SPECTRUM PHARMACEUTICALS INC Form 10-Q August 09, 2010

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

(Mark One)

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

OR

o <b>TRANSITION REPORT PU</b>	RSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
<b>EXCHANGE ACT OF 1934</b>	
For the transition period from	to

Commission File Number 000-28782 SPECTRUM PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware93-0979187(State or other jurisdiction(I.R.S. Employer

of incorporation or organization)

(I.R.S. Employer
Identification No.)

157 Technology Drive Irvine, California **92618** (Zip Code)

(Address of Principal Executive Offices)

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 b 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 b

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 August 2, 2010 Common Stock, \$0.001 par value 50,141,123

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#### PART I FINANCIAL INFORMATION

#### ITEM 1. Financial Statements (Unaudited)

# SPECTRUM PHARMACEUTICALS, INC.

# **Condensed Consolidated Balance Sheets** (Unaudited)

(In thousands, except share and per share data)

Aggeta	J	Tune 30, 2010	Dec	eember 31, 2009
Assets				
Current assets:				
Cash and cash equivalents	\$	47,310	\$	82,336
Marketable securities		35,380		31,005
Accounts receivable, net		8,545		8,658
Inventories, net		3,122		3,230
Prepaid expenses and other current assets		855		1,028
Total current assets		95,212		126,257
Bank certificates of deposit & treasuries		11,823		11,438
Property and equipment, net		3,487		1,928
Zevalin related intangible assets, net		31,465		33,325
Other assets		163		185
Total assets	\$	142,150	\$	173,133
Liabilities and Stockholders Equity				
Current liabilities:				
Accounts payable and other accrued obligations	\$	23,678	\$	16,606
Accrued compensation		2,432		3,360
Current portion of deferred revenue		12,300		8,300
Common stock warrant liability		2,234		6,635
Accrued drug development costs		4,061		4,598
Total current liabilities		44,705		39,499
Capital lease obligations		55		69
Deferred revenue and other credits, net of current portion		32,282		24,943
Zevalin related contingent obligations		298		298
Total Liabilities		77,340		64,809
Commitments and contingencies				
Stockholders equity:				
Preferred Stock, par value \$0.001 per share, 5,000,000 shares authorized:				
Series B Junior participating preferred stock, 1,000,000 shares authorized, no				
shares issued and outstanding at June 30, 2010 and December 31, 2009		410		410
		419		419

Series E Convertible voting preferred stock, 2,000 shares authorized, stated par value \$10,000 per share, \$0.8 million aggregate liquidation value, issued and outstanding, 68 shares at June 30, 2010 and December 31, 2009 Common stock, par value \$0.001 per share, 100,000,000 shares authorized;

Issued and outstanding, 49,662,712 and 48,926,314 shares at June 30, 2010 and		
December 31, 2009, respectively	50	49
Additional paid-in capital	374,688	369,482
Accumulated other comprehensive loss	(101)	(70)
Accumulated deficit	(310,246)	(261,556)
Total stockholders equity	64,810	108,324
Total liabilities and stockholders equity	\$ 142,150	\$ 173,133

The accompanying notes to condensed consolidated financial statements are an integral part of these statements.

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

(In thousands, except shares and per share data)

	Three-months ended June 30, 2010 2009					Six-months ended June 30 2010 2009			
Revenues: Product sales, net License and contract revenue	\$	9,268 3,075	\$	6,016 2,125	\$	16,390 7,042	\$	18,054 4,250	
Total revenues	\$	12,343	\$	8,141	\$	23,432	\$	22,304	
Operating costs and expenses: Cost of product sales (excludes amortization of		3,592		1 420		6,837		2 272	
purchased intangibles assets) Selling, general and administrative		13,802		1,439 9,192		24,664		3,273 15,543	
Research and development		6,285		6,391		42,829		12,045	
Amortization of purchased intangibles		930		950		1,860		1,900	
Total operating expenses		24,609		17,972		76,190		32,761	
Loss from operations Change in fair value of common stock warrant		(12,266)		(9,831)		(52,758)		(10,457)	
liability		2,826		(20,113)		4,401		(20,622)	
Other (loss) income, net		(236)		125		(333)		229	
Net loss Net loss attributable to non-controlling interest		(9,676)		(29,819)		(48,690)		(30,850) 1,146	
Net loss attributable to Spectrum Pharmaceuticals, Inc. stockholders	\$	(9,676)	\$	(29,819)	\$	(48,690)	\$	(29,704)	
Net loss per share									
Basic and diluted	\$	(0.20)	\$	(0.87)	\$	(1.00)	\$	(0.90)	
Weighted average common shares outstanding Basic and diluted	49,020,236		3	4,137,640	4	8,844,918	33,051,118		

