

SPECTRUM PHARMACEUTICALS INC

Form 10-Q

May 04, 2011

**Table of Contents**

**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 March 31, 2011**

**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: 001-35006**

**SPECTRUM PHARMACEUTICALS, INC.  
(Exact name of registrant as specified in its charter)**

**Delaware  
(State or other jurisdiction of  
incorporation or organization)**

**93-0979187  
(I.R.S. Employer  
Identification No.)**

**11500 South Eastern Avenue, Suite 240  
Henderson, Nevada 89052**

**(Address of principal executive offices) (Zip Code)  
(702) 835-6300**

**(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  No

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  No

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  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(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  No

As of April 22, 2011, 52,041,781 shares of the registrant's common stock were outstanding.



**SPECTRUM PHARMACEUTICALS, INC.**  
**FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2011**  
**INDEX**

	<b>Page</b>
<b><u>PART I FINANCIAL INFORMATION</u></b>	
<b><u>ITEM 1. FINANCIAL STATEMENTS (unaudited)</u></b>	
<u>Condensed Consolidated Balance Sheets as of March 31, 2011 and December 31, 2010</u>	3
<u>Condensed Consolidated Statements of Operations for the three months ended March 31, 2011 and 2010</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2011 and 2010</u>	5
<u>Notes to Condensed Consolidated Financial Statements</u>	6
<b><u>ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u></b>	17
<b><u>ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u></b>	25
<b><u>ITEM 4. CONTROLS AND PROCEDURES</u></b>	26
<b><u>PART II OTHER INFORMATION</u></b>	
<b><u>ITEM 1A. RISK FACTORS</u></b>	26
<b><u>ITEM 6. EXHIBITS</u></b>	27
<b><u>SIGNATURES</u></b>	28
<u>Exhibit 31.1</u>	
<u>Exhibit 31.2</u>	
<u>Exhibit 32.1</u>	
<u>Exhibit 32.2</u>	

**Table of Contents**

**PART I: FINANCIAL STATEMENTS**  
**SPECTRUM PHARMACEUTICALS, INC.**  
**Condensed Consolidated Balance Sheets**  
(In thousands, except share and per share data)  
(Unaudited)

	<b>March 31, 2011</b>	<b>December 31, 2010</b>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 38,822	\$ 53,557
Marketable securities	41,317	42,117
Accounts receivable, net of allowance for doubtful accounts of \$444 and \$339, respectively	51,997	21,051
Inventories, net	6,620	4,234
Prepaid expenses and other current assets	802	906
Total current assets	139,558	121,865
Bank certificates of deposit & treasuries	8,836	8,569
Property and equipment, net	3,116	3,158
Zevalin related intangible assets, net of accumulated amortization of \$13,225 and \$12,295, respectively	28,675	29,605
Other assets	5,392	434
<b>TOTAL ASSETS</b>	<b>\$ 185,577</b>	<b>\$ 163,631</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current Liabilities:		
Accounts payable and other accrued obligations	\$ 39,442	\$ 38,704
Accrued compensation and related expenses	2,254	3,313
Deferred revenue	12,300	12,300
Common stock warrant liability	9,154	3,904
Accrued drug development costs	7,128	5,101
Total current liabilities	70,278	63,322
Capital lease obligations	33	40
Deferred revenue and other credits less current portion	22,419	25,495
Zevalin related contingent obligations	298	298
Total liabilities	93,028	89,155
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized of which 1,000,000 shares have been designated as Series B junior participating preferred		

Edgar Filing: SPECTRUM PHARMACEUTICALS INC - Form 10-Q

stock, no shares issued and outstanding

Series E convertible voting preferred stock \$10,000 par value; 2,000 shares authorized; 20 and 26 shares issued and outstanding at March 31, 2011 and December 31, 2010, respectively (aggregate liquidation value of \$240)

	123	160
Common stock, \$0.001 par value 100,000,000 shares authorized; 52,021,781 and 51,459,284 issued and outstanding at March 31, 2011 and December 31, 2010, respectively	52	51
Additional paid-in capital	390,138	384,757
Accumulated other comprehensive loss	(141)	(92)
Accumulated deficit	(297,623)	(310,400)

Total stockholders' equity	92,549	74,476
----------------------------	--------	--------

TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 185,577	\$ 163,631
--	------------	------------

See accompanying notes to unaudited condensed consolidated financial statements.

