SPECTRUM PHARMACEUTICALS INC
Form 10-Q
November 04, 2010

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

FORM 10-Q

þ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2010

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)
(949) 788-6700
(Registrant s telephone number, including area code)

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 the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No þ
As of October 22, 2010, 50,487,717 shares of the registrant s common stock were outstanding.

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PART I: FINANCIAL INFORMATION

SPECTRUM PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

(In thousands, except share and per share data)

(Unaudited)

	September 30, 2010	December 31, 2009
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 45,387	$ 82,336
Marketable securities	39,209	31,005
Accounts receivable, net	9,465	8,658
Inventories, net	3,795	3,230
Prepaid expenses and other current assets	1,080	1,028
Total current assets	98,936	126,257
Bank certificates of deposit & treasuries	7,376	11,438
Property and equipment, net	3,245	1,928
ZEVALIN related intangible assets, net	30,535	33,325
Other assets	400	185
TOTAL ASSETS	$ 140,492	$ 173,133
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable and other accrued obligations	$ 26,573	$ 16,606
Accrued compensation and related expenses	2,556	3,360
Deferred revenue	12,300	8,300
Common stock warrant liability	605	6,635
Accrued drug development costs	5,004	4,598
Total current liabilities	47,038	39,499
Capital lease obligations	48	69
Deferred revenue and other credits less current portion	28,717	24,943
ZEVALIN related contingent obligations	298	298
Total liabilities	76,101	64,809
Commitments and contingencies		
Stockholders Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized of which 1,0000,000 shares have been designated as Series B junior participating preferred stock, no shares issued and outstanding (September 30, 2010 and December 31, 2009)		
Series E convertible voting preferred stock $10,000 par value; 2,000 shares authorized; 68 shares issued and outstanding (September 30, 2010 and December 31, 2009) (aggregate liquidation value of $0.8 million)	419	419
	50	49

Common stock, $0.001 par value 100,000,000 shares authorized; 50,370,342 (September 30, 2010) and 48,926,314 (December 31, 2009) issued and outstanding		
Additional paid-in capital	378,797	369,482
Accumulated other comprehensive loss	(35)	(70)
Accumulated deficit	(314,840)	(261,556)
Total stockholders equity	64,391	108,324
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	$ 140,492	$ 173,133

See accompanying notes to unaudited condensed consolidated financial statements.

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SPECTRUM PHARMACEUTICALS, INC.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Revenues:				
Product sales, net	$ 13,660	$ 4,976	$ 30,050	$ 23,030
License and contract revenue	3,075	2,125	10,117	6,375
Total revenues	$ 16,735	$ 7,101	$ 40,167	$ 29,405
Operating costs and expenses:				
Cost of product sales (excludes amortization of purchased intangible assets)	3,789	2,429	10,626	5,702
Selling general and administrative	11,411	6,995	36,075	22,538
Research and development	7,485	5,488	50,314	17,533
Amortization of purchased intangibles	930	950	2,790	2,850
Total operating costs and expenses	23,615	15,862	99,805	48,623
Loss from operations	(6,880)	(8,761)	(59,638)	(19,218)
Change in fair value of common stock warrant liability	1,629	8,863	6,030	(11,759)
Other income, net	578	372	245	601
(Loss) income before provision for income taxes	(4,673)	474	(53,363)	(30,376)
Provision for income taxes	79		79	
Net loss attributable to non-controlling interest				1,146
Net (loss) income attributable to Spectrum Pharmaceuticals, Inc. stockholders	$ (4,594)	$ 474	$ (53,284)	$ (29,230)
Net (loss) income per share:				
Basic	$ (0.09)	$ 0.01	$ (1.08)	$ (0.80)
Diluted	$ (0.09)	$ (0.07)	$ (1.08)	$ (0.80)
Weighted average shares outstanding:				
Basic	49,739,072	42,364,983	49,146,245	36,189,156
Diluted	49,739,072	44,191,257	49,146,245	36,189,156

See accompanying notes to unaudited condensed consolidated financial statements.

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

	September 30, 2010	2009
Cash Flows From Operating Activities:		
Net loss	$ (53,284)	$ (29,230)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of deferred revenue	(10,117)	(6,375)
Depreciation and amortization	3,320	3,248
Stock-based compensation	6,267	6,013
Change in fair value of common stock warrants	(6,030)	11,759
Fair value of common stock issued in connection with asset acquisition	1,661	935
Non-controlling interest in consolidated entities		(1,146)
Changes in operating assets and liabilities:		
Accounts receivable, net	(807)	561
Inventories, net	(565)	(319)
Prepaid expenses and other assets	(277)	314
Accounts payable and other accrued obligations	9,516	7,663
Accrued compensation and related expenses	(804)	(480)
Accrued drug development costs	406	
Landlord contributions to tenant improvements	995	
Deferred revenue and other credits	16,896	(35)
Net cash used in operating activities	(32,813)	(7,092)
Cash Flows From Investing Activities:		
Net purchases of marketable securities	(4,097)	(65,538)
Investment in ZEVALIN acquisition		(22,687)
Acquisition of property and equipment	(1,396)	(388)
Net cash used in investing activities	(5,493)	(88,613)
Cash Flows From Financing Activities:		
Proceeds from issuance of common stock and warrants, net of related offering costs and expenses		95,810
Proceeds from issuance of common stock from stock option exercises	1,082	1,145
Proceeds from issuance of common stock to employees shelf takedown		1,167
Proceeds from issuance of common stock under the ESPP plan	306	
Repurchase of warrants		(71)
Repurchase of stock options pursuant to tender offer		(2,520)
Repayment of capital leases	(21)	
Net cash provided by financing activities	1,367	95,531
Net decrease in cash and cash equivalents	(36,949)	(174)

Cash and cash equivalents	beginning of period		82,336		9,860
Cash and cash equivalents	end of period	$	45,387	$	9,686
Supplemental Disclosure of Cash Flow Information:					
Financed portion of leasehold improvements		$	451	$	

See accompanying notes to condensed consolidated financial statements.