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) (In thousands)

	Six-months 2010	ended June 30, 2009
Cash flows from operating activities:		
Net loss	\$ (48,690)	(29,704)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Amortization of deferred revenue	(7,042)	* ' '
Depreciation and amortization	2,136	2,178
Share-based compensation expense	4,212	4,793
Fair value adjustments of common stock warrants	(4,401)	
Fair value of common stock issued in connection with drug license		185
Non-controlling interest in consolidated entities		(1,146)
Changes in operating assets and liabilities: Accounts receivable	112	2 471
Inventories	113 108	3,471
Prepaid expenses and other current assets	173	(514) 228
Accounts payable and other accrued obligations	7,072	9,154
Accrued compensation	(928)	•
Accrued drug development cost	(537)	
Landlord contributions to tenant improvements	1,446	
Deferred revenue and other credits	16,935	(49)
Deterrous te venue una outer ereante	10,555	(12)
Net cash (used in) provided by operating activities	(29,403)	4,289
Cash flows from investing activities:		
Net purchases of marketable securities	(4,769)	(8,862)
Investment in Zevalin acquisition		(22,687)
Purchases of property and equipment	(1,835)	(344)
Net cash used in investing activities	(6,604)	(31,893)
Cash flows from financing activities:		
Proceeds from issuance of common stock and warrants, net of related offering costs and expenses		27,070
Proceeds from exercise of stock options	690	89
Proceeds from contributions to ESPP	305	
Proceeds from sale of common stock to employees shelf takedown		1,167
Repurchase of warrants		(71)
Repurchase of stock options pursuant to tender offer		(2,520)
Repayment of capital lease obligations	(14)	1

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Net cash provided by financing activities	981	25,735
Net decrease in cash and cash equivalents Cash and cash equivalents, beginning of period	(35,026) 82,336	(1,869) 9,860
Cash and cash equivalents, end of period	\$ 47,310	7,991
Schedule of non-cash investing and financing activities: Fair value of common stock issued in connection with drug license	\$	\$ 185
Fair value of restricted stock granted to employees and directors	\$ 977	\$ 226
Fair value of stock issued to match employee 401k contributions	\$ 329	\$ 219
Fair value of equity awarded to consultants	\$ 233	\$ 111

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 (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., or Allergan, Nippon Kayaku Co. Ltd., or Nippon Kayaku, and Handok Pharmaceuticals Co. Ltd., or Handok. Belinostat, is being studied in multiple indications including a Phase 2 registrational trial for relapsed or refractory peripheral T-cell lymphoma, or PTCL, under a strategic collaboration with TopoTarget A/S, or TopoTarget.

# Basis of Presentation

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

# Segment and Geographic Information

We operate in one business segment: acquiring, developing and commercializing prescription drug products. Accordingly, the accompanying condensed consolidated 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.

### 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.

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#### Significant Accounting Policies

Our significant accounting policies, as disclosed in the notes to the audited financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2009, as filed with the SEC, have not changed significantly as of June 30, 2010. Accordingly, these interim condensed consolidated financial statements should be read in conjunction with the Form 10-K.

# Acquisitions and Collaborations

For all in-licensing products, 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-licensing products qualify as a business and whether to account for such products as a business combination or an asset acquisition.

### Basic and Diluted Net Loss per Share

We calculate basic and diluted net loss per share using the weighted average number of common shares outstanding during the periods presented, and adjust the amount of net loss used in this calculation for preferred stock dividends (if any) declared during the period.

We incurred a net loss for the three-month and six-month periods ended June 30, 2010 and 2009 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. We did not declare preferred stock dividends for the periods presented.

