended September 30, 2009, we amortized approximately $2.1 and $6.4 million to licensing revenue, and as of September 30, 2009, classified approximately $8.5 million of unamortized deferred revenue as current portion of deferred revenue.

Research and Development

Research and development expenses include salaries and benefits, clinical trial and related manufacturing costs, contract and other outside service fees, and facilities and overhead costs related to our research and development efforts. Research and development expenses also consist of costs incurred for proprietary and collaborative research and development and include activities such as product registries and investigator-sponsored trials. In accordance with ASC No. 730, Research and Development , research and development costs are expensed as incurred. In certain instances, we enter into agreements with third parties for research and development activities, where we may prepay fees for services at the initiation of the contract. In accordance with ASC No. 730-20, Research and Development: Research & Development Arrangements , we record such prepayment as a prepaid asset and charge research and development expense over the period of time the contracted research and development services are performed. In connection with the October 2008 co-development agreement, Allergan bears 65% of the development costs incurred for Apaziquone in bladder cancer, commencing January 1, 2009. During the three-month and nine-month periods ended September 30, 2009, Allergan reimbursed us approximately $2.7 and $7.9 million of research and development costs, which were credited against total related research and development expense.

As of each Balance Sheet date, we review purchase commitments 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 ASC No. 260, 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.

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.

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The following table presents the data used in the calculations of basic and diluted net income (loss) per share for the three-month and nine-month periods ended September 30, 2009 and 2008.

	Three-Months Ended September 30, 2009	Three-Months Ended September 30, 2008	Nine-months Ended September 30, 2009	Nine-months Ended September 30, 2008
Net loss attributable to common stockholders	$ (8,389)	$ (8,816)	$ (17,471)	$ (6,804)
Net loss per share:				
Basic	$ (0.20)	$ (0.28)	$ (0.48)	$ (0.22)
Weighted average shares outstanding	42,762,048	31,538,023	36,632,549	31,424,358

Accounting for Employee Share-Based Compensation

In accordance with ASC No. 718, Compensation-Stock Compensation , 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 ASC No. 718, we have elected to recognize compensation expense 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 period ended September 30, 2009 and 2008, as follows:

	Three-months Ended September 30, 2009	Three-months Ended September 30, 2008	Nine-months Ended September 30, 2009	Nine-months Ended September 30, 2008
Research and development	$ 722	$ 630	$ 3,015	$ 2,630
General and administrative	498	461	2,998	1,577
Total share based charges	$ 1,220	$ 1,091	$ 6,013	$ 4,207

Income Taxes

We recorded no tax provision for the three-month or nine-month periods ended September 30, 2009, 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 a change in tax rates is recognized in income in the period that includes the enactment date. The Company has determined that the net deferred tax asset does not meet the more likely than not criteria under ASC No. 740, Income

Taxes , and, accordingly, a valuation allowance has been recorded to reduce the net deferred tax asset to zero.

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Comprehensive Loss

Comprehensive loss is calculated in accordance with ASC No. 220, Comprehensive Income . ASC No. 220 requires the disclosure of all components of comprehensive income, including net income and changes in equity during a period from transactions and other events and circumstances generated from non-owner sources. Our accumulated other comprehensive loss at September 30, 2009 consisted primarily of net unrealized gains on investments in marketable securities as of that date.

Recent Accounting Pronouncements

In June 2009, the Financial Accounting Standards Board, or FASB, approved its ASC, as the single source of authoritative United States accounting and reporting standards applicable for all non-governmental entities. Rules and interpretive releases of the SEC under authority of federal securities laws are also sources of authoritative U.S. generally accepted accounting principles, or GAAP, for SEC registrants. The ASC, which changes the referencing of financial standards, is effective for interim or annual financial periods ending after September 15, 2009. Therefore, commencing the third quarter of 2009, all references made to U.S. GAAP, as available through the date of this filing, refer to the new ASC numbering system prescribed by the FASB. The adoption of this accounting pronouncement is not expected to have any significant impact on our financial statements.

Effective January 1, 2009, ASC No. 808, Collaborative Arrangements , requires certain income statement presentation of transactions with third parties and of payments between parties to the collaborative arrangement, along with disclosure about the nature and purpose of the arrangement. The adoption of this accounting pronouncement did not have a significant impact on our financial statements.

Effective January 1, 2009, ASC No. 805, Business Combinations , requires an acquirer to recognize the assets acquired, the liabilities assumed, and any non-controlling interest in the acquiree at the acquisition date, measured at their fair values as of that date, with limited exceptions. This statement also requires the acquirer in a business combination achieved in stages to recognize the identifiable assets and liabilities, as well as the non-controlling interest in the acquiree, at the full amounts of their fair values. ASC No. 805 makes various other amendments to authoritative literature intended to provide additional guidance or to confirm the guidance in that literature to that provided in this statement. The adoption of this accounting pronouncement did not have a significant impact on our financial statements.

Effective April 1, 2009, ASC No. 855, Subsequent Events , establishes general standards of accounting for and disclosures of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. In particular, this statement sets forth (1) the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements; (2) the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements; and (3) the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. This statement is effective for interim or annual periods ending after June 15, 2009 and we adopted it on April 1, 2009. The required disclosures are included in Note 7, Subsequent Events, based on a review of events subsequent to the Balance Sheet date through November 12, 2009, the date of this filing.

In June 2009, the FASB issued SFAS No. 166, Accounting for Transfers of Financial Assets an amendment of FASB Statement No. 140 , which amends the derecognition guidance in SFAS No. 140 and eliminates the exemption from consolidation for qualifying special-purpose entities. This statement is effective for financial asset transfers occurring after the beginning of an entity s first fiscal year that begins after November 15, 2009. We are currently evaluating the potential impact of this statement.

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In June 2009, the FASB issued SFAS No. 167, Amendments to FASB Interpretation No. 46(R), which amends the consolidation guidance applicable to variable interest entities. The amendments will significantly affect the overall consolidation analysis under FASB Interpretation No. 46(R). This statement is effective as of the beginning of the first fiscal year that begins after November 15, 2009. We are currently evaluating the potential impact of this statement.

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.

3. Accounts Receivable Trade

Accounts receivable Trade, at September 30, 2009 and December 31, 2008, were comprised as follows:

	September 30, 2009	December 31, 2008
	($ in 000 s)	
Accounts receivable gross	$ 4,618	$ 9,926
Allowances for discounts, chargebacks and returns	(27)	(4,774)
Allowances for doubtful accounts	(150)	(150)
Accounts receivable, net of allowances	$ 4,441	$ 5,002

As of December 31, 2008, we had recorded allowances of approximately $1.6 million for chargebacks and discounts and $3.1 million for sales returns, primarily due to limited experience with sales and return patterns. During the nine-month period ended September 30, 2009, we gained additional experience on sales returns. Based on this experience, through September 30, 2009, we accordingly adjusted the sales returns reserves to $1.1 million. As of that date, the reserves for chargebacks, discounts and returns exceeded the related accounts receivables by $1.7 million. Such excess amount has been reclassified as accrued liabilities.

4. Inventories

Inventories at September 30, 2009 and December 31, 2008, were comprised as follows:

	September 30, 2009	December 31, 2008
	($ in 000 s)	($ in 000 s)
Finished Goods	$ 1,829	$ 1,492
Work In Process		312
Raw Materials	372	68
Less: reserve for inventory allowances	(41)	(31)
	$ 2,160	$ 1,841

We continually review product inventories on hand. Inventory levels are evaluated relative to product demand, remaining shelf life, future marketing plans and other factors, and reserves for obsolete and slow-moving inventories are recorded for amounts which may not be realizable.

5. Commitments and Contingencies

Facility and Equipment Leases

As of September 30, 2009, we had obligations under a facility lease, which expires on July 1, 2016, and various operating and capital equipment leases.