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

1. Business and Basis of Presentation

Business

Spectrum Pharmaceuticals, Inc. (Spectrum , the Company , we , our , or us) is a biotechnology company wit integrated commercial and drug development operations, with a primary focus in oncology. Our strategy is comprised of acquiring, developing and commercializing a broad and diverse pipeline of late-stage clinical and commercial products. We market two oncology drugs, ZEVALIN® and FUSILEV® and have two drugs, apaziquone and belinostat, in late stage development along with a diversified pipeline of novel drug candidates. We have assembled an integrated in-house scientific team, including formulation development, clinical development, medical research, regulatory affairs, biostatistics and data management, and have established a commercial infrastructure for the marketing of our drug products. We also leverage the expertise of our worldwide partners to assist in the execution of our strategy. Apaziquone is presently being studied in two large Phase 3 clinical trials for non-muscle invasive bladder cancer, or NMIBC, under strategic collaborations with Allergan, Inc., (Allergan), Nippon Kayaku Co. Ltd., (Nippon Kayaku), and Handok Pharmaceuticals Co. Ltd., (Handok). Belinostat, is being studied in multiple indications including a Phase 2 registrational trial for relapsed or refractory peripheral T-cell lymphoma, (PTCL), under a strategic collaboration with TopoTarget A/S (TopoTarget).

Basis of Presentation

We have prepared the accompanying unaudited condensed consolidated financial statements, pursuant to the rules and regulations of the Securities and Exchange Commission (the SEC). We have condensed or omitted certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles (GAAP) pursuant to such rules and regulations. The unaudited condensed consolidated financial statements reflect all adjustments, which are normal and recurring, that are, in the opinion of management, necessary to fairly state the financial position as of September 30, 2010 and the results of operations and cash flows for the related interim periods ended September 30, 2010 and 2009. The results of operations for the three and nine months ended September 30, 2010 are not necessarily indicative of the results that may be expected for the year ending December 31, 2010 or for any other period.

Significant Accounting Policies

The accounting policies followed by us and other information are contained in the notes to the Company s audited consolidated financial statements for the year ended December 31, 2009 included in our Annual Report on Form 10-K filed on April 5, 2010 with the SEC. We have not changed our significant accounting policies as of September 30, 2010. You should read this Quarterly Report on Form 10-Q in connection with the information contained in our Annual Report on Form 10-K filed on April 5, 2010.

Segment and Geographic Information

We operate in one reportable segment: acquiring, developing and commercializing prescription drug products. Accordingly, we report the accompanying condensed consolidated financial statements in the aggregate, including all of our activities in one reportable segment. Foreign operations were not significant for any of the periods presented herein.

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Use of Estimates

The preparation of financial statements in conformity with GAAP requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and disclosure of contingent obligations in the financial statements and accompanying notes. 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.

Recent Accounting Pronouncements

In June 2009, the FASB issued authoritative guidance that requires companies to perform an analysis to determine whether such companies variable interest or interests give it a controlling financial interest in a variable interest entity. This analysis identifies the primary beneficiary of a variable interest entity as the enterprise that has both the power to direct the activities of a variable interest entity that most significantly impact the entity s economic performance, and the obligation to absorb losses or the right to receive benefits of the entity that could potentially be significant to the variable interest entity. This guidance also requires ongoing reassessments of whether an enterprise is the primary beneficiary of a variable interest entity and eliminates the quantitative approach previously required for determining the primary beneficiary. We adopted the provisions of this guidance in the first quarter of 2010, and determined that none of the entities with which we currently conduct business or collaborations are variable interest entities to be consolidated.

New Accounting Standards Not Yet Adopted

In April 2010, the FASB issued an accounting standards update that provides guidance on the milestone method of revenue recognition for research and development arrangements. This guidance allows an entity to make an accounting policy election to recognize revenue that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. This guidance is effective for fiscal years beginning on or after June 15, 2010, which will be our 2011 fiscal year, and may be applied prospectively to milestones achieved after the adoption date or retrospectively for all periods presented, with earlier application permitted. We are currently evaluating the potential impact of adopting this guidance on our consolidated financial statements.

In October 2009, the FASB issued an accounting standards update that requires an entity to allocate arrangement consideration at the inception of an arrangement to all of its deliverables based on their relative selling prices, eliminates the use of the residual method of allocation, and requires the relative-selling-price method in all circumstances in which an entity recognizes revenue of an arrangement with multiple deliverables. This guidance is effective for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, which will be our 2011 fiscal year, with earlier application permitted. We are currently evaluating the potential impact of adopting this guidance on our consolidated financial statements.

Acquisitions and Collaborations

For all in-licensed products, pursuant authoritative guidance issued by the FASB, we perform an analysis to determine whether we hold a variable interest or interests that give us a controlling financial interest in a variable interest entity. On the basis of our interpretations and conclusions, we determine whether the acquisition falls under the purview of variable interest entity accounting and if so, consider the necessity to consolidate the acquisition.

We also perform an analysis to determine if the inputs and/or processes acquired in an acquisition qualify as a business. On the basis of our interpretations and conclusions, we determine if the in-licensed products qualify as a business and whether to account for such products as a business combination or an asset acquisition.

Basic and Diluted Earnings per Share

We calculate basic and diluted net income (loss) per share using the weighted average number of common shares outstanding during the periods presented, and adjust the amount of net income (loss) used in this calculation for preferred stock dividends (if any) declared during the period. In periods of a net loss position, basic and diluted weighted average shares are the same. For the diluted earnings per share calculation, we adjust the weighted average number of common shares outstanding to include dilutive stock options, warrants and other common stock equivalents outstanding during the period.