The following table sets forth the number of shares excluded from the computation of diluted earnings per share, as to do so would have been anti-dilutive:

	As of Ju	ıne 30,
	2010	2009
Series E Preferred Shares	136,000	136,000
Stock Options	8,885,948	8,090,000
Warrants	4,097,312	8,379,912
	13,119,260	16,605,912

#### Recent Accounting Pronouncements

In June 2009, the Financial Accounting Standards Board, or the FASB, issued a new accounting standard (FIN 46(R), Consolidation of Variable Interest Entities ), which 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 fiscal year 2011, and may be applied prospectively to milestones achieved after

the adoption date or retrospectively for all periods presented, with earlier application permitted. We have not yet evaluated the potential impact of adopting this guidance on our consolidated financial statements.

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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 fiscal year 2011, with earlier application permitted. We have not yet evaluated the potential impact of adopting this guidance on our consolidated financial statements.

# 2. Cash and Cash Equivalents and Marketable Securities

As of June 30, 2010, we held substantially all of our cash and cash equivalents and marketable securities at major financial institutions, which must invest our funds in accordance with our investment policy. The principal objectives of our investment 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 matching scheduled investment maturities with our cash requirements and investing in highly rated instruments.

Cash, cash equivalents and investments in marketable securities, including long term bank certificates of deposits, totaled \$94.5 million and \$124.8 million as of June 30, 2010 and December 31, 2009, respectively. Long term bank certificates of deposit includes a \$0.5 million restricted certificate of deposit, collateralizing tenant improvement obligations to the lessor of our principal offices. The following is a summary of such investments:

		Gross	Gross				Ma	arketable		
	Amortized Cost	Unrealized Unrealized  Gains Losses			Estimated Fair Value	Cash	Long Term			
					(\$ in 000			Current		
June 30, 2010 Cash and cash										
equivalents	\$ 47,310	\$	\$	\$	47,310	\$47,310	\$		\$	
Bank CDs	24,345				24,345			13,277		11,068
U.S. Government securities	20,440				20,440			19,685		755
Corporate debt	20,110				20,110			15,005		,,,,
securities	2,418				2,418			2,418		
Other securities (included in other										
assets)	35		23	}	12					12
Total investments	\$ 94,548	\$	\$ 23	\$	94,525	\$47,310	\$	35,380	\$	11,835
10001111100	Ψ > 1,0 10	Ψ	Ψ	Ψ	> 1,626	Ψ,ε 10	4	22,233	4	11,000
Dogombor 21, 2000										
<b>December 31, 2009</b>	\$ 82,336	\$	\$	\$	82,336	\$82,336	\$		\$	
	,	•			- ,	, - ,- ,-				

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Cash and cash							
equivalents							
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

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#### 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 June 30, 2010, are classified in the table below in one of the three categories described above:

	Fair Value Measurements at June 30, 2010								
	Level 1		I	Level 2 Level 3 (\$ in 000 s)			Total		
Assets:									
Cash and cash equivalents	\$	47,310	\$		\$		\$	47,310	
U.S. Treasury bills				750				750	
FDIC insured bank CDs				24,345				24,345	
Medium term corporate notes				2,418				2,418	
U.S. Treasury-backed securities				19,690				19,690	
Cash and cash equivalents and marketable									
securities		47,310		47,203				94,513	
Other securities		12						12	
	\$	47,322	\$	47,203	\$		\$	94,525	
Liabilities:									
Common stock warrant liability						2,234		2,234	
	\$		\$		\$	2,234	\$	2,234	

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

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

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

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

In determining fair value, we utilize valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible, as well as consider counterparty credit risk in the assessment of fair value. 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 marked at fair market value, based on values provided 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 June 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 six months ended June 30, 2010:

Fair Value Measurements of Common Stock

	Warrants Using Significant Unobservable Inputs (Level 3) (\$ in 000 s)			
Balance at December 31, 2009 Adjustments resulting from expiration of warrants recognized in earnings	\$	6,635 (788)		
Adjustments resulting from change in value of warrants recognized in earnings		(3,613)		
Balance at June 30, 2010	\$	2,234		

During the six-months ended June 30, 2010, the fair value of common stock warrants decreased approximately \$4.4 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 June 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.

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 still reported at their historical carrying values.