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Minimum lease requirements, including the renewal terms of the facility lease for each of the next five years and thereafter, under the property and equipment operating leases and capital leases, are as follows:

September 30, 2009	Lease Commitments	Capital Lease Commitments
	Amounts In Thousands	
2009 (Remainder of year)	$ 103	$ 13
2010	428	50
2011	455	50
2012	484	46
2013	513	
2014	542	
Thereafter	863	
	$ 3,388	$ 159

Licensing Agreements

Almost all of our drug candidates are being developed pursuant to license agreements that provide us with rights in certain territories to, among other things, develop, sublicense, manufacture and sell the drugs. We are generally required to use commercially reasonable efforts to develop the drugs, are generally responsible for all development, patent filing and maintenance, sales and marketing and liability insurance costs, and are generally contingently obligated to make milestone payments to the licensors if we successfully reach development and regulatory milestones specified in the license agreements. In addition, we are obligated to pay royalties and, in some cases, milestone payments based on net sales, if any, after marketing approval is obtained from regulatory authorities.

The potential contingent development and regulatory milestone obligations under all of our licensing agreements are generally tied to progress through the FDA approval process, which approval significantly depends on positive clinical trial results. The following items are typical of milestone events: conclusion of Phase 2 or commencement of Phase 3 clinical trials; filing of new drug applications in each of the United States, Europe and Japan; and approvals from each of the regulatory agencies in those jurisdictions.

Given the uncertainty of the drug development and regulatory approval process, we are unable to predict with any certainty when any of the milestones will occur, if at all. Accordingly, the milestone payments represent contingent obligations that will be recorded as expense when the milestone is achieved. While it is difficult to predict when milestones will be achieved, we estimate that if all of our contingent milestones are successfully achieved within our anticipated timelines, our potential contingent cash development and regulatory milestone obligations, aggregating to approximately $75.8 million as of September 30, 2009, would be due approximately as follows: $1.7 million within 12 months; $4.9 million in 2 to 3 years; $5.1 million in 4 to 5 years; and $64.1 million after 5 years. In the event these milestones are achieved, we believe it is likely that the increase in the potential value of the related drug product will significantly exceed the amount of the milestone obligation.

Service Agreements

In connection with the research and development of our drug products, we have entered into contracts with numerous third party service providers, such as radio-pharmacies, distributors, clinical trial centers, clinical research organizations, data monitoring centers, and with drug formulation, development and testing laboratories. The financial terms of these contracts are varied and generally obligate us to pay in stages, depending on the occurrence of certain events specified in the contracts, such as contract execution, reservation of service or production capacity, actual performance of service, or the successful accrual and dosing of patients.

At each period end, we accrue for all costs of goods and services received, with such accruals based on factors such as estimates of work performed, patient enrollment, completion of patient studies and other events. As of September 30, 2009, we were committed under such contracts for up to approximately $10.7 million for future goods and services,

including approximately $6.4 million maturing within one year. Generally, we are in a position to accelerate, slow down or discontinue any or all of the projects that we are working on at any given point in time. Should we decide to discontinue and/or slow down the work on any project, the associated costs for those projects would get limited to the extent of the work completed. Generally, we are able to terminate these contracts due to the discontinuance of the related project(s) and thus avoid paying for the services that have not yet been rendered and our future purchase obligations would reduce accordingly.

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Employment Agreement

We have entered into an employment agreement with Dr. Shrotriya, our President and Chief Executive Officer, which expires January 2, 2011. The employment agreement automatically renews for a one-year calendar term unless either party gives written notice of such party s intent not to renew the agreement at least 90 days prior to the commencement of the new term. The employment agreement requires Dr. Shrotriya to devote his full working time and effort to the business and affairs of the Company during the term of the agreement. The employment agreement provides for a minimum annual base salary with annual increases, periodic bonuses and option grants as determined by the Compensation Committee of the Board of Directors.

6. Stockholders Equity

Common Stock

Pursuant to the terms of the asset purchase agreement with Targent, LLC (Targent), in March 2009, we issued to Targent 125,000 shares of our common stock as a milestone payment in connection with the acceptance by the FDA of the sNDA for FUSILEV in combination with 5-FU (fluorouracil) to prolong survival in the palliative treatment of patients with advanced colorectal cancer. The fair value of the stock, $185,000, was recorded as a stock-based research and development charge for the nine-month period ended September 30, 2009.

In May 2009, we sold off our shelf registration statement on Form S-3 (No. 333-150260) (the Shelf Registration Statement), an aggregate of 432,200 shares of common stock to certain of our employees at a purchase price of $2.70 per share, which was the closing price of our common stock on May 6, 2009. This offering resulted in gross proceeds to us of approximately $1.2 million. The investors in this offering included Dr. Rajesh Shrotriya, M.D., our Chairman, President and Chief Executive Officer, and Shyam Kumaria, our Vice President of Finance. Dr. Shrotriya purchased 290,000 shares of common stock and Mr. Kumaria purchased 85,000 shares of common stock. We decided to conduct this offering with certain of our employees to allow such employees to invest their personal cash directly into the Company at the current fair market value of our stock. The purchase agreements include provisions prohibiting the investors from disposing of the shares of common stock purchased in the offering for ninety days. The offering was approved by the Placement Committee of the Board of Directors. In addition, the Audit Committee of the Board of Directors approved the offering pursuant to our Related Party Transaction Policies and Procedures.

On May 26, 2009, we sold off the Shelf Registration Statement 3,913,895 shares of our common stock at a purchase price of $5.11 per share for net cash proceeds of approximately $19 million, after placement agent fees and other offering costs of approximately $1 million. In connection with this offering, 1,956,947 warrants exercisable at $5.11 between November 27, 2009 and February 25, 2010, were issued to the investors.

On June 15, 2009, we sold off the Shelf Registration Statement 1,715,266 shares of our common stock at a purchase price of $5.83 per share for net cash proceeds of approximately $9.5 million, after placement agent fees and other offering costs of approximately $0.5 million. In connection with this offering, 857,633 warrants exercisable at $5.83 between December 15, 2009 and March 15, 2010, were issued to the investors.

On June 30, 2009, we sold off the Shelf Registration Statement 2,936,037 shares of our common stock at a purchase price of $7.15 per share for net cash proceeds of approximately $20 million, after placement agent fees and other offering costs of approximately $1 million. In connection with this offering, 1,468,020 warrants exercisable at $7.10 between December 30, 2009 and March 30, 2010, were issued to the investors.

On September 18, 2009, we sold off the Shelf Registration Statement 6,622,517 shares of our common stock at a purchase price of $7.55 per share for net cash proceeds of approximately $47.5 million, after placement agent fees and other offering costs of approximately $2.5 million. In connection with this offering, 2,649,007 warrants exercisable at $7.55 between March 22, 2010 and June 21, 2010, were issued to the investors.

Common Stock Reserved for Future Issuance

As of September 30, 2009, approximately 19.0 million shares of our common stock, when fully vested, were issuable upon conversion or exercise of rights granted under prior financing arrangements, stock options and warrants, as follows:

Conversion of Series E preferred shares	136,000
Exercise of stock options (see note below)	7,865,395

Exercise of warrants (see note below)	11,028,919
Total shares of common stock reserved for future issuances	19,030,314

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As of September 30, 2009, options representing 4,011,695 shares of our common stock and warrants to purchase up to 4,097,312 shares of our common stock were actually eligible for exercise; the remainder of the options and warrants are subject to vesting restrictions discussed elsewhere.