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We incurred a net loss for the three and nine months ended September 30, 2010 and the nine-months ended September 30, 2009 and as such, did not include the effect of potentially dilutive common stock equivalents in the diluted earnings per share calculation, as their effect would be anti-dilutive. During the three months ended September 30, 2009 we recorded net income, accordingly, the following table presents the data used in the calculation of basic and diluted net earnings per share for the three month period ended September 30, 2009:

(in thousands, except share and per share data)	Net Income (Loss) Attributable to Spectrum Pharmaceuticals Stockholders	Shares (Denominator)	Earnings (Loss) Per Share
Three Months Ended September 30, 2009			
Basic earnings per share:	$ 474	42,364,983	$ 0.01
Diluted earnings per share:			
Dilutive preferred shares		136,000	
Dilutive Options		1,592,323	
Incremental shares assumed issued on exercise of in the money warrants		97,951	
Change in fair value of common stock warrants assumed exercised during the quarter	(3,460)		
Diluted earnings per share	$ (2,986)	44,191,257	$ (0.07)

2. Cash, Cash Equivalents and Marketable Securities

As of September 30, 2010, we held substantially all of our cash, cash equivalents and marketable securities at major financial institutions, which must 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, the Federal Deposit Insurance Corporation and third party insure these investments. However, these investments are not insured against the possibility of a complete loss of earnings or principal and are inherently subject to the credit risk related to the continued credit worthiness of the underlying issuer and general credit market risks. We manage such risks on our portfolio by investing in highly liquid, highly rated instruments and not investing in long-term maturity instruments.

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Cash, cash equivalents and investments in marketable securities, including long term bank certificates of deposits, totaled $92.0 million and $124.8 million as of September 30, 2010 and December 31, 2009, respectively. Long term bank certificates of deposit include a $500,000 restricted certificate of deposit that collateralizes tenant improvement obligations to the lessor of our principal offices. The following is a summary of such investments (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated fair Value	Cash	Marketable Security Current	Marketable Security Long Term
September 30, 2010							
Cash and cash equivalents	$ 45,387	$	$	$ 45,387	$ 45,387	$	$
Bank CDs (including restricted certificate of deposit $0.5 million)	24,417			24,417		17,041	7,376
Money market currency funds	2,764			2,764		2,764	
U.S. Government securities	16,993			16,993		16,993	
Corporate debt securities	2,411			2,411		2,411	
Other securities (included in other assets)	35		11	24			24
Total investments	$ 92,007	$	$ 11	$ 91,996	$ 45,387	$ 39,209	$ 7,400
December 31, 2009							
Cash and cash equivalents	$ 82,336	$	$	$ 82,336	$ 82,336	$	$
Bank CDs	20,948			20,948		12,260	8,688
Money market currency funds	4,800			4,800		4,800	
U.S. Government securities	16,542			16,542		13,792	2,750
Corporate debt securities	153			153		153	
Other securities (included in other assets)	47		12	35			35

Total investments	$ 124,826	$	$ 12	$ 124,814	$ 82,336	$ 31,005	$ 11,473

3. Fair Value Measurements

The carrying values of our cash and cash equivalents, marketable securities, other securities and common stock warrants, carried at fair value as of September 30, 2010 are classified in the table below in one of the three categories described below (in thousands):

	Fair Value Measurements			
	Level 1	**Level 2**	**Level 3**	**Total**
		($ in '000 s)		
Assets:				
Cash and cash equivalents	$ 45,387	$	$	$ 45,387
FDIC insured bank CDs		24,417		24,417
Money market currency funds		2,764		2,764
U.S. Government securities		16,993		16,993
Corporate debt securities		2,411		2,411
Cash and cash equivalents and marketable securities	45,387	46,585		91,972
Other securities	24			24
	$ 45,411	$ 46,585	$	$ 91,996
Liabilities:				
Common stock warrant liability			605	605
	$	$	$ 605	$ 605

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

Level 1: Quoted prices (unadjusted) in active markets for identical assets or liabilities that are accessible at the measurement date. 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. These inputs include quoted prices for similar assets or liabilities; quoted market prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

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

In determining fair value, we utilize valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible, as well as consider counterparty credit risk in the assessment of fair value. Cash equivalents consist of certificates of deposit and are valued at cost, which approximates fair value due to the short-term maturities of these instruments. Marketable securities consist of certificates of deposit, US Government Treasury bills, US treasury-backed securities and corporate deposits, which are stated at fair market value, based on values provided us by the financial institutions where we invest our funds.

We had classified all of our marketable securities as Level 1 measurements as of December 31, 2009. Based on the recent guidance on disclosures for fair value measurements, as of September 30, 2010, we have reclassified all of our marketable securities under Level 2 measurements.

The following summarizes the activity of Level 3 inputs measured on a recurring basis for the nine months ended September 30, 2010:

		Fair Value Measurements of Common Stock Warrants Using Significant Unobservable Inputs (Level 3) ($ in 000 s)
Balance at December 31, 2009	$	6,635
Adjustments resulting from expiration of warrants recognized in earnings		(788)
Adjustments resulting from change in value of warrants recognized in earnings		(5,242)
Balance at September 30, 2010	$	605

During the nine months ended September 30, 2010, the fair value of common stock warrants decreased approximately $6.0 million due to the change in value of warrants recognized in earnings during the period and expiration of certain warrants issued in 2009. The fair value of common stock warrants are measured on their respective origination dates and at the end of each reporting period using Level 3 inputs. The significant assumptions we use in the calculations under the Black-Scholes Option Pricing Model as of September 30, 2010, included an expected term based on the remaining contractual life of the warrants, a risk-free interest rate based upon observed interest rates appropriate for the expected term of the instruments, volatility based on the historical volatility of our common stock, and a zero dividend rate based on our past, current and expected practices of granting dividends on common stock.

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We did not elect the fair value option, as allowed, to account for financial assets and liabilities that were not previously carried at fair value. Therefore, material financial assets and liabilities that are not carried at fair value, such as trade accounts receivable and payable, are reported at their historical carrying values.

4. Accounts Receivable Trade

Accounts receivable, net of allowance for doubtful accounts consisted of the following:

	September 30, 2010	December 31, 2009
	($ in '000s)	
Accounts receivable	$ 10,010	$ 8,808
Allowances for untreated kits	(170)	
Allowances for doubtful accounts	(375)	(150)
	$ 9,465	$ 8,658

Allowances for chargebacks, discounts, rebates and returns are included in other accrued obligations on the accompanying condensed consolidated balance sheets. Allowances consisted of the following:

	September 30, 2010	December 31, 2009
	($ in '000s)	
Allowance for chargebacks and discounts	$ 1,086	$ 860
Allowance for rebates	4,338	388
Allowance for returns	1,256	1,176
	$ 6,680	$ 2,424

5. Inventories

Inventories, net of allowances consisted of the following:

	September 30, 2010	December 31, 2009
	($ in '000s)	
Raw materials	$ 244	$ 280
Work-in-process	74	
Finished goods	3,477	2,950
	$ 3,795	$ 3,230

We continually review product inventories on hand, evaluating inventory levels relative to product demand, remaining shelf life, future marketing plans and other factors, and record reserves for obsolete and slow-moving inventories for amounts which we may not realize.