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#### 4. Accounts Receivable Trade

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

	June 201	December 31, 2009 000 s)		
Accounts receivable, gross	\$ 9	,	\$	8,808
Allowances for untreated kits Allowances for doubtful accounts		(169) (342)		(150)
Accounts receivable, net	\$ 8	3,545	\$	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:

	une 30, 2010 (\$ in	ember 31, 2009 s)
Allowance for chargebacks, discounts and rebates Allowance for returns	\$ 3,027 1,664	\$ 860 1,176
Total allowances	\$ 4,691	\$ 2,036

#### 5. Inventories

Inventories, net of allowances consisted of the following:

	June 30, 2010		December 31, 2009		
	(\$ in	000	s)		
Finished goods Raw materials	\$ 2,952 280	\$	3,039 280		
Less: reserve for inventory allowances  Inventories, net	\$ (110) 3,122	\$	(89)		

We continually review product inventories on hand, evaluate 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.

### 6. Commitments and Contingencies

#### Facility and Equipment Leases

As part of our Irvine facility lease renewal in 2009, our landlord agreed to contribute up to approximately \$1.5 million towards the costs of tenant improvements. The tenant improvements were substantially completed as of June 30, 2010 at an aggregate cost of approximately \$1.4 million. The landlord s contribution will be amortized on a straight-line basis over the term of the lease as a reduction to rent expense. Our Irvine facility lease expires on July 1, 2016. As of June 30, 2010, we have obligations under this facility lease and various other 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:

June 30, 2010	Operating Lease Commitments (\$ in	Capital Lease Commitments 000 s)		
2010 (Remainder of year)	\$ 221	\$ 25		
2011	455	50		
2012	484	46		
2013	513			
2014	542			
Thereafter	863			
	\$ 3,078	\$ 121		

Rent expense for the three-month periods ended June 30, 2010 and 2009 was \$0.2 million and \$0.1 million, respectively; and for the six-month periods ended June 30, 2010 and 2009 was approximately \$0.4 million and \$0.3 million, respectively.

# 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,

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 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 \$192.4 million as of June 30, 2010, would be due approximately as follows: \$10.2 million within 12 months; \$52.2 million in 2 to 3 years; \$26.5 million in 4 to 5 years; and \$103.5 million after 5 years.

Europe and Japan; and approvals from each of the regulatory agencies in those jurisdictions.

# 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 June 30, 2010,

we were committed under such contracts for up to approximately \$9.9 million for future goods and services, including approximately \$8.6 million 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 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.

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#### **Employment Agreement**

We have entered into an employment agreement with Dr. Rajesh C. 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 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 the Board of Directors.

#### Litigation

As of June 30, 2010, 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.

# 7. Stockholders 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 September 2013. Below is a summary of warrant activity during the six-month period ended June 30, 2010:

	Common Stock	Weighted Average Exercise		
	Warrants		Price	
Outstanding at the beginning of period	11,028,919	\$	6.52	
Issued				
Repurchased				
Exercised				
Forfeited				
Expired	(6,931,607)		6.55	
Outstanding at the end of period	4,097,312	\$	6.45	
Exercisable at the end of period	4,097,312	\$	6.45	

The following table summarizes information about warrants outstanding at June 30, 2010:

		Weighted			
	Warrants	Average Remaining		eighted Verage	Warrants
Range of Exercise Price	Outstanding	Life	Exerc	cise Price	Exercisable
Under \$2.50	50,000	2.25	\$	1.79	50,000
\$5.01 \$6.00	300,000	1.47		5.15	300,000
\$6.01 \$7.00	3,747,312	0.71		6.62	3,747,312
	4,097,312		\$	6.45	4,097,312

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#### Share-Based Compensation

We recorded share-based employee compensation expense as follows:

	Th	ree-montl	ıs end	ed June				
		3	0,		Six	-months e	nded ,	June 30,
	2010			2009		2010		2009
				( <b>\$</b> in	000	s)		
Research and development	\$	801	\$	1,814	\$	1,858	\$	2,294
General and administrative		936		2,011		2,354		2,499
Total share based compensation expense	\$	1,737	\$	3,825	\$	4,212	\$	4,793

Presented below is a summary of activity, for all our share-based incentive award plans, during the six-month period ended June 30, 2010:

# Stock Options:

During the six-month period ended June 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 six-month periods ended June 30, 2010 and 2009 were estimated at approximately \$4.49 and \$2.85, respectively using the Black-Scholes option pricing model with the following assumptions:

Six-months ended June 30,

				D111 1110111111111111111111111111111111		
				2010	2	009
Dividend yield				0.00%		0.00%
Expected volatility				71.01%		71.80%
Risk free interest rate				2.37%		2.26%
Expected life (years)				5		5
	Common	Weighted Average Exercise Price		Weighted Average Remaining	_	gregate trinsic
	Stock			Term	1	Value
	Options			(In Years)	<b>(\$</b> i	in 000 s)
Outstanding at the beginning of period	7,945,245	\$	4.04			
Granted	1,545,970		4.49			
Expired	(96,923)		6.33			
Forfeited	(122,670)		4.36			
Exercised	(385,674)		1.79			
Outstanding at the end of period	8,885,948	\$	4.24	7.97	\$	5,549
Vested and expected to vest, at the end of	0.067.440					· · ·
period	8,865,448		4.23	7.97	\$	5,549
Exercisable at the end of period	5,662,227		4.25	7.39	\$	3,512

The aggregate intrinsic value in the table above represents the total difference between the closing price of our common stock of \$3.92 on June 30, 2010 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 June 30, 2010. This amount changes on the basis of the fair market value of our common stock. As of June 30, 2010, we have approximately 11.3 million shares available for future grants.

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During the three-month and six-month periods ended June 30, 2010 the share-based charge in connection with the expensing of stock options was approximately \$1.3 million and \$3.1 million, respectively. As of June 30, 2010, there was approximately \$7.5 million of unrecognized stock-based compensation cost related to stock options which is expected to be recognized over a weighted average period of approximately 2.47 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 six-month periods ended June 30, 2010, the share-based charge in connection with the expensing of restricted stock awards was approximately \$0.2 million and \$0.8 million, respectively. As of June 30, 2010, there was approximately \$0.9 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 1.07 years.

	Restricted Stock Awards	Av Gra	eighted verage ant date r Value
Non-vested at the beginning of period	353,125	\$	2.33
Granted	229,000		4.65
Vested	(145,250)		2.94
Forfeited	(21,250)		1.71
Non-vested at the end of period	415,625	\$	3.43

#### 401(k) Plan Matching Contribution:

During the three-month and six-month periods ended June 30, 2010, we issued 36,991 and 74,679 shares of common stock valued at approximately \$0.2 million and \$0.3 million as our match on the 401(k) contributions of our employees. During the three-month and six-month periods ended June 30, 2009, we issued 28,497 and 98,500 shares of common stock valued at approximately \$0.1 million and \$0.2 million as our match on the 401(k) contributions of our employees.

#### 2009 Employee Stock Purchase Plan (ESPP)

Effective July 2009, we adopted the 2009 Employee Stock Purchase Plan, or ESPP. Offerings under the ESPP are for a duration of six months and consist of one purchase interval. The ESPP limits stock purchases to no more than \$25,000 per individual per calendar year. Shares are purchased at 85% of the lower of the beginning or end of the period price. As of June 30, 2010, employees had contributed approximately \$0.3 million, resulting in the issuance of 91,699 shares with a fair value of \$0.4 million as of that date. For the six months ended June 30, 2010, we recognized approximately \$55,000, as share-based compensation expense related to the ESPP. No similar shares were issued or expense was recorded for the six-months period ended June 30, 2009.

#### Common Stock Reserved for Future Issuance

As of June 30, 2010, approximately 13.1 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	8,885,948
Exercise of warrants	4.097.312

#### Total shares of common stock reserved for future issuances

13,119,260

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#### 8. Subsequent Events

In July 2010, we issued 425,000 shares of our common stock in exchange for certain intellectual property and drug assets. The fair market value of the stock, approximately \$1.7 million, will be charged to research and development expense during the quarter ending September 30, 2010. Also, in July 2010, we issued warrants for consulting services to purchase 75,000 shares of our common stock exercisable through June 2015, at an exercise price of \$3.82, the fair market value of the stock on date of issuance. The fair value of the option, computed using the Black-Scholes Option pricing model, will be charged to expense over the period of consulting services.

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

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;

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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 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 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 biotechnology company with fully integrated commercial and drug development operations, with a primary focus in oncology. We market two oncology drugs, 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 Peripheral T-Cell Lymphoma, or PTCL, under a strategic collaboration with TopoTarget. Both the apaziquone and belinostat studies are being conducted under a Special Protocol Assessment by the FDA.

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.

<u>Maximizing the growth potential for our marketed drugs, ZEVALIN and FUSILEV</u>. 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, medical science liaisons and a complement of other marketing personnel support the sales and marketing of these drugs.