Share-Based Compensation

On June 26, 2009, at our annual meeting of stockholders, our stockholders voted to approve (i) the 2009 Employee Stock Purchase Plan (the 2009 ESPP), which provides for the purchase of shares of our common stock by our employees with their own cash, and (ii) the 2009 Incentive Award Plan (the 2009 Plan), which provides for the grant of incentive and nonqualified stock options, restricted stock, restricted stock units, and stock appreciation rights to members of our Board of Directors, employees and consultants. On June 26, 2009, subsequent to the stockholders approval of the 2009 Plan, the Board approved an amendment to our 2003 Amended and Restated Incentive Award Plan (the 2003 Plan) to decrease the number of shares available for issuance under the 2003 Plan from a maximum of 15,000,000 shares to 10,000,000 shares.

2009 Employee Stock Purchase Plan

There are initially 5,000,000 shares of common stock available for issuance under the 2009 ESPP. Beginning on January 1, 2010, and each January 1st thereafter, the number of shares of common stock available for issuance under the 2009 ESPP shall increase by an amount equal to the lesser of (i) 1,000,000 shares or (ii) an amount determined by the ESPP Administrator. However, in no event shall the number of shares of common stock available for future sale under the 2009 ESPP exceed 10,000,000 shares, subject to capitalization adjustments occurring due to dividends, splits, dissolution, liquidation, mergers, or changes in control.

The 2009 ESPP provides that there shall be consecutive periods during which an option to purchase common stock under the 2009 ESPP may be exercised (Offering Periods), each of which will last approximately six months. The first Offering Period shall commence on July 1, 2009 and shall terminate on December 31, 2009. Thereafter, the first Offering Period of a given year shall commence on January 1st of that year and shall terminate on June 30th of the same year. The second Offering Period of a given year shall commence on July 1st of each year and shall terminate on December 31st of each year.

The purchase price per share for which shares of common stock will be sold pursuant to the 2009 ESPP is an amount equal the lesser of: (a) 85% of the fair market value of common stock on the first day of the Offering Period or (b) 85% of the fair market value of common stock on the last day of the Offering Period.

The 2009 ESPP replaces our 2001 Employee Stock Purchase Program, which was terminated by the Board effective June 26, 2009.

2009 Incentive Award Plan

There are initially 10,000,000 shares of common stock available for issuance under the 2009 Plan. Beginning on January 1, 2010, and each January 1st thereafter, the number of shares of common stock available for issuance under the 2009 Plan shall increase by the greater of (i) 2,500,000 and (ii) a number of shares such that the total number of shares of common stock available for issuance under the Plan shall equal 30% of the then number of shares of common stock issued and outstanding.

As of September 30, 2009, approximately 9.9 million incentive award shares were available for grant under our 2009 Incentive Award Plan.

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Presented below is a summary of activity, for all our share-based incentive award plans, during the nine-month period ended September 30, 2009:

Stock Options:

During the nine-month ended September 30, 2009, the Compensation Committee granted stock options at exercise prices equal to or greater than the closing price of our common stock on the trading day prior to the grant date. The weighted average grant date fair value of stock options granted during the nine-month period ended September 30, 2009 was estimated at approximately $2.88, using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%; expected volatility (based on the historical volatility of our common stock) of 71.9%; risk free interest rate of 2.26%; and an expected life of 5 years.

	Common Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Term (In Years)	Aggregate Intrinsic Value (In Thousands)
Outstanding at beginning of year	7,115,772	$ 4.80		
Granted	3,507,350	4.72		
Expired	(92,000)	4.97		
Forfeited	(64,000)	4.04		
Repurchased	(2,165,372)	7.75		
Exercised	(436,355)	2.69		
Outstanding, at the end of period	7,865,395	$ 4.07	8.19	$ 21,108
Vested and expected to vest, at end of period	6,924,659	$ 4.24	5.18	$ 19,155
Exercisable, at the end of period	4,011,695	$ 4.08	7.04	$ 10,716

Due to our rapid growth over the past few years and a low personnel turnover rate, in early 2009, we had a limited number of shares available for future grant under the 2003 Plan. Primarily in order to increase the pool of shares available for future grant under such plan, we conducted a tender offer to eligible employees to acquire options granted to certain employees of the company pursuant to the Third Amended and Restated 1997 Stock Incentive Plan and 2003 Plan, and which were outstanding at March 23, 2009. Eligible employees were employees of Spectrum or its subsidiaries who held options with exercise prices in excess of $5.00. The cash amount offered to those employees was $0.01 for options with an exercise price over $10.00 and $1.15 for the options with an exercise price between $5.00 and $9.99.

On April 23, 2009, a total of 2,165,372 shares underlying eligible options were tendered by eligible employees and were accepted by us, representing 73% of the shares underlying eligible options that were eligible to be tendered in the offer. We made a cash payment in the aggregate of approximately $2.4 million to the eligible employees participating in the offer.

The aggregate intrinsic value in the table above represents the total difference between the closing price of our common stock of $6.73 on September 30, 2009 and the exercise price of the options, multiplied by the number of all in-the-money options that would have been received by the option holders had all option holders exercised their options on September 30, 2009. This amount changes based on the fair market value of our common stock.

During the three-month and nine-month periods ended September 30, 2009, the share-based charge in connection with the expensing of stock options was approximately $1.0 million and $5.2 million. As of September 30, 2009, there was approximately $8.0 million of unrecognized stock-based compensation cost related to stock options which is expected to be recognized over a weighted average period of approximately 2.9 years.

Restricted Stock:

The fair value of restricted stock awards is the grant date closing market price of our common stock, and is charged to expense over the period of vesting. These awards are subject to forfeiture to the extent that the recipient s service is terminated prior to the shares becoming vested.

During the three-month and nine-month periods ended September 30, 2009, the share-based charge in connection with the expensing of restricted stock awards was approximately $0.1 million and $0.5 million. As of September 30, 2009, there was approximately $0.6 million of unrecognized share-based compensation cost related to non-vested restricted stock awards, which is expected to be recognized over a weighted average period of approximately 1.3 years.

	Restricted Stock Awards		Weighted Average Grant Date Fair Value
Nonvested at beginning of period	377,500	$	3.04
Granted	230,000		1.46
Vested	(221,250)		3.14
Forfeited	(2,500)		5.45
Nonvested at end of period	383,750	$	2.02

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401(k) Plan Matching Contribution:
During the three-month and nine-month periods ended September 30, 2009, we issued 16,795 and 115,295 shares of common stock as our match of approximately $120,000 million and $340,000 million on the 401(k) contributions of our employees.
Warrants Activity:
We have issued warrants to purchase shares of our common stock to investors as part of financing transactions, or in connection with services rendered by placement agents or consultants. Our outstanding warrants expire on varying dates through September 2013. Below is a summary of warrant activity during the nine-month period ended September 30, 2009:

	Common Stock Warrants		Weighted Average Exercise Price
Outstanding at beginning of period	5,444,555	$	7.28
Issued	6,931,607		3.67
Repurchased	(95,238)		6.62
Exercised			
Forfeited			
Expired	(1,252,005)		10.03
Outstanding, at the end of period	11,028,919	$	6.52
Exercisable, at the end of period	4,097,312	$	11.34

7. Subsequent Event
Effective November 6, 2009, we entered into a license agreement with Nippon Kayaku Co., Ltd. (Nippon Kayaku) pursuant to which we agreed to enter into a collaboration for the development and commercialization of Apaziquone for use in treating non-muscle invasive bladder cancer. The agreement provides that Nippon Kayaku has the exclusive right to develop and commercialize Apaziquone for the intravesical treatment of non-muscle invasive bladder cancer in humans in Asia (as is defined in the agreement), including Japan and China, but excluding Korea. We retained commercial rights for Korea, however, Nippon Kayaku has co-exclusive rights to conduct clinical development activities in South Korea solely for the purpose of providing support to filings outside of Korea. In addition, Nippon Kayaku has non-exclusive rights to manufacture Apaziquone in its Territory and outside of Asia for the purpose of Apaziquone sales as per the agreement. In consideration for the rights granted under the agreement, Nippon Kayaku has agreed to pay us an upfront fee of $15 million that is due in January 2010. In addition, Nippon Kayaku will pay us up to $136 million based on the achievement of certain regulatory and sales milestones. Also, Nippon Kayaku has agreed to pay us royalties based on a percentage of net sales of Apaziquone in its territory. Nippon Kayaku will conduct Apaziquone clinical trials pursuant to a mutually agreed upon development plan. Nippon Kayaku will be responsible for all expenses relating to the development and commercialization of Apaziquone in its territory. We will be responsible for supplying the Product to Nippon Kayaku for clinical supplies as well as commercial supplies for a set period of time unless Nippon Kayaku elects to manufacture or supply itself. The agreement will remain in effect, on a country-by-country basis, until the expiration of the obligation of Nippon Kayaku to pay royalties on sales of Apaziquone in such country. Nippon Kayaku may terminate the agreement at its election upon nine months notice to us. Additionally, either party may terminate the agreement for an uncured material breach by the other party.