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6. Income Taxes

Our provision for income taxes is computed using the asset and liability method, under which deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the financial reporting and tax bases of assets and liabilities, and for the expected future tax benefit to be derived from tax loss and credit carryforwards. Deferred tax assets and liabilities are determined using the enacted tax rates in effect for the years in which those tax assets are expected to be realized. A valuation allowance is established when it is more likely than not the future realization of all or some of the deferred tax assets will not be achieved. The evaluation of the need for a valuation allowance is performed on a jurisdiction by jurisdiction basis, and includes a review of all available positive and negative evidence. As of September 30, 2010 and December 31, 2009, we maintained a valuation allowance against deferred tax assets that we concluded have not met the more likely than not threshold. Changes in the valuation allowance when they are recognized in the provision for income taxes are included as a component of the estimated annual effective tax rate.

We recognize excess tax benefits associated with share-based compensation to stockholders equity only when realized. When assessing whether excess tax benefits relating to share-based compensation have been realized, we follow the with-and-without approach, excluding any indirect effects of the excess tax deductions. Under this approach, excess tax benefits related to share-based compensation are not deemed to be realized until after the utilization of all other tax benefits available to us.

We recognize the impact of a tax position in our financial statements only if that position is more likely than not of being sustained upon examination by taxing authorities, based on the technical merits of the position. Any interest and penalties related to uncertain tax positions will be reflected in income tax expense.

7. Commitments and Contingencies

Facility Lease

As part of our Irvine facility lease renewal in 2009, the landlord agreed to contribute up to approximately $1.5 million toward the cost of tenant improvements. The tenant improvements were completed in the second quarter of 2010, at an aggregate cost of approximately $1.4 million, of which $451,000 is being financed. This landlord contribution is being amortized on a straight-line basis over the term of the lease as a reduction to rent expense.

Licensing Agreements

We are developing almost all of our drug candidates pursuant to license agreements that provide us with rights in certain territories, among other things, to develop, sublicense, manufacture and sell the drugs. We are generally required to use commercially reasonable efforts to develop the drugs, and 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 various regulatory authorities approval process, which approval significantly depends on positive clinical trial results. The following items are typical of such 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.

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Given the uncertainty of the drug development and regulatory approval process, we cannot predict with any certainty when any of the milestones will occur, if at all. Accordingly, the milestone payments represent contingent obligations that we will record as expense when such milestone is achieved.

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. 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 be 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 can thus avoid paying for the services that have not yet been rendered and our future purchase obligations would reduce accordingly.

Employment Agreement

We have entered into an employment agreement with Dr. Rajesh C. Shrotriya, our President and Chief Executive Officer, which expires January 2, 2012. The employment agreement automatically renews for subsequent 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 our business and affairs 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 our Board of Directors.

Litigation

We are involved with various legal matters arising in the ordinary course of our business. Although the ultimate resolution of these various matters cannot be determined at this time, we do not believe that such matters, individually or in the aggregate, will have a material adverse effect on our consolidated results of operations, cash flows or financial condition.

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8. Stockholder s Equity

Warrant 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 consultants. Our outstanding warrants expire on varying dates through June 2015. Below is a summary of warrant activity during the nine months ended September 30, 2010:

	Common Stock Warrants	Weighted Average Exercise Price
Outstanding at beginning of period	11,028,919	$ 6.52
Issued	75,000	3.82
Repurchased		
Exercised		
Forfeited		
Expired	(6,931,607)	6.55
Outstanding, at the end of period	4,172,312	$ 6.41
Exercisable, at the end of period	4,122,312	$ 6.48

Approximately 3.7 million of the outstanding warrants are scheduled to expire by September 30, 2011.

Share-Based Compensation

We record share-based employee compensation expense for all equity-based programs, including stock options, restricted stock grants, 401(k) plan matching and our employee stock purchase plan. Total expense recorded for the three and nine month periods ended September 30, 2010 and 2009 are as shown below:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
	($ in ‘000 s)			
Research and development	$ 253	$ 722	$ 2,111	$ 3,015
General and administrative	1,803	498	4,156	2,998
Total share based compensation expense	$ 2,056	$ 1,220	$ 6,267	$ 6,013

Stock Options

During the nine month period ended September 30, 2010, the Compensation Committee of our Board of Directors 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 periods ended September 30, 2010 and 2009 were estimated at approximately $2.53 and $2.88, respectively using the Black-Scholes option pricing model with the following assumptions:

	Nine-months ended September 30,	
	2010	2009
Divided yield	0.00%	0.00%

Expected volatility	70.8%	71.9%
Risk free interest rate	2.06%	2.26%
Expected life (years)	5	5

Share based compensation expense is recognized only for those awards that are ultimately expected to vest, and we have applied a forfeiture rate to unvested awards for the purpose of calculating the compensation cost. These estimates will be reversed in future periods if actual forfeitures differ from our estimates.

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During the three and nine months ended September 30, 2010 our share-based charge in connection with the expensing of stock options was approximately $1.7 million and $4.7 million, respectively. As of September 30, 2010, there was approximately $7.4 million of unrecognized stock-based compensation cost related to stock options which we expect to recognize over a weighted average period of approximately 2.52 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 and nine month periods ended September 30, 2010, the share-based charge in connection with the expensing of restricted stock awards was approximately $121,000 and $879,000, respectively. As of September 30, 2010, there was approximately $818,000 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 1.82 years.

401(k) Plan Matching Contribution

During the three and nine month periods ended September 30, 2010, we issued 33,584 and 108,263 shares of common stock as our match of approximately $134,000 and $463,000 on the 401(k) contributions of our employees. During the three 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 and $340,000 on the 401(k) contributions of our employees.