**ZEVALIN:** We intend to continue to grow the ZEVALIN brand, which was recently approved in first-line setting for non-Hodgkin s lymphoma, or 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 intend to submit to the FDA data supporting the removal of the Bio Scan requirement prior to ZEVALIN administration and to achieve uniformity and transparency for reimbursement of ZEVALIN in the community setting.

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**FUSILEV:** Starting late 2008 through early 2009, there was a disruption of leucovorin supplies. We mobilized our resources to help the oncology community address the situation. At the time, we worked with the FDA and the oncology community and were able to supply FUSILEV (levoleucovorin) to fulfill part of the shortage and benefit several thousand cancer patients. Once again, beginning in June 2010, a similar situation 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 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 the FDA has requested additional data, which we plan to submit as soon as available. Maximizing the asset value of apaziquone and optimizing our development portfolio. We continue to build

on our core expertise in clinical development for the treatment of cancer.

Apaziquone (in bladder cancer): In October 2008, we received from Allergan an upfront \$41.5 million fee and a \$1.5 million milestone upon completion of enrollment in our 2 Phase 3 studies. Further, pursuant to our 2009 collaboration agreement with Nippon Kayaku and Handok Pharmaceuticals, we received \$16 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. Top-line data from these two recently enrolled Phase 3 NMIBC trials is expected 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 peripheral T-Cell Lymphoma or, 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.

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 currently on the market or in advanced clinical trials.

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

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# **Financial Condition**

#### Liquidity and Capital Resources

Since inception in 1987 through June 30, 2010, our cumulative losses are approximately \$310 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 they are offset, if at all, by the out-license of any of our drugs.

On June 30, 2010, we had available to us approximately \$94.5 million in cash, cash equivalents and marketable securities, which we believe, 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. 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, 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 six-month period ended June 30, 2010, our total research and development expenditure, including indirect expenditures, but excluding the \$30 million onetime fee for the license of belinostat, was approximately \$12.8 million. The principal components of direct expenses for that period relate to the development of apaziquone approximately \$3.5 million; belinostat approximately \$2.6 million; and ZEVALIN approximately \$1.1 million.

Our primary focus areas for the rest of 2010, 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. Our anticipated net use of cash for operations in the fiscal year ending December 31, 2010 is expected to amount to approximately \$40.0 million, excluding the \$30 million upfront payment for belinostat, or similar inlicenced drugs or other acquisitions.

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.

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In addition to our present portfolio of drug product candidates, we continuously 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

During the six-month period ended June 30, 2010, net cash used in operations was approximately \$29.4 million, comprised primarily of the upfront payment for belinostat of \$30.0 million and \$17.5 million received from the out-licensing of apaziquone from Nippon Kayaku and Handok and an enrollment milestone payment from Allergan, off setting operational cash needs. During the six-month period ended June 30, 2009, net cash provided by operations was approximately \$4.3 million. The positive operating cash flows in 2009 were primarily attributable to revenues derived from sales of FUSILEV and the arbitration settlement related to ZEVALIN.

#### Net Cash used in Investing Activities

Net cash used in investing activities of approximately \$6.6 million during the six-months ended June 30, 2010 was primarily due to tenant improvements of \$1.4 million and the classification of our investments that did not meet the accounting definition of cash or cash equivalents. During the six-month period ended June 30, 2009, net cash used in investing activities of approximately \$31.9 million was due to our investment in ZEVALIN classification of our investments.

#### Net Cash provided by Financing Activities

Net cash provided by financing activities totaled approximately \$1.0 million for the six-month period ended June 30, 2010 due to cash proceeds received from exercise of stock options and the investment by employees in our stock under the ESPP. During the six-month period ended June 30, 2009, net cash provided by financing activities totaled approximately \$25.7 million. Approximately \$28.2 million, net of offering costs, was derived from the sale of common stock, offset by \$2.5 million paid pursuant to a tender offer for stock options.

# **Results of Operations**

# Results of Operations for the three-month period ended June 30, 2010 compared to the three-month period ended June 30, 2009

For the three-month period ended June 30, 2010, we recorded a net loss of approximately \$9.7 million, compared to a loss of \$29.8 million for the three-month period ended June 30, 2009. The decrease in the net loss was primarily the result of our recording approximately \$2.8 million of income from warrant obligations during the three-month period ended June 30, 2010 as compared to a net loss of \$20.1 million during the same period of 2009. Other principal components of the year-to-year changes in line items are discussed below.