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ITEM 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, in reliance upon the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, without limitation, statements regarding our future product development activities and costs, the revenue potential (licensing, royalty and sales) of our product candidates, the success, safety and efficacy of our drug products, product approvals, product sales, revenues, development timelines, product acquisitions, liquidity and capital resources and trends, and other statements containing forward-looking words, such as, believes, may, could, will, expects, intends, estimates, anticipates, plans, seeks, o forward-looking statements are based on the beliefs of our management as well as assumptions made by and information currently available to our management. Readers should not put undue reliance on these forward-looking statements. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified; therefore, our actual results may differ materially from those described in any forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in our periodic reports filed with the Securities and Exchange Commission, or the SEC, including our Annual Report on Form 10-K for the fiscal year ended December 31, 2008 and our Quarterly Reports on Form 10-Q for the periods ended March 31, 2009 and June 30, 2009, as well as those discussed elsewhere in this Quarterly Report on Form 10-Q, and the following factors:

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

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

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

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

efforts of our development partners;

the ability of our manufacturing partners to meet our timelines;

our ability to identify new product candidates;

the timing and/or results of pending or future clinical trials;

competition in the marketplace for our drugs;

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

actions by the FDA and other regulatory agencies;

securing positive reimbursement for our products;

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

the availability and price of acceptable raw materials and components from third-party suppliers;

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

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

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

demand and market acceptance for our approved products;

We do not plan to update any such forward-looking statements and expressly disclaim any duty to update the information contained in this report except as required by law.

You should read the following discussion of the financial condition and results of our operations in conjunction with the condensed consolidated financial statements and the notes to those financial statements included in Item I of Part 1 of this quarterly report.

Business Outlook

We are a commercial stage biopharmaceutical company committed to developing and commercializing innovative therapies with a focus primarily in the areas of oncology, hematology and urology. We have a fully developed commercial infrastructure that is responsible for the sales and marketing of two drugs in the United States, namely ZEVALIN and FUSILEV. Our lead developmental drug is Apaziquone, which is presently being studied in two large Phase 3 clinical trials for bladder cancer under a strategic collaboration with Allergan, Inc., or Allergan.

The following is an update of our business strategy for 2009, as described in our Annual Report on Form 10-K for the year ended December 31, 2008.

Maximizing the growth potential for our marketed drugs, ZEVALIN and FUSILEV.

Our near-term outlook depends on sales and marketing successes associated with our two marketed drugs. We launched Fusilev in August 2008 and were able to successfully achieve broad utilization in community offices and institutions. Our second drug, Zevalin, was acquired by us in December 2008. A dedicated commercial organization comprised of sales representatives, account managers, medical science liaisons and a complement of other marketing personnel support the sales and marketing of these drugs.

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ZEVALIN® ([90Y]-ibritumomab tiuxetan), or ZEVALIN:

We have accomplished several important milestones for ZEVALIN since the beginning of the third quarter. Effective September 3, 2009, ZEVALIN received FDA approval for an expanded label as a part of first-line therapy for follicular non-Hodgkin s lymphoma, or NHL. ZEVALIN is now approved for the treatment of patients with previously untreated follicular NHL, who achieve a partial or complete response to first-line chemotherapy and with relapsed or refractory, low-grade or follicular B-cell NHL, including patients who have rituximab-refractory follicular NHL.

Also, in November 2009, the Centers for Medicare & Medicaid Services, or CMS, issued a decision (or rule) to allow reimbursement for ZEVALIN, in the Hospital Outpatient Prospective Payment System (HOPPS), based on the Average Sales Price (ASP) methodology, applicable to other injectable drugs and biologicals. This reimbursement methodology should create consistency and accuracy in reimbursement for ZEVALIN for hospital outpatient departments. This reimbursement methodology will go in to effect January 1, 2010. Our next step is getting similar reimbursement in the community setting.

Based on the achievement of these important milestones, we have begun a controlled expansion of our sales and commercial support teams, and expect that by the end of this year we will have optimally expanded our commercial infrastructure, principally directed at the field organization.

FUSILEV® (levoleucovorin) for injection, or FUSILEV:

FUSILEV is currently approved for rescue therapy 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.

On October 8, 2009, we received a Complete Response letter from the FDA regarding our October 2008 supplemental New Drug Application, or sNDA filing for advanced metastatic colorectal cancer. The FDA stated in the Complete Response letter that the submission did not demonstrate that FUSILEV is non-inferior to leucovorin; and recommended that we meet with the FDA to discuss options for continuing to seek approval for FUSILEV in advanced metastatic colorectal cancer. We plan to meet with the FDA in January 2010 to discuss options for FUSILEV in this indication.

Expansion in the sales of FUSILEV depend upon FDA approval for the use of FUSILEV in 5-FU (flouroacil) containing regimens for the treatment of colorectal cancer and favorable reimbursement. The delay in approval of the sNDA by the FDA will impact the sales of FUSILEV till such time the FDA approves the sNDA.

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Maximizing the asset value of Apaziquone.

Apaziquone (EOquin® in bladder cancer):

In 2008, we took a giant step forward with our lead development asset, Apaziquone, when we signed a strategic collaboration with Allergan. We retained exclusive rights to Apaziquone in Asia, including Japan and China while Allergan received exclusive rights to Apaziquone for the treatment of bladder cancer in the rest of the world, including the United States, Canada and Europe. In the United States, we will co-promote Apaziquone with Allergan and share in its profits and expenses. This drug is presently being studied, under a special protocol assessment procedure with the FDA and scientific advice from the European Medicines Agency, or EMEA, the European equivalent of the FDA, in two large Phase 3 clinical trials for non-muscle invasive bladder cancer. Our goal is to complete enrollment in these two trials by the end of 2009.

Effective November 6, 2009, we entered into a license agreement with Nippon Kayaku Co., Ltd. (Nippon Kayaku) pursuant to which we agreed to enter into a collaboration for the development and commercialization of Apaziquone for use in treating non-muscle invasive bladder cancer. The agreement provides that Nippon Kayaku has the exclusive right to develop and commercialize Apaziquone for the intravesical treatment of non-muscle invasive bladder cancer in humans in Asia (as is defined in the agreement), including Japan and China, but excluding Korea. We retained commercial rights for Korea, however, Nippon Kayaku has co-exclusive rights to conduct clinical development activities in South Korea solely for the purpose of providing support to filings outside of Korea. In addition, Nippon Kayaku has non-exclusive rights to manufacture Apaziquone in its Territory and outside of Asia for the purpose of Apaziquone sales as per the agreement. In consideration for the rights granted under the agreement, Nippon Kayaku has agreed to pay us an upfront fee of $15 million that is due in January 2010. In addition, Nippon Kayaku will pay us up to $136 million based on the achievement of certain regulatory and sales milestones. Also, Nippon Kayaku has agreed to pay us royalties based on a percentage of net sales of Apaziquone in its territory. Nippon Kayaku will conduct Apaziquone clinical trials pursuant to a mutually agreed upon development plan. Nippon Kayaku will be responsible for all expenses relating to the development and commercialization of Apaziquone in its territory. We will be responsible for supplying the Product to Nippon Kayaku for clinical supplies as well as commercial supplies for a set period of time unless Nippon Kayaku elects to manufacture or supply itself. The agreement will remain in effect, on a country-by-country basis, until the expiration of the obligation of Nippon Kayaku to pay royalties on sales of Apaziquone in such country. Nippon Kayaku may terminate the agreement at its election upon nine months notice to us. Additionally, either party may terminate the agreement for an uncured material breach by the other party.