Employee Stock Purchase Plan

Effective July 2009, we adopted the 2009 Employee Stock Purchase Plan (Purchase Plan). The Purchase Plan provides our eligible employees with an incentive by providing a method whereby they may voluntarily purchase shares of our common stock upon terms described in the Purchase Plan. The Purchase Plan is designed to be operated on the basis of six consecutive month offering periods commencing January 1 and July 1 of each year. The Purchase Plan provides that eligible employees may authorize payroll deductions to purchase shares of our common stock at 85% of the fair market value of common stock on the first or last day of the applicable purchase period. A participant may purchase a maximum of 50,000 shares of common stock during a 6-month offering period, not to exceed $25,000 worth of stock on the offering date during each plan year. The Purchase Plan terminates in 2019.

As of September 30, 2010, Purchase Plan participant contributions of $145,640 are included in other current liabilities in the accompanying condensed consolidated balance sheet. A total of 5,000,000 shares of common stock are authorized for issuance under the Purchase Plan, and as of September 30, 2010, 157,414 shares have been issued under the Purchase Plan.

Common Stock Reserved for Future Issuance

As of September 30, 2010, approximately 13.5 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	9,156,521
Exercise of warrants	4,172,312
Total shares of common stock reserved for future issuances	13,464,833

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9. Subsequent Events

On November 1, 2010 we received notice that we have been awarded grants totaling $978,000 under the Qualifying Therapeutic Discovery Project (QTDP) Program administered under section 48D of the Internal Revenue Code. The QTDP tax credit is provided under new section 48D of the Internal Revenue Code, enacted as part of the Patient Protection and Affordable Care Act of 2010 (P.L. 111-148). The credit is a tax benefit targeted to therapeutic discovery projects that show a reasonable potential to:

- Result in new therapies to treat areas of unmet medical need or prevent, detect or treat chronic or acute diseases and conditions,
- Reduce the long-term growth of health care costs in the United States, or
- Significantly advance the goal of curing cancer within 30 years.

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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 products and product candidates, the success, safety and efficacy of our drug products, 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, or continues 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, 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;
- risks associated with doing business internationally;
- 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;
- the ability to timely deliver product supplies to our customers;
- our ability to identify new product candidates and to successfully integrate those product candidates into our operations;
- the timing and/or results of pending or future clinical trials, and our reliance on contract research organizations;
- our ability to protect our intellectual property rights;
- 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, including international agencies;

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securing positive reimbursement for our products;
the impact of any product liability, or other litigation to which we are, or may become a party;
the impact of legislative or regulatory reform of the healthcare industry and the impact of recently enacted healthcare reform legislation;
the availability and price of acceptable raw materials and components from third-party suppliers, and their ability to meet our demands;
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;
our ability to maintain the services of our key executives and technical and sales and marketing personnel;
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 our 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 and our audited consolidated financial statements and related notes for the year ended December 31, 2009 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission.

Business Outlook

We are a commercial stage biopharmaceutical company committed to developing and commercializing innovative therapies with a primary focus in oncology. We have a fully developed commercial infrastructure that currently markets and sells two drugs in the United States, ZEVALIN® and FUSILEV®. We have several drug candidates in development, the most advanced of which are apaziquone, which is presently being studied in two large Phase 3 clinical trials for non-muscle invasive bladder cancer, or NMIBC under a strategic collaboration with Allergan, Nippon Kayaku and Handok; and belinostat, which is being studied in multiple indications, including in a Phase 2 registrational trial for relapsed or refractory PTCL, under a strategic collaboration with TopoTarget. Both the apaziquone and belinostat studies are being conducted under a Special Protocol Assessment by the United States Food and Drug Administration, or FDA.

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The following is an update of our business strategy for 2010, as described in our Annual Report on Form 10-K for the year ended December 31, 2009 filed with the SEC.

***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. A dedicated commercial organization comprised of sales representatives, account managers, and a complement of other marketing personnel support the sales and marketing of these drugs.

ZEVALIN: We plan to continue to grow the ZEVALIN brand, which was recently approved in first-line setting for non-Hodgkin s lymphoma, (NHL). ZEVALIN is currently approved for treatment of patients with previously untreated follicular NHL, who achieve a partial or complete response to first-line chemotherapy and treatment of patients with relapsed or refractory, low-grade or follicular B-cell NHL. In addition, we plan to submit to the FDA data supporting the removal of the Bio Scan requirement prior to ZEVALIN administration and to communicate effectively about the uniformity and transparency for reimbursement of ZEVALIN achieved in the community setting.

FUSILEV: In late 2008 and early 2009, there was a disruption in the supplies of leucovorin. FUSILEV (levoleucovorin) contains the pure isomer of the active ingredient in leucovorin. At the time of the shortage, we mobilized our resources to alleviate the situation, and working with the FDA and the oncology community we were able to supply FUSILEV to fulfill part of the shortage and benefit several thousand cancer patients. Once again, beginning in June 2010, a similar supply disruption has occurred. We are again working with the FDA and the oncology community to supply FUSILEV and address the disruption in supplies of leucovorin, which is critical to the care and survival of cancer patients. In the long run, expansion of FUSILEV sales largely depends upon our obtaining FDA approval for use of FUSILEV in combination with 5-FU containing regimens for the treatment of colorectal cancer; and subsequent favorable reimbursement. In October 2008, we had filed a supplemental New Drug Application, or sNDA for advanced metastatic colorectal cancer. In October 8, 2009, we received a Complete Response letter from the FDA regarding our sNDA. We met with the FDA in January 2010 and, on October 29, 2010, submitted a formal response to the Complete Response letter issued regarding our supplemental sNDA for FUSILEV for Injection for use in combination chemotherapy with 5-fluorouracil (5-FU) in the palliative treatment of advanced metastatic colorectal cancer.

***Maximizing the asset value of apaziquone and optimizing our development portfolio*.** We continue to build on our core expertise in clinical development of drug candidates for the treatment of cancer.