During the three-months ended June 30, 2010, we recorded \$9.3 million from product sales with approximately \$6.9 million related to sales of ZEVALIN and approximately \$2.4 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 a total cost of product sold being approximately \$3.6 million. Product revenues recorded in the three-month period ended June 30, 2009 were approximately \$6.0 million with approximately \$3.3 million related to sales of ZEVALIN and approximately \$2.7 million related to sales of FUSILEV, with a total cost of product sold being approximately \$1.4 million. The increase in ZEVALIN revenues in 2010 results from a combination of increased sales volume and selling price adjustments. We expect ZEVALIN revenues for the remainder of 2010 to continue at a pace similar to the quarter ended June 30, 2010. Revenues from the sales of FUSILEV have fluctuated in 2009 and 2010. During the 1st and 2nd quarters of 2009, FUSILEV sales were higher due to the supply disruption of leucovorin, described elsewhere herein. The disruption in supply abated in the 2<sup>nd</sup> quarter of 2009, and subsequent FUSILEV sales were significantly lower than experienced in the 1st half of 2009. Commencing towards the end of the 2nd quarter of 2010, a similar disruption has emerged; and accordingly, the 2<sup>nd</sup> quarter of 2010 sales of FUSILEV have seen growth over the prior quarter of 2010. We are unable to determine how long the current disruption in supplies of leucovorin will last. During the three-month periods ended June 30, 2010 and 2009, we recognized approximately \$2.1 and \$2.2 million, of licensing revenues from the amortization of \$41.5 million upfront payment we received from Allergan in 2008. We also recognized \$1.0 million of licensing revenues from the amortization of the \$16.0 million upfront payment we received from Nippon Kayaku and Handok in the first quarter of 2010.

Selling, general and administrative expenses increased by approximately \$4.6 million, from approximately \$9.2 million in the three-month period ended June 30, 2009 to approximately \$13.8 million in the three-month period ended June 30, 2010. 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 2010 to continue at a pace similar to the first half of 2010.

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Total research and development expenses were virtually unchanged, being approximately \$6.3 million and \$6.4 million in the three-month periods ended June 30, 2010 and 2009, respectively (net of approximately \$2.2 million and \$2.5 million reimbursed by Allergan for development costs related to apaziquone during the same period of 2010 and 2009, respectively). We expect research and development expenses for the remainder of 2010 to continue at a pace similar to the quarter ended June 30, 2010.

We recorded approximately \$2.8 million of income from warrant obligations during the three-month period ended June 30, 2010 compared to a net loss of approximately \$20.1 million in the same period of 2009. The income in 2010 was due to the expiration of warrants and due to a decrease in the value of the warrants. In 2009, the loss was caused by an increase in the number of warrants issued and an increase in the company stock price.

We incurred a non-cash charge of approximately \$0.9 million and \$1.0 million due to the amortization of intangibles from the acquisition of ZEVALIN in the three-month periods ended June 30, 2010 and 2009, respectively.

Other loss of approximately \$0.2 million consisted of net realized currency loss and net interest income during the three-month period ended June 30, 2010, compared to a net interest income of approximately \$0.1 million for the three-month period ended June 30, 2009. 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.

# Results of Operations for the six-month period ended June 30, 2010 compared to the six-month period ended June 30, 2009

For the six-months ended June 30, 2010, we recorded a net loss of approximately \$48.5 million (including \$30 million onetime payment for licencing of belinostat), compared to a net loss of \$29.7 million for the six-month period ended June 30, 2009. The principal components of the year-to-year changes in line items are discussed below.