Optimizing our development portfolio. We continue to build on our core expertise in clinical development for the treatment of cancer and urology.

RenaZorb®: In August 2009, we acquired 100% of the rights to RenaZorb® and RENALAN® , a lanthanum-based nanotechnology compounds with potent and selective phosphate binding properties, for all uses pursuant to an amended and restated agreement that we entered into with Altair Nanomaterials, Inc and Altair Nanotechnologies, Inc., or Altair. In 2005, the Company had acquired the worldwide license from Altair to develop and commercialize Altair s lanthanum-based nanotechnology compounds and related technology or all human therapeutic uses. The August 2009 acquisition expanded the worldwide, exclusive license to include all uses. In conjuction with the expanded license, Altair assigned all intellectual property associated with RenaZorb® (associated with human uses), RENALAN® (associated and animal or veterinarian use), its lanthanum-based nanotechnology and all of its other life sciences research and development to us. In consideration, we issued 113,809 shares of our common stock, with a then fair value of approximately $750,000. Moving forward, we are responsible for all development, commercialization and intellectual property costs that accrue after the August 2009 execution date for the amended and restated agreement.

Ozarelix: We have initiated a multi-center, randomized, double-blind, placebo-controlled Phase 2b study to evaluate the efficacy of Ozarelix compared to placebo in the treatment of lower urinary tract symptoms secondary to Benign Prostatic Hyperplasia in men as assessed by the International Prostrate Symptom Score at Week 14. We are currently enrolling patients in the study in North America; and intend to expand the study to enroll patients in India.

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Other: We remain reliant on in-licensing strategies to seek drugs for development. Most recently, we have undertaken a criteria-based portfolio review, which is expected to result in streamlining our pipeline drugs, allowing for greater focus and integration of our development and commercial goals. The portfolio will be assessed based on factors that include, among others things, probability of clinical success, time and cost of development, market potential, synergies with marketed and other developmental drugs, and competitive landscape. As a result of this portfolio evaluation, a determination will be made whether to: 1) continue with the drug s clinical development; 2) terminate its development; or 3) out-license rights to a third party for development and commercialization.

Managing our financial resources effectively. We remain committed to fiscal discipline, a policy which has allowed us to become exceptionally well capitalized among our peers, despite a very challenging fiscal environment. This policy includes the pursuit of dilutive and non-dilutive funding options, prudent expense management, and the achievement of critical synergies within our operations in order to maintain a reasonable burn rate. Along these lines, this year we have raised approximately $100 million to support the marketing of our approved drugs as well as position us to take advantage of growth opportunities. In addition, our recently announced partnership with Nippon Kayaku for Apaziquone in Asia provides us with $15 million in non-dilutive funding. With regard to prudent expense management, despite the build-up in operational infrastructure to facilitate the marketing of two drugs, we intend to be fiscally prudent in any expansion we undertake. Also, 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.

Expanding commercial bandwidth through licensing and business development. It remains our goal to identify, for acquisition or partnering, drugs that will create strong synergies with our currently marketed drugs, including drugs in development. To this end, we will continue to explore strategic collaborations as these relate to drugs that are either in advanced clinical trials or are currently on the market.

Financial Condition

Liquidity and Capital Resources

Our cumulative losses, since inception in 1987 through September 30, 2009, are approximately $275 million. We expect to continue to incur additional losses for at least the next few years, as we implement our growth strategy of commercializing ZEVALIN and FUSILEV, while continuing to develop our portfolio of late-stage drug products, unless they are offset, if at all, by the out-license of any of our drugs.

We believe that the approximately $143 million in cash, cash equivalents and marketable securities which we had available on September 30, 2009 will allow us to fund our current planned operations for at least the next twelve to eighteen months. We may, however, seek to obtain additional capital through the sale of debt or equity securities, if necessary, especially in conjunction with opportunistic acquisitions or license of drugs. There can be no assurance that we will be able to obtain such additional capital when needed, or that we will be able to obtain such additional capital on terms favorable to us or our stockholders, if at all. If additional funds are raised by issuing equity securities, the percentage ownership of our stockholders will be reduced, stockholders may experience additional dilution or such equity securities may provide for rights, preferences or privileges senior to those of the holders of our common stock. If additional funds are raised through the issuance of debt securities, the terms of such securities may place restrictions on our ability to operate our business. If and when appropriate, just as we have done in the past, we may pursue non-dilutive financing alternatives as well.

Our long-term strategy, however, is to generate profits from the sale and licensing of our drug products. Accordingly, in the next several years, we expect to supplement our cash position with sales of ZEVALIN and FUSILEV and generate licensing revenues from out-licensing our other drug products.

We are not able to provide any revenue guidance at this time. For ZEVALIN, sales growth is largely dependent on the successful relaunch of ZEVALIN for use as part of first-line consolidation treatment for follicular NHL and establishing a consistent and accurate reimbursement standard based on an ASP methodology. As noted above, we recently obtained a CMS decision for a reimbursement standard based on ASP methodology in the HOPPS setting. For FUSILEV, sales largely depend upon obtaining FDA approval for use of FUSILEV in combination with 5-FU

containing regimens for the treatment of colorectal cancer and favorable reimbursement. As previously discussed, the FDA stated in their October 2009 Complete Response letter that the submission did not demonstrate that FUSILEV is non-inferior to leucovorin; and the FDA recommended that we meet with them to discuss options for continuing to seek approval of FUSILEV in advanced metastatic colorectal cancer. We plan to meet with the FDA in January to discuss options for FUSILEV in this indication. Further, the FDA did not request any changes to the currently approved indications and package insert. We are unable to reasonably estimate when, if ever, we will realize sustainable net profit from sales of these two products or any of our other products, if they are approved by the FDA.

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With regard to estimated future development expenditures, as described elsewhere in this report, as well as the risk factors in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008 as updated by any subsequent quarterly reports on Form 10-Q, our drug development efforts are subject to the considerable uncertainty inherent in any new drug development. Due to the uncertainties involved in progressing through clinical trials, and the time and cost involved in obtaining regulatory approval and in establishing collaborative arrangements, among other factors, we cannot reasonably estimate the timing, completion dates, and ultimate aggregate cost of developing each of our drug product candidates. Accordingly, the following discussion of our current assessment of expenditures may prove inadequate and our assessment of the need for cash to fund our operations may prove too optimistic.

Our expenditures for research and development consist of direct product specific costs, including, but not limited to, upfront license fees, milestone payments, active pharmaceutical ingredients, clinical trials, and patent related costs, and non-product specific, or indirect, costs. During the nine-month period ended September 30, 2009, our total research and development expenditure was approximately $17.5 million (net of $8.0 million received from Allergan), of which approximately $10.1 million was in direct costs. The principal components of direct expenses for that period related to the development of Apaziquone approximately $7.6 million; FUSILEV approximately $0.8 million; Ozarelix approximately $0.6 million and ZEVALIN approximately $0.5 million.