Apaziquone (in bladder cancer): In October 2008, we received from Allergan an upfront $41.5 million fee and in December 2009 earned a $1.5 million milestone upon completion of enrollment in our two Phase 3 studies. Further, pursuant to our 2009 collaboration agreement with Nippon Kayaku and Handok, we received $16.0 million in upfront milestone payments in early 2010. We are entitled to additional payments upon the achievement of future development and regulatory milestones under these agreements.

Pursuant to our October 2008 strategic collaboration agreement with Allergan to co-develop and co-market apaziquone for bladder cancer, we continue to conduct the two Phase 3 registrational trials pursuant to a joint development plan, with Allergan bearing 65% of these development costs. We expect top-line data from these two recently enrolled Phase 3 NMIBC trials in 2012.

Belinostat: In February 2010, we entered into a licensing and collaboration agreement with TopoTarget, for the development of belinostat, a drug being studied in multiple indications, including in a Phase 2 registrational trial for patients with PTCL. The licensing and collaboration agreement provides that we have the exclusive right to make, develop and commercialize belinostat in North America and India, with an

option for the same rights in China. Currently, we anticipate filing a new drug application for belinostat in PTCL in 2011. We also anticipate TopoTarget completing enrollment by year-end in the ongoing randomized Phase 2 trial for carcinoma of unknown primary, or CUP, that is being currently being conducted and fully funded by TopoTarget.

Strategic 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 plan to continue to explore strategic collaborations.

Managing our financial resources effectively. We remain committed to fiscal discipline, a policy which has allowed us to become well capitalized as compared to our peers, despite a very challenging fiscal environment.

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Financial Condition

Liquidity and Capital Resources

Since inception in 1987 through September 30, 2010, our cumulative losses, have aggregated approximately $315.0 million. We expect to continue to incur additional losses for a few more years, as we implement our growth strategy of commercializing ZEVALIN and FUSILEV, while continuing to develop our portfolio of late-stage drug products, unless offset, if at all, by the out-licensing of any of our drugs.

We believe that the approximately $92.0 million in cash, cash equivalents and marketable securities, which we have available on September 30, 2010, 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 licensing of drugs. We may be unable to obtain such additional capital when needed, or on terms favorable to us or our stockholders. If we raise additional funds 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 we raise additional funds 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. However, we are not able to provide any specific net income guidance at this time.

With regard to estimated future development expenditures, 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, patent related costs, and non-product specific, or indirect, costs. During the nine-month period ended September 30, 2010, our total research and development expenditure, including indirect expenditures, and the $30 million upfront fee for the license of belinostat, was approximately $50.3 million (net of $6.2 million received from Allergan). The principal components of direct expenses for that period related to the development of: apaziquone $5.1 million, belinostat $3.5 million and ZEVALIN $1.5 million.

Our primary focus areas for the foreseeable future, and the programs that are expected to represent a significant part of our expenditures, are the on-going clinical studies of apaziquone and belinostat and the commercialization of ZEVALIN and FUSILEV. 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.

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While we do not receive any funding from third parties for 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 has borne 65% of the development costs of apaziquone. Also, Nippon Kayaku and Handok are responsible for all the development costs related to apaziquone in their respective territories.

In addition to our present portfolio of drug product candidates, we continually evaluate proprietary products for acquisition. 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.

Net Cash used in Operating Activities

Net cash used in operating activities was $32.8 million for the nine months ended September 30, 2010 which includes the non-recurring $30.0 million upfront payment for belinostat. The principal components of such cash usage was a net loss in the period of $53.3 million adjusted for net non-cash credits of $4.9 million, offset by changes in working capital of $25.4 million during the period.

Net Cash used in Investing Activities

Net cash used in investing activities, $5.5 million during the nine months ended September 30, 2010, was primarily due to the $4.1 million purchase of marketable securities and a $1.4 million increase in property and equipment acquisitions, of which $1.0 million relates to landlord contributions to tenant improvements.

Net Cash provided by Financing Activities

Net cash provided by financing activities, $1.4 million for the nine months ended September 30, 2010, primarily relates to proceeds from the issuance of common stock as a result of the exercise of stock options and purchases of shares under our Employee Stock Purchase Plan.

Results of Operations

Three months ended September 30, 2010 and 2009

Net Revenues. Net revenues increased $9.6 million, or 135%, to $16.7 million in the three months ended September 30, 2010 from $7.1 million in the three months ended September 30, 2009. We recognized $13.7 million from product sales, of which $7.7 million related to sales of ZEVALIN and $6.0 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 of $3.8 million. Product revenues recorded in the three months ended September 30, 2009 were $5.0 million, of which $4.7 million related to sales of ZEVALIN and $0.3 million related to sales of FUSILEV, with cost of product sold being $2.4 million. Revenues from the sales of FUSILEV have fluctuated in 2009 and 2010. During the first half of 2009, FUSILEV sales were higher due to the leucovorin supply disruption described elsewhere herein. The disruption in supply abated in the second quarter of 2009, and subsequent FUSILEV sales were significantly lower than experienced in the first half of 2009. Commencing late in the second quarter of 2010, a similar disruption emerged and accordingly, the third quarter of 2010 sales of FUSILEV have grown significantly. We are unable to determine how long the current disruption in supplies of leucovorin will last. We cannot predict our ability to manufacture sufficient quantities to meet fluctuating commercial demand. During the three months ended September 30, 2010 and 2009, we also recognized $3.1 million and $2.1 million, respectively, of licensing revenues from the amortization of $41.5 million upfront payment we received from Allergan in 2008, and $16.0 million upfront payment we received from Nippon Kayaku and Handok in the first quarter of 2010.

Cost of Product Sales. As a result of increased product revenues, the cost of product sales increased $1.4 million to $3.8 million in the three months ended September 30, 2010 from $2.4 million in the three months ended September 30, 2009.

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Selling, General and Administrative. Selling, general and administrative expenses increased $4.4 million, or 63%, to $11.4 million, in the three months ended September 30, 2010 from $7.0 million in the three months 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 related payroll costs. We expect selling, general and administrative expenses for the remainder of 2010 to continue at a pace similar to the first nine months of 2010.