During the six-months ended June 30, 2010, we recorded approximately \$16.4 million from product sales with approximately \$13.4 million related to sales of ZEVALIN and approximately \$3.0 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 a total cost of product sold being \$6.8 million. Product revenues recorded in the six-month period ended June 30, 2009 were approximately \$18.1 million with approximately \$5.9 million related to sales of ZEVALIN and approximately \$12.2 million related to sales of FUSILEV, with a total cost of product sold being \$3.2 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 1st and 2nd quarters of 2009, FUSILEV sales were higher due to the supply disruption of generic leucovorin, described elsewhere herein. The disruption in supply abated in the 2<sup>nd</sup> quarter of 2009, and subsequent FUSILEV sales were significantly lower than experienced in the 1st half of 2009. Commencing in the 2nd quarter of 2010, a similar disruption has emerged; and accordingly, the 2<sup>nd</sup> quarter of 2010 sales of FUSILEV have seen growth over the prior quarter of 2010. We are unable to determine how long the current disruption in supplies of leucovorin will last. During the six-month periods ended June 30, 2010 and 2009, we recorded approximately \$4.2 million and approximately \$4.3 million of licensing revenues from the amortization of the \$41.5 million upfront payment we received from Allergan in 2008. We also recognized \$2.0 million of licensing revenues from the amortization of the \$16 million upfront payment we received from Nippon Kayaku and Handok 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. During the six-month period ended June 30, 2010, we reevaluated the basis for deferral having determined that there are no further ongoing obligations and recorded approximately \$0.9 million as license revenue. No similar revenue was recorded in the same period of 2009.

Selling, general and administrative expenses increased by approximately \$9.2 million, from approximately \$15.5 million in the six-month period ended June 30, 2009 to approximately \$24.7 million in the six-month period ended June 30, 2010. 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 2010 to continue at a pace similar to the first half of 2010.

Total research and development expenses increased by approximately \$30.8 million, from approximately \$12.0 million in the six-month period ended June 30, 2009 to approximately \$42.8 million in the six-month period ended June 30, 2010, primarily related to the one-time \$30 million upfront payment for the licensing of belinostat (net of approximately \$4.9 million and \$5.2 million reimbursed by Allergan for development costs related to apaziquone during the same period of 2010 and 2009, respectively). We expect research and development expenses for the remainder of 2010 to continue at a pace similar to the quarter ended June 30, 2010, excluding the one-time upfront payment of \$30.0 million for the licensing of belinostat.

We recorded approximately \$4.4 million of income from warrant obligations during the six-month period ended June 30, 2010 as compared to a loss of \$20.6 million in the same period of 2009. The income in 2010 was due to the expiration of warrants and due to a decrease in the value of the warrants. In 2009, the loss was caused by an increase in the number of warrants issued and an increase in the company s stock price.

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We incurred a non-cash charge of approximately \$1.9 million due to the amortization of intangibles from the acquisition of ZEVALIN in each of the six-month periods ended June 30, 2010 and 2009.

Other loss of approximately \$0.3 million consisted of net realized currency loss and net interest income during the six-month period ended June 30, 2010, compared to net interest income of approximately \$0.2 million for the six-month period ended June 30, 2009. 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.

### 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.

For the six-month periods ended June 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.

	CI.					oubtful ecounts	
		rgebacks and scounts	R	eturns (\$ in	and 1	Untreated Kits s)	Total
Period ended June 30, 2010: Balances at beginning of the period	\$	860	\$	1,176	\$	150	\$ 2,186
Add / (less) provisions: Related to the sales of current fiscal period		2,347		735		415	3,497
Less: Credits or actual allowances: Related to sales from prior fiscal periods		180		247		54	481
Balances at the close of the period	\$	3,027	\$	1,664	\$	511	\$ 5,202
Period ended June 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		463					463
Less: Credits or actual allowances: Related to sales from prior fiscal periods		1,074		2,057			3,131
Balances at the close of the period	\$	1,020	\$	1,087	\$	150	\$ 2,257

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The bases and 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.

# 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 (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 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 charging revenue, thereby reducing gross revenues and creating a reserve for returns which is classified as accrued liabilities.

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#### 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.

#### **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 six months ended June 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.

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#### 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 (3) general credit market risks as have existed since late 2007, 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 continuing 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. As of June 30, 2010, our investments 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 June 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 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.

We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Vice President of Finance, of the effectiveness of the design and operation of our disclosure controls and procedures as of June 30, 2010, the end of the period covered by this quarterly report. Based on such evaluation, our Chief Executive Officer and Vice President of Finance 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 and were thus not effective as of June 30, 2010.

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 Chief Executive Officer and our Vice President of Finance, 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 June 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 IA. 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 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.

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.

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# ITEM 6. Exhibits

Exhibit No.	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)/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: August 9, 2010 By: /s/ Shyam K. Kumaria

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

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