Our primary focus areas for the rest of 2009 and early 2010, and the programs that are expected to represent a significant part of our expenditures, are the on-going clinical studies of Apaziquone and the commercialization of ZEVALIN and FUSILEV. Key factors that we will monitor as we determine the funding of other development projects are as follows:

- the continued commercialization of ZEVALIN and FUSILEV;
- continued patient enrollment in our two (2) phase 3 Apaziquone clinical trials at anticipated rates; and
- continued positive results from our preclinical studies and clinical trials.

While we are currently focused on advancing our key product 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 in response to the scientific and clinical success of each product candidate, as well as an ongoing assessment as to the product candidate s commercial potential.

Further, while we do not receive any funding from third parties for the research and development that we conduct, co-development and out-licensing agreements with other companies for any of our drug products may reduce our expenses. In this regard, we entered into a collaboration agreement with Allergan whereby, commencing January 1, 2009, Allergan bears 65% of the development costs of Apaziquone. In addition, Nippon Kayaku shall be responsible for all development expenses of Apaziquone for its countries in its territory.

In addition to our present portfolio of drug product candidates, we are actively seeking proprietary products for acquisition or licensing. If we are successful in acquiring rights to additional products, we may pay up-front licensing fees in cash and/or common stock and our research and development expenditures would likely increase. In addition, any future acquisitions may require additional financing.

Net Cash used for Operating Activities

During the nine-month period ended September 30, 2009, net cash used in operations was approximately $7.1 million compared to net cash used in operations of $2.7 million in the comparative period of 2008. The 2008 cash flows were favorably impacted by revenues of $20.7 million from the sale of interests in certain non-core assets. The operating cash outflows in 2009, are primarily attributable to higher selling, general and administrative costs incurred due, in a large part, to the marketing efforts associated with ZEVALIN and were substantially mitigated by the revenues derived from FUSILEV and ZEVALIN, and the participation by Allergan in the development activities for Apaziquone.

Net Cash used in Investing Activities

Net cash used in investing activities of approximately $89 million was due to our investment in ZEVALIN and the investment of our funds into highly liquid marketable securities, not meeting the accounting definition of cash or cash equivalents.

Net Cash provided by Financing Activities

Net cash provided by financing activities totaled approximately $95.5 million for the nine-month period ended September 30, 2009. Approximately $97 million, net of offering costs, was derived from the sale of approximately 15.2 million shares of common stock, and approximately $1.1 million from the exercise of stock options for 432,200 shares of our common stock; offset by $2.5 million paid for approximately 2.2 million options, purchased pursuant to a tender offer conducted in April 2009.

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Results of Operations

Results of Operations for the three-month period ended September 30, 2009 compared to the three-month period ended September 30, 2008

For the three-month period ended September 30, 2009, we recorded a net loss of approximately $8.4 million, compared to a net loss of approximately $8.8 million for the three-month period ended September 30, 2008. The principal components of the year-to-year changes in line items are discussed below.

During the three-months ended September 30, 2009, we recognized approximately $5.0 million from product sales with approximately $4.7 million related to sales of ZEVALIN and approximately $0.3 million related to sales of FUSILEV (each net of estimates for promotional, price and other adjustments, including adjustment of the allowance for product returns), with cost of product sold being $2.4 million. No similar revenues were recorded in the three-month period ended September 30, 2008. During the three-month period ended September 30, 2009, we also recognized $2.1 million of licensing revenues from the amortization of the $41.5 million upfront payment we received from Allergan in 2008. We are not able to provide any specific revenue or net income guidance at this time.

We also incurred an approximately $1.0 million non-cash charge due to the amortization of intangibles from the acquisition of ZEVALIN during the three-month period ended September 30, 2009. No similar cost was incurred during the three-month period of 2008.

Total research and development expenses decreased by approximately $0.5 million, from approximately $6.0 million in the three-month period ended September 30, 2008 to approximately $5.5 million in the three-month period ended September 30, 2009, primarily due to sharing of Apaziquone related development costs by our development partner, Allergan. In addition, we incurred reduced development expense in other development products. We expect research & development expenses for the remainder of 2009 to continue at a pace similar to the quarter ended September 30, 2009.

Selling, general and administrative expenses increased by approximately $3.9 million, from approximately $3.1 million in the three-month period ended September 20, 2008 to approximately $7.0 million in the three-month period ended September 30, 2009. The primary reason for the increase is due to increased direct sales and marketing expenses, incurred in connection with the commercial activities associated with ZEVALIN and FUSILEV and related payroll costs. We expect selling, general and administrative expenses for the remainder of 2009 to continue at a pace similar to the quarter ended September 30, 2009.

Other income consisted of net interest income of approximately $72,000 and $300,000 realized currency gains during the three-month period ended September 30, 2009, compared to a net interest income of approximately $276,000 for the three-month period ended September 30, 2008. In the current economic environment, our principal investment objective is preservation of capital. Accordingly, for the foreseeable future we expect to earn minimal interest yields on our investments, till such time as the credit markets recover.

Results of Operations for the nine-month period ended September 30, 2009 compared to the nine-month period ended September 30, 2008

For the nine-month period ended September 30, 2009 we recorded a net loss of $17.5 million, compared to net loss of approximately $6.8 million for the nine-month period ended September 30, 2008. The principal components of the year-to-year changes in line items are discussed below.

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During the nine-months ended September 30, 2009, we recognized approximately $23 million of product sales, comprising approximately $10.6 million from sales of ZEVALIN and approximately $12.4 million from sales of FUSILEV (each net of estimates for promotional, price and other adjustments, including adjustment of the allowance for product returns) with cost of product sold being approximately $5.7 million. As of December 31, 2008, we had deferred the recognition of approximately $3.1 million revenue for product returns, until we were able to obtain more data on product sales and returns. Based on the experience gained to date, we believe that as of September 30, 2009, a product returns reserve of approximately $1.1 million is adequate, and accordingly recognized the difference of approximately $1.9 million as a component of revenue for the nine months ended September 30, 2009.

During the nine months ended September 30, 2009, we also recognized $6.4 million of licensing revenues from the amortization of the $41.5 million upfront payment we received from Allergan in 2008. During the nine-month period ended September 30, 2008, we entered into an asset purchase agreement with Par Pharmaceuticals, Inc, or Par, our marketing partner for sumatriptan injection, pursuant to which we received a non-refundable non-recurring $20 million cash payment from Par for the transfer of our share of the profits from the commercialization of sumatriptan injection. During this period, we also recorded revenue from the transfer of rights to certain of our abbreviated New Drug Applications to Sagent Pharmaceuticals, Inc. for $660,000. We did not earn similar revenues during the nine-month period ended September 30, 2009.

We also incurred an approximately $2.8 million non-cash charge due to the amortization of intangibles from the acquisition of ZEVALIN during the nine month period ended September 30, 2009. No similar cost was incurred during the same period of 2008.

Total research and development expenses, excluding amortization costs associated with ZEVALIN described below, decreased by approximately $1.6 million, from approximately $19.1 million in the nine-month period ended September 30, 2008 to approximately $17.5 million in the nine-month period ended September 30, 2009, primarily due to sharing of Apaziquone related development costs by our development partner, Allergan. In addition, we incurred reduced development expense in other development products, primarily Ozarelix.

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Selling, general and administrative expenses increased by approximately $13.6 million, from approximately $8.9 million in the nine-month period ended September 30, 2008 to approximately $22.5 million in the nine-month period ended September 30, 2009. The primary reason for the increase is due to increased direct sales and marketing expenses, incurred in connection with the commercial activities associated with ZEVALIN and FUSILEV and related payroll costs.

Other income consisted of net interest income of approximately $301,000 and $300,000 realized currency gains during the nine-month period ended September 30, 2009, compared to a net interest income of approximately $556,000 for the nine-month period ended September 30, 2008.