Research and Development. Research and development expenses increased $2.0 million, or 36%, to $7.5 million, in the three months ended September 30, 2010 from $5.5 million in the three months ended September 30, 2009. The principal component of the increase was a one-time charge of $1.7 million, representing the fair value of 425,000 common shares issued as consideration for the asset acquisition in July 2010, of in process research and development. We expect research and development expenses for the remainder of 2010 to continue at a pace similar to the quarter ended September 30, 2010.

Amortization of Purchased Intangibles. We incurred a non-cash charge of $930,000 and $950,000, for the three months ended September 30, 2010 and 2009, respectively, due to the amortization of intangibles from the acquisition of ZEVALIN.

Change in Fair Value of Common Stock Warrant Liability. We recorded income of $1.6 million for the change in the fair value of the warrant obligations during the three month period ended September 30, 2010 compared to income of $8.9 million in the same period of 2009.

Other Net Income. The principal components of other income of $0.6 million and $0.4 million during the three month periods ended September 30, 2010 and 2009, respectively, which consisted of currency gains and losses and net interest income. 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, until such time as the credit markets recover.

Nine months ended September 30, 2010 and 2009

Net Revenues. Net revenues increased $10.8 million, or 37%, to $40.2 million during the nine months ended September 30, 2010 from $29.4 million in the nine months ended September 30, 2009. We recorded approximately $30.1 million from product sales with $21.1 million related to sales of ZEVALIN and $9.0 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 $10.6 million. Product revenues recorded in the nine months ended September 30, 2009 were $23.0 million, of which $10.6 million related to sales of ZEVALIN and $12.4 million related to sales of FUSILEV, with cost of product sold being $5.7 million. The increase in ZEVALIN sales is attributable to a combination of increases in unit sales and selling prices. Revenues from the sales of FUSILEV have fluctuated in 2009 and 2010. During the first half of 2009, FUSILEV sales were higher due to the leucovorin supply disruption described elsewhere herein. The disruption in supply abated in the second quarter of 2009, and subsequent FUSILEV sales were significantly lower than experienced in the first half of 2009. Commencing late in the second quarter of 2010, a similar disruption has emerged and accordingly, in the second and third quarters of 2010, sales of FUSILEV have grown significantly. We cannot predict our ability to manufacture sufficient quantities to meet fluctuating commercial demand. During the nine months ended September 30, 2010 and 2009, we also recorded $10.1 million and $6.4 million, respectively, of licensing revenues from the amortization of the upfront payments received from Allergan in 2008 and from Nippon Kayaku and Handok payments received in 2010. In January 2007, we received approximately $0.9 million, representing our 50% share of an economic interest that Aeterna Zentaris had from an arrangement with Nippon Kayaku for certain rights to Ozarelix in Japan and recognized the amount as deferred revenue. In early 2010 we reevaluated the basis for deferral having determined that there are no further ongoing obligations and recorded the approximately $0.9 million as license revenue during the nine months ended September 30, 2010.

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Cost of Product Sales. As a result of increased product revenues, the cost of product sales increased $4.9 million to $10.6 million in the nine months ended September 30, 2010 from $5.7 million in the nine months ended September 30, 2009.

Selling, General and Administrative. Selling, general and administrative expenses increased $13.6 million, or 60%, to $36.1 million in the nine months ended September 30, 2010, from $22.5 million in the nine months ended September 30, 2009. The increase is primarily due to increased direct sales and marketing expenses incurred in connection with the commercial activities associated with ZEVALIN and related payroll costs.

Research and Development. Total research and development expenses increased $32.8 million, or 187%, to $50.3 million in the nine months ended September 30, 2010, from $17.5 million in the nine months ended September 30, 2009. The increase is primarily due to the $30.0 million upfront payment for the licensing of belinostat, and the one-time charge of $1.7 million, representing the fair value of 425,000 shares of our common stock issued as consideration for the asset acquisition, in July 2010, of in process research and development.

Amortization of Purchased Intangibles. We incurred a non-cash charge of $2.8 million and $2.9 million, for the nine months ended September 30, 2010 and 2009, respectively, due to the amortization of intangibles from the acquisition of ZEVALIN.

Change in Fair Value of Common Stock Warrant Liability. We recorded income of $6.0 million for the change in the fair value of the warrant obligations during the nine month period ended September 30, 2010 compared to a loss of $11.8 million in the same period of 2009.

Other Net Income. The principal components of other income of $0.2 million and $0.6 million during the nine month periods ended September 30, 2010 and 2009, respectively consisted of currency gains and losses and net interest income.

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. We consider various factors in determining such provisions, which are described in detail below. Such estimated amounts are deducted from our gross sales to determine our net revenues. Provisions for bad and doubtful accounts are deducted from gross receivables to determine net receivables. Provisions for chargebacks, returns, rebates and discounts are classified as part of our accrued obligations. Changes in our estimates, if any, are recorded in the statement of operations in the period the change is determined. If we materially over or under estimate the amount, there could be a material impact on our condensed consolidated financial statements.

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For the nine months ended September 30, 2010 and 2009, the following is a roll forward of the provisions for return, discounts and rebates and chargebacks allowances and estimated doubtful account allowances.

	Chargebacks and Discounts	Rebates	Returns ($ in '000s)	Doubtful accounts and untreated kits	Total
Period ending September 30, 2010:					
Balances at beginning of the period	$ 860	388	$ 1,176	$ 150	$ 2,574
Add / (less) provisions:					
Related to the sales of current fiscal period	693	4,205	2,372	533	7,803
Related to the sales of prior fiscal years					
Less: Credits or actual allowances:					
Related to sales from current fiscal year	178		1,116	138	1,432
Related to sales from prior fiscal periods	289	255	1,176		1,720
Balances at the close of the period	$ 1,086	$ 4,338	$ 1,256	$ 545	$ 7,225
Period ending September 30, 2009:					
Balances at beginning of period	$ 1,631	$	$ 3,144	$ 150	$ 4,925
Add / (less) provisions:					
Related to the sales of current fiscal period	3,839	587	101		4,527
Related to the sales of prior fiscal years			(2,057)		(2,057)
Less: Credits or actual allowances:					
Related to sales from current fiscal year	3,206		80		3,286
Related to sales from prior fiscal periods	1,631	387			2,018
Balances at the close of the period	$ 633	$ 200	$ 1,108	$ 150	$ 2,091

The methods of estimating these allowances, used by us, are described below.