**Table of Contents**

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

	<b>Three Months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
Revenues:		
Product sales, net	\$ 40,523	\$ 7,122
License and contract revenue	3,075	3,967
Total revenues	43,598	11,089
Operating costs and expenses:		
Cost of product sales (excludes amortization of purchased intangible assets)	6,580	3,245
Selling, general and administrative	12,751	10,862
Research and development	5,830	36,544
Amortization of purchased intangible assets	930	930
Total operating costs and expenses	26,091	51,581
Income (loss) from operations	17,507	(40,492)
Change in fair value of common stock warrant liability	(5,250)	1,575
Other income, net	520	(97)
Income (loss) before provision for income taxes	12,777	(39,014)
Benefit (provision) for income taxes		
Net income (loss)	\$ 12,777	\$ (39,014)
Net income (loss) per share:		
Basic	\$ 0.25	\$ (0.80)
Diluted	\$ 0.23	\$ (0.80)
Weighted average shares outstanding:		
Basic	51,297,523	48,667,653
Diluted	55,529,536	48,667,653

See accompanying notes to unaudited condensed consolidated financial statements.





**Table of Contents**

**SPECTRUM PHARMACEUTICALS, INC.**  
**Condensed Consolidated Statements of Cash Flows**

(In thousands)

(Unaudited)

	<b>March 31,</b>	
	<b>2011</b>	<b>2010</b>
<b>Cash Flows From Operating Activities:</b>		
Net income (loss)	\$ 12,777	\$ (39,014)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Amortization of deferred revenue	(3,075)	(3,967)
Depreciation and amortization	1,152	1,064
Stock-based compensation	4,064	2,475
Change in fair value of common stock warrant liability	5,250	(1,575)
Provision for bad debt	105	
Changes in operating assets and liabilities:		
Accounts receivable, net	(31,051)	2,399
Inventories, net	(2,386)	382
Prepaid expenses and other assets	108	35
Accounts payable and other accrued obligations	(4,262)	(2,075)
Accrued compensation and related expenses	(1,059)	(1,772)
Accrued drug development costs	2,027	(881)
Deferred revenue and other credits	(1)	16,915
Net cash used in operating activities	(16,351)	(26,014)
<b>Cash Flows From Investing Activities:</b>		
Maturities of marketable securities	9,685	
Purchases of marketable securities	(9,163)	(20,408)
Purchases of property and equipment	(180)	(296)
Net cash provided by (used in) investing activities	342	(20,704)
<b>Cash Flows From Financing Activities:</b>		
Proceeds from issuance of common stock from stock option exercises	1,281	19
Repayment of capital leases	(7)	
Net cash provided by financing activities	1,274	19
Net decrease in cash and cash equivalents	(14,735)	(46,699)
Cash and cash equivalents beginning of period	53,557	82,336

Edgar Filing: SPECTRUM PHARMACEUTICALS INC - Form 10-Q

Cash and cash equivalents end of period	\$ 38,822	\$ 35,637
Supplemental Disclosure of Cash Flow Information:		
Conversion of preferred stock to common stock	\$ 37	\$
Targent milestone included in other assets and accrued liabilities	\$ 5,000	\$

See accompanying notes to condensed consolidated financial statements.

**Table of Contents**

**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 with 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, and is 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 ) for interim reporting. We have condensed or omitted certain information and footnote disclosures normally included in our annual 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 March 31, 2011 and the results of operations and cash flows for the related interim periods ended March 31, 2011 and 2010. The results of operations for the three months ended March 31, 2011 are not necessarily indicative of the results that may be expected for the year ending December 31, 2011 or for any other periods.

**Variable Interest Entity**

Our Canadian affiliate, Spectrum Pharma Canada, is owned 50% by us and was organized in Quebec, Canada in January 2008. We fund 100% of the expenditures and as a result we are the party with the controlling financial interest. We are the primary beneficiary of Spectrum Pharma, which is determined to be a variable interest entity. As a result of this characterization, it is consolidated in our financial statements as though it is a wholly-owned subsidiary. We have eliminated all significant intercompany balances and transactions among the consolidated entities from the consolidated financial statements.

**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, 2010 included in our Annual Report on Form 10-K filed on March 10, 2011 with the SEC for interim reporting. We have not changed our significant accounting policies as of March 31, 2011. 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 March 10, 2011.