Nature of each accrual that reduces gross revenue to net revenue

Provisions for product returns, sales discounts and rebates and estimates for chargebacks are established as a reduction of product sales revenue at the time revenues are recognized. Such estimated amounts are deducted from our gross sales to determine our net revenues and gross receivables to net receivables. Changes in our estimates, if any, would be recorded in the income statement in the period the change is determined. If we materially over or under estimate the amount, there could be a material impact on our financial statements.

For the nine-month periods ended September 30, 2009 and 2008, the following is a roll forward of the provisions for return, discounts and rebates and chargebacks allowances and estimated doubtful account allowances.

	($ in Thousands)			
	Chargebacks & Discounts	Returns	Doubtful Accounts	Total
Period ending September 30, 2009:				
Balances at beginning of the period	$ 1,631	$ 3,144	$ 150	$ 4,925
Provisions:				
Related to the sales of current fiscal year	3,839	101		3,940
Related to the sales of prior fiscal years		(2,057)		(2,057)
Credits or actual allowances:				
Related to sales from current fiscal year	3,206	80		3,286
Related to sales from prior fiscal years	1,631			1,631
Balances at the close of the period	$ 633	$ 1,108	$ 150	$ 1,891
Period ending September 30, 2008:				
Balances at beginning of period				
Provisions:				
Related to the sales of current fiscal year	$ 46	$ 102	$	$ 148
Related to the sales of prior fiscal years				
Credits or actual allowances:				
Related to sales from current fiscal year				
Related to sales from prior fiscal years				

Balances at the close of the period	$ 46	$ 102	$	$ 148

Note: Provisions described in the table above for the period ended September 30, 2008 were primarily made due to non-recognition of revenue on sales of FUSILEV for the period due to lack of information on returns for product shipped during the period. Provisions for the current period have been reflected as part of accruals on the balance sheet.

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Discounts and rebates

Discounts (generally prompt payment discounts) are accrued at the end of every reporting period based on the gross sales made to the customers during the period and based on their terms of trade for a product. We generally review the terms of the contracts, specifically price and discount structures, payment terms, etc. in the contracts between the customer and us to estimate the discount accrual.

Customer rebates are estimated at every period end, based on direct purchases, depending on whether any rebates have been offered, The rebates are recognized when products are purchased and a periodic credit is given. Medicaid rebates are based on the data we receive from the public sector benefit providers, which is based on the final dispensing of our product by a pharmacy to a benefit plan participant.

Chargebacks

Chargebacks represent a provision against gross accounts receivable and related reduction to gross revenue. A chargeback is the difference between the price the wholesale customer, in our case the wholesaler or distributor pays (the wholesale acquisition cost, or WAC) and the price (contracted price) that a contracted customer(e.g., a Group Purchasing Organization, or GPO, member) pays for a product. We accrue for chargebacks in the relevant period on the presumption that all units of product sold to members of the GPOs will get charged back. We estimate chargebacks at the time of sale of our products to the members of the GPOs based on:

(1) volume of all products sold via distributors to members of the GPOs and the applicable chargeback rates for the relevant period;

(2) applicable WAC and the contract prices agreed with the GPOs; and

(3) the information of inventories remaining on hand at the wholesalers and distributors at the end of the period, actual chargeback reports received from our wholesalers and distributors as well as the chargebacks not yet billed (product shipped less the chargebacks already billed back) in the calculation and validation of our chargeback estimates and reserves.

Product returns allowances

Customers are typically permitted to return products within 30 days after shipment, if incorrectly shipped or not ordered, and within a window of time 6 months before and 12 months after the expiration of product dating, subject to certain restocking fees and preauthorization requirements, as applicable. Currently, our returns policy does not allow for replacement of product. The returned product is destroyed if it is damaged, quality is compromised or past its expiration date. Based on our returns policy, we refund the sales price to the customer as a credit and record the credit against receivables. In general, returned product is not resold. As of each balance sheet date, we estimate potential returns, based on several factors, including: inventory held by distributors, sell through data of distributor sales to end users, customer and end-user ordering and re-ordering patterns, aging of accounts receivables, rates of returns for directly substitutable products and pharmaceutical products for the treatment of therapeutic areas similar to indications served by our products, shelf life of our products and based on the extensive experience of our management with selling the similar oncology products. We record an allowance for future returns by debiting Revenue, thereby reducing gross revenues and crediting a reserve for returns to reduce gross receivables.

Doubtful Accounts

An allowance for doubtful accounts is estimated based on the customer payment history and a review of the aging of the accounts receivables as of the balance sheet date. We accrue for such doubtful accounts by recording an expense and creating an allowance for such accounts. If we are privy to information on the solvency of a customer or observe a payment history change, we make an estimate of the accrual for such doubtful receivables or even write the receivable off.

Off-Balance Sheet Arrangements

None.

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Contractual and Commercial Obligations

The following table summarizes our contractual and other commitments, including obligations under facility and equipment leases, as of September 30, 2009 (in thousands):

	Total	Less than 1 Year	1-3 Years	3-5 Years	After 5 Years
Contractual Obligations (1)					
Capital Lease Obligations (2)	$ 159	$ 50	$ 109		
Operating Lease Obligations (3)	3,388	424	925	$ 1,040	$ 999
Purchase Obligations (4)	10,700	6,434	4,266		
Contingent Milestone Obligations (5)	75,807	1,734	4,943	5,046	64,084
Total	$ 90,054	$ 8,642	$ 10,243	$ 6,086	$ 65,083

(1) The table of contractual and commercial obligations excludes contingent payments that we may become obligated to pay upon the occurrence of future events whose outcome is not readily predictable, such as obligations pursuant to employment agreements.

(2) The capital lease obligations are related to leased office equipment.

(3) The operating lease obligations are primarily for the facility lease for our corporate office,

which extends through June 2016.

(4) Purchase obligations represent the amount of open purchase orders and contractual commitments to vendors for products and services that have not been delivered, or rendered, as of September 30, 2009. Approximately 60% of the purchase obligations consist of expenses associated with clinical trials and related costs for Apaziquone for each of the periods presented.

(5) Milestone obligations are payable contingent upon successfully reaching certain development and regulatory milestones. While the amounts included in the table above represent all of our potential cash development and regulatory

milestone obligations as of September 30, 2009, given the unpredictability of the drug development process, and the impossibility of predicting the success of current and future clinical trials, the timelines estimated above do not represent a forecast of when payment milestones will actually be reached, if at all. Rather, they assume that all development and regulatory milestones under all of our license agreements are successfully met, and represent our best estimates of the timelines. In the event that the milestones are met, we believe it is likely that the increase in the potential value of the related drug product will significantly exceed the amount of the milestone obligation.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with Accounting Standards Codification, or ASC, No. 105, Generally Accepted Accounting Principles . The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. The estimation process requires assumptions to be made about future events and conditions, and is consequently inherently subjective and uncertain. Actual results could differ materially from our estimates. On an ongoing basis, we evaluate our estimates, including cash requirements, by assessing: planned research and development activities and general and administrative requirements; required clinical trial activity; market need for our drug candidates; and other major business assumptions.

The SEC defines critical accounting policies as those that are, in management s view, most important to the portrayal of our financial condition and results of operations and most demanding of our judgment. We consider the following policies to be critical to an understanding of our consolidated financial statements and the uncertainties associated with the complex judgments made by us that could impact our results of operations, financial position and cash flows.

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities primarily consist of bank checking deposits, short-term treasury securities, and institutional money market funds, corporate debt and equity, municipal obligations, including market auction debt securities, 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 ASC No. 320, Investments-Debt and Equity Securities . Investments that we intend to hold for more than one year are classified as long-term investments.

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Revenue Recognition

We follow the provisions as set forth by current accounting rules, which primarily include Staff Accounting Bulletin ASC No. 605-15 Revenue Recognition , Revenue Recognition , and ASC No. 605-25, Revenue Recognition: Multiple-Element Arrangements .