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.

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Chargebacks

Chargebacks represent a provision recorded as an accrued obligation 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 (or the wholesale acquisition cost, or WAC) and the price (contracted price) that a contracted customer (e.g., a member of a Group Purchasing Organization (GPO)) 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 agreed contract prices 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.

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 in the contracts between the customer and us to estimate the discount accrual.

Allowances for Product Returns

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 which is classified as accrued liabilities.

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

Since inception, we have not engaged in material off-balance sheet activities, including the use of structured finance, special purpose entities or variable interest entities.

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Critical Accounting Policies and Estimates

Our condensed consolidated financial statements are prepared in accordance with GAAP. These accounting principles require us to make certain estimates, judgments and assumptions. We believe that the estimates, judgments and assumptions upon which we rely are reasonable based upon information available to us at the time that these estimates, judgments and assumptions are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities as of the date of the financial statements as well as the reported amounts of revenues and expenses during the periods presented. To the extent there are material differences between these estimates, judgments or assumptions and actual results, our financial statements will be affected. The accounting policies that reflect our more significant estimates, judgments and assumptions and which we believe are the most critical to aid in fully understanding and evaluating our reported financial results include the following:

Revenue recognition
Share-Based compensation
Warrant Accounting

During the nine months ended September 30, 2010, there were no significant changes in our critical accounting policies and estimates. Please refer to Management s Discussion and Analysis of Financial Condition and Results of Operations contained in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2009 for a more complete discussion of our critical accounting policies and estimates.

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, 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 investing in highly liquid, highly rated instruments and not investing in long-term maturity instruments.

Our investments, as of September 30, 2010, were primarily in money market accounts, certificates of deposit, 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 and well capitalized and that our instruments are held in accounts segregated from the assets of the institutions. However, due to the continuing volatility in the financial and credit markets and the liquidity issues faced by most banking institutions, we constantly monitor the financial viability of these institutions and the safety and liquidity of our funds.

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, 2010, 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.

In addition, we are exposed to foreign currency exchange rate fluctuations on the portion of our cash held in Euros and Canadian dollars. We maintain foreign currency balances to facilitate payments to vendors, suppliers and license partners when our obligations are denominated in Euros and Canadian dollars.

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ITEM 4. CONTROLS AND PROCEDURES

We have established disclosure controls and procedures (as 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 principal executive officer and 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.

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 the design and operation of our disclosure controls and procedures as of September 30, 2010, the end of the period covered by this quarterly report. Based on such evaluation, our principal executive officer and our principal financial officer concluded that, because of the material weakness in internal control over financial reporting discussed below and in Management s annual report on internal control over financial reporting included in our Annual Report on Form 10-K for the year ended December 31, 2009, our disclosure controls and procedures required improvement in order to prevent such a recurrence. As a result we have enhanced our access to accounting literature and research materials, engaged third party professionals with whom we consult on complex accounting applications and recently hired an experienced healthcare executive with over eighteen years of experience as a chief financial officer in the life science industry to serve as our principal financial officer.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis. In our assessment of the effectiveness of internal control over financial reporting as of December 31, 2009, we identified a material weakness specifically related to the accounting for and disclosure of derivatives associated with our warrant instruments. Upon identification of the material weakness, we carried out an evaluation of our internal control over financial reporting and of the improvements to our internal control over financial reporting required to remedy such material weakness. Under the supervision and with the participation of our management, including our principal executive officer and our principal financial officer, we designed and implemented improvements to our internal control over financial reporting which we believe will remedy the material weakness previously identified. Such improvements include: hiring additional personnel with the requisite experience and training to supplement our current accounting professionals, engaging third party accounting professionals to consult with regarding complex accounting applications; and enhancing access to accounting literature, research materials and documents. In light of the unremediated material weakness and the improvements implemented by us with respect to our internal control over financial reporting, we also performed additional post-closing procedures and analyses in order to prepare the Condensed Consolidated Financial Statements contained herein. We continue to evaluate the effectiveness of our internal control over financial reporting and of the improvements implemented by us with respect to our internal control over financial reporting; and we expect to complete the remediation of the foregoing material weakness before the end of our 2010 fiscal year.

Except as discussed above, there has been no change in our internal control over financial reporting during the quarter ended September 30, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II OTHER INFORMATION

ITEM 1A. RISK FACTORS

There have been no material changes in our assessment of risk factors affecting our business since those presented in our Annual Report on Form 10-K, Item 1A, for the fiscal year December 31, 2009 as filed with the SEC.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

On July 23, 2010, pursuant to the terms of an asset purchase agreement dated July 19, 2010, for certain assets and intellectual property, we issued 425,000 shares of our common stock to accredited investors (as designees of the Seller of the assets and intellectual property). We received no cash proceeds in connection with this issuance. We issued such shares without registration under the Securities Act in reliance upon the exemptions from registration provided under Section 4(2) of the Securities Act and Regulation D promulgated thereunder. The foregoing transaction did not involve any public offering; we made no solicitation in connection with the issuance; we obtained representations from the Seller, and the designees of the Seller regarding their investment intent, experience and sophistication; and the investors either received or had access to adequate information about us in order to make an informed investment decision. No underwriting discounts or commissions were paid in conjunction with the issuance.

On July 1, 2010, pursuant to the terms of a consulting agreement, we issued warrants to purchase 75,000 shares of our common stock to a consultant as compensation for services provided under the consulting agreement. We received no cash proceeds in connection with this issuance. We issued such warrants without registration under the Securities Act in reliance upon the exemptions from registration provided under Section 4(2) of the Securities Act and Regulation D promulgated thereunder. The foregoing transaction did not involve any public offering; we made no solicitation in connection with the issuance; we obtained representations from the consultant regarding its investment intent, experience and sophistication; and the consultant either received or had access to adequate information about us in order to make an informed investment decision. No underwriting discounts or commissions were paid in conjunction with the issuance.

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ITEM 6. EXHIBITS

Exhibit Number	Description
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)/15(d)-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)/15(d)-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 4, 2010

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

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INDEX TO EXHIBITS

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+ Filed herewith.