**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.

**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.

**Table of Contents****Recent Accounting Pronouncements**

In December 2010, the Financial Accounting Standards Board ( FASB ) issued an accounting standards update that provides guidance on the recognition and classification of the annual fee imposed by the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act on pharmaceutical companies that manufacture or import branded prescription drugs. Under this guidance, the annual fee should be estimated and recognized in full as a liability upon the first qualifying sale with a corresponding deferred cost that is amortized to operating expense using a straight-line method of allocation unless another method better allocates the fee over the calendar year in which it is payable. The annual fee ranges from \$2.5 billion to \$4.1 billion for all affected entities in total, a portion of which will be allocated to us on the basis of the amount of our branded prescription drug sales for the preceding year as a percentage of the industry's branded prescription drug sales for the same period. The annual fee is not deductible for federal income tax purposes. This guidance became effective for calendar years beginning after December 31, 2010. We adopted the provisions of the guidance in the first quarter of 2011, and current estimates do not result in a material impact on our consolidated financial statements.

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. Under the milestone method contingent consideration received from the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved, which we believe is more consistent with the substance of our performance under our various licensing and collaboration agreements. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to the entity. A milestone is substantive if the consideration earned from the achievement of the milestone is consistent with our performance required to achieve the milestone or the increase in value to the collaboration resulting from our performance, relates solely to our past performance, and is reasonable relative to all of the other deliverables and payments within the arrangement. Our license and collaboration agreements with our partners provide for payments to us upon the achievement of development milestones, such as the completion of clinical trials or regulatory approval for drug candidates. As of January 1, 2011, our agreements with partners included potential future payments to us for development milestones totaling approximately \$323.0 million, including potential milestone payments totaling \$304.0 million and \$19.0 million from our agreements with Allergan and Handok Pharmaceuticals, respectively. Given the challenges inherent in developing and obtaining approval for pharmaceutical and biologic products, there was substantial uncertainty whether any such milestones would be achieved at the time these licensing and collaboration agreements were entered into. In addition, we evaluated whether the development milestones met the remaining criteria to be considered substantive. As a result of our analysis, we consider our development milestones to be substantive and, accordingly, we expect to recognize as revenue future payments received from such milestones as we achieve each milestone. The election to adopt the milestone method did not impact our financial position or results of operations as of and for the three month period ended March 31, 2011. However, this policy election may result in revenue recognition patterns for future milestones that are materially different from those recognized for milestones received prior to adoption.

Milestone payments received prior to January 1, 2011 from arrangements where we have continuing performance obligations have been deferred and are recognized as revenue ratably over the period of time from the achievement of the milestone and our estimated date on which the next milestone will be achieved. Management makes its best estimate of the period of time until the next milestone is expected to be reached. Final milestone payments are recorded and recognized upon achieving the respective milestone, provided that collection is reasonably assured. The Company will continue to recognize milestones payments received prior to January 1, 2011 in this manner. As of March 31, 2011, we have deferred revenue of approximately \$33.8 million from milestone payments received prior to January 1, 2011 that will be recognized ratably through 2013.



**Table of Contents**

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 became 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 have adopted the guidance in the first quarter of 2011, and determined that the potential impact of adopting this guidance will not have a material impact 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. As of March 31, 2011, we determined there were no variable interest entities required to be consolidated.

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. The excess of the purchase price over the fair value of the net assets acquired can only be recognized as goodwill in a business combination.

**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.

(in thousands, except share and per share data)	<b>Net Income</b>	<b>Weighted- Average Shares Outstanding (Denominator)</b>	<b>Earnings Per Share</b>
<b>Three Months Ended March 31, 2011</b>			
Basic earnings per share:	\$ 12,777	51,297,523	\$ 0.25
Diluted earnings per share:			
Dilutive preferred shares		40,000	
Dilutive options		3,297,552	
Incremental shares assumed issued on exercise of in the money warrants		124,035	
Unvested restrictive stock		207,996	
Targent milestone which may be settled in cash or stock		562,430	
Diluted earnings per share	\$ 12,777	55,529,536	\$ 0.23

Potentially dilutive securities not included above since they were  
antidilutive:

Antidilutive warrants	\$ 5,250	198,437
Antidilutive options		277,900



**Table of Contents****2. Cash, Cash Equivalents and Marketable Securities**

As of March 31, 2011, 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.