Generally, revenue is recognized when all four of the following criteria are met:

(i) persuasive evidence that an arrangement exists;

(ii) delivery of the products has occurred, or services have been rendered;

(iii) the selling price is both fixed and determinable; and

(iv) collectibility is reasonably assured.

We sell our products to wholesalers and distributors of oncology products and directly to the end user, directly or through GPOs (e.g., certain hospitals or hospital systems and clinics with whom we have entered into a direct purchase agreement). Our wholesalers and distributors purchase our products and sell the products directly to the end users, which include, but are not limited to, hospitals, clinics, medical facilities, managed care facilities and private oncology based practices etc. Revenue from product sales is recognized upon shipment of product when title and risk of loss have transferred to the customer, and the following additional criteria specified by SFAS 48 are met:

(i) the price is substantially fixed and determinable;

(ii) our customer has economic substance apart from that provided by us;

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

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

(v) we have a reasonable basis to estimate future returns.

Provisions for estimated product returns, sales discounts, rebates and charge backs are established as a reduction of gross product sales at the time such revenues are recognized. Thus, revenue is recorded, net of such estimated provisions.

Consistent with industry practice, our product return policy permits our customers to return products within 30 days after shipment, if incorrectly shipped or not ordered, and within a window of time 6 months before and 12 months after the expiration of product dating, subject to certain restocking fees and preauthorization requirements, as applicable. Currently, our returns policy does not allow for replacement of product. The returned product is destroyed if it is damaged, it s quality is compromised or it is past its expiration date. Based on our returns policy, we refund the sales price to the customer as a credit and record the credit against receivables. In general returned product is not resold. We generally reserve the right to decline granting a return and to decide on product destruction. As of each balance sheet date, we estimate potential returns, based on several factors, including: inventory held by distributors, sell through data of distributor sales to end users, customer and end-user ordering and re-ordering patterns, aging of accounts receivables, rates of returns for directly substitutable products and other pharmaceutical products for the treatment of therapeutic areas similar to indications served by our products, shelf life of our products and the extensive experience of our management with selling the same and similar oncology products. We record an allowance for future returns by debiting revenue, thereby reducing gross revenues and crediting a reserve for returns to reduce gross receivables. If allowances exceed the related accounts receivables, we reclassify such excess to accrued obligations. We also 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.

Up-front fees representing non-refundable payments 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 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.

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Research and Development

Research and development expenses include salaries and benefits, clinical trial and related manufacturing costs, contract and other outside service fees, and facilities and overhead costs related to our research and development efforts. Research and development expenses also consist of costs incurred for proprietary and collaboration research and development and include activities such as product registries and investigator-sponsored trials. In accordance with ASC No. 730, Research and Development , research and development costs are expensed as incurred. In certain instances we enter into agreements with third parties for research and development activities, where we may prepay fees for services at the initiation of the contract. In accordance with ASC No. 730-20, Research and Development: Research and Development Arrangements , we record such prepayment as a prepaid asset and charge research and development expense over the period of time the contracted research and development services are performed. In connection with the October 2008 codevelopment agreement, Allergan bears 65% of the development costs incurred for Apaziquone in bladder cancer, commencing January 1, 2009. During the nine months ended September 30, 2009, approximately $7.9 million of development costs were reimbursed by Allergan, and credited against total related research and development expense.

As of each Balance Sheet date, we review purchase commitments 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.

Accounting for Share-Based Employee Compensation

In estimating the fair value of share-based compensation, we use the quoted 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.

Recent Accounting Pronouncements

See Note 2: Recent Accounting Pronouncements of our accompanying consolidated financial statements for a description of recent accounting pronouncements that have a potentially significant impact on our financial reporting and our expectations of their impact on our results of operations and financial condition.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

The primary objective of our investment activities is to preserve principal, while at the same time maximizing yields without significantly increasing risk. We do not utilize hedging contracts or similar instruments.

We are exposed to certain market risks. Our primary exposures relate to (1) interest rate risk on our investment portfolio, (2) credit risk of the companies bonds in which we invest, and (3) general credit market risks as have existed since late 2007 and became more prominent during 2008 and (4) the financial viability of the institutions which hold our capital and through which we have invested our funds. We manage such risks on our investment portfolio by matching scheduled investment maturities with our cash requirements and investing in highly rated instruments.

In response to the dislocation in the credit markets since the latter part of 2007, in early 2008 we converted substantially all of our investments, including all of our market auction debt securities, into safer and highly liquid instruments. Our investments, as of September 30, 2009, were primarily in money market accounts, short-term corporate bonds, U.S. Treasury bills and U.S. Treasury-backed securities. 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 recent 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.

Because of our ability to generally redeem these investments at par at short notice, changes in interest rates would have an immaterial effect on the fair value of these investments. If a 10% change in interest rates were to have occurred on September 30, 2009, any decline in the fair value of our investments would not be material in the context of our financial statements. In addition, we are exposed to certain market risks associated with credit ratings of corporations whose corporate bonds we may purchase from time to time. If these companies were to experience a significant detrimental change in their credit ratings, the fair market value of such corporate bonds may significantly

decrease. If these companies were to default on these corporate bonds, we may lose part or all of our principal. We believe that we effectively manage this market risk by diversifying our investments, and investing in highly rated securities.

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In addition, we are exposed to foreign currency exchange rate fluctuations relating to payments we make to vendors, suppliers and license partners using foreign currencies. In particular, some of our obligations are incurred in Euros and Canadian dollars. We mitigate such risk by maintaining a limited portion of our cash in Euros, Canadian dollars and other currencies.

ITEM 4. Controls and Procedures

We have established disclosure controls and procedures (as such terms are defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer (our principal executive officer) and Vice President of Finance (our principal financial officer), as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide a reasonable level of assurance of reaching our desired disclosure control objectives.

As required by Rule 13a-15(b) under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and our principal financial officer, of the effectiveness of our disclosure controls and procedures as of September 30, 2009, the end of the period covered by this report. Based on the foregoing, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of September 30, 2009.

There has been no change in our internal control over financial reporting during the quarter ended September 30, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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ITEM 6. Exhibits

Exhibit No.	Description
1.1	Placement Agency Agreement by and between the Registrant, and Rodman & Renshaw, LLC, dated September 18, 2009 (Filed as Exhibit 1.1 to Form 8-K, as filed with the Securities and Exchange Commission on September 23, 2009, and incorporated herein by reference).
4.1	Form of Common Stock Purchase Warrant (Filed as Exhibit 4.1 to Form 8-K, as filed with the Securities and Exchange Commission on September 23, 2009, and incorporated herein by reference).
10.1	Form of Stock Purchase Agreement, dated September 18, 2009 (Filed as Exhibit 1.1 to Form 8-K, as filed with the Securities and Exchange Commission on September 23, 2009, and incorporated herein by reference).
31.1+	Certification of Principal Executive Officer, pursuant to Rule 13a-14(a)/15d-14(a) promulgated under the Securities Exchange Act of 1934.
31.2+	Certification of Principal Financial Officer, pursuant to Rule 13a-14(a)/15d-14(a) promulgated under the Securities Exchange Act of 1934.
32.1+	Certification of Principal Executive Officer, pursuant to rule 13a-14(b)/15d-14(b) promulgated under the Securities Exchange Act of 1934 and 18 U.S.C Section 1350.
32.2+	Certification of Principal Financial Officer, pursuant to rule 13a-14(b)/15d-14(b) promulgated under the Securities Exchange Act of 1934 and 18 U.S.C Section 1350.

+ Filed herewith.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

SPECTRUM PHARMACEUTICALS, INC.

Date: November 12, 2009

By: /s/ Shyam K. Kumaria
Shyam K. Kumaria,
Vice President, Finance
(Authorized Signatory and Principal Financial and Accounting Officer)

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