Cash, cash equivalents and investments in marketable securities, including long term bank certificates of deposits, totaled \$89.0 million and \$104.2 million as of March 31, 2011 and December 31, 2010, 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):

	Gross Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated fair Value	Cash	Marketable Security Current	Security Long Term
<b>March 31, 2011</b>							
Cash and cash equivalents	\$ 38,822	\$	\$	\$ 38,822	\$ 38,822	\$	\$
Bank CDs (including restricted certificate of deposit of \$500)	28,580			28,580		19,744	8,836
Money market currency funds	18,818			18,818		18,818	
U.S. Government securities	2,755			2,755		2,755	
Other securities (included in other assets)	26		11	15			15
Total investments	\$ 89,001	\$	\$ 11	\$ 88,990	\$ 38,822	\$ 41,317	\$ 8,851

**December 31, 2010**

Cash and cash equivalents	\$ 53,557	\$	\$	\$ 53,557	\$ 53,557	\$	\$
Bank CDs (including restricted certificate of deposit of \$500)	29,985			29,985		21,416	8,569
	15,488			15,488		15,488	

Money market currency funds								
U.S. Government securities	2,909			2,909			2,909	
Corporate debt securities	2,304			2,304			2,304	
Other securities (included in other assets)	35		9	26				26
Total investments	\$ 104,278	\$	\$ 9	\$ 104,269	\$ 53,557	\$ 42,117	\$	8,595

**Table of Contents****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 March 31, 2011 are classified in the table below in one of the three categories of the fair value hierarchy described below:

2011	Fair Value Measurements (\$ in 000 s)			Total
	Level 1	Level 2	Level 3	
Assets:				
Cash and cash equivalents	\$ 38,822	\$	\$	\$ 38,822
FDIC insured bank CDs		28,580		28,580
Money market currency funds		18,818		18,818
U.S. Government securities		2,755		2,755
Cash and cash equivalents and marketable securities	38,822	50,153		88,975
Other securities	15			15
	\$ 38,837	\$ 50,153	\$	\$ 88,990
Liabilities:				
Common stock warrant liability			9,154	9,154
	\$	\$	\$ 9,154	\$ 9,154

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 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.

**Table of Contents**

The following summarizes the activity of Level 3 inputs measured on a recurring basis for the three months ended March 31, 2011:

	<b>Fair Value Measurements of Common Stock Warrants Using Significant Unobservable Inputs (Level 3) (\$ in 000 s)</b>
Balance at December 31, 2010	\$ 3,904
Adjustments resulting from expiration of warrants recognized in earnings	
Adjustments resulting from change in value of warrants recognized in earnings	5,250
Balance at March 31, 2011	\$ 9,154

During the three months ended March 31, 2011, the fair value of common stock warrants increased approximately \$5.2 million due to the change in value of warrants recognized in earnings during the period. 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 March 31, 2011, 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 reported at their historical carrying values.

**4. Inventories**

Inventories, net of allowances consisted of the following:

	<b>March 31, 2011</b>	<b>December 31, 2010</b>
	(\$ in 000 s)	
Raw materials	\$ 1,677	\$ 962
Work-in-process	1,890	
Finished goods	3,053	3,272
	\$ 6,620	\$ 4,234

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.



**Table of Contents****5. Accounts payable and accrued obligations**

Accounts payable and other accrued obligations consisted of the following:

	<b>March 31, 2011</b>	<b>December 31, 2010</b>
	(\$ in 000 s)	
Trade payables	\$ 11,423	\$ 8,734
Allowance for rebates	6,974	14,474
Accrued product royalty	8,901	4,026
Allowance for returns	3,200	2,000
Accrued data and distribution fees	2,113	1,874
Allowance for chargebacks	300	350
Other accrued obligations	6,531	7,246
	<b>\$ 39,442</b>	<b>\$ 38,704</b>

**6. Income Taxes**

On an interim basis, we estimate what the anticipated annual effective tax rate will be and record a quarterly income tax provision in accordance with this anticipated annual rate. The effective tax rate may be subject to fluctuations during the year as new information is obtained, which may affect the assumptions used to estimate the annual effective tax rate, including factors such as the valuation allowances against deferred tax assets, the recognition or derecognition of tax benefits related to uncertain tax positions, expected utilization of R&D tax credits and changes in or the interpretation of tax laws in jurisdictions where we conduct business.

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 March 31, 2011 and December 31, 2010, 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.

**Table of Contents**

**7. Commitments and Contingencies**

**Facility Lease**

We sublease our principal executive office in Henderson, Nevada under a non cancelable operating lease expiring April 30, 2014. We also lease our research and development facility in Irvine, California under a non cancelable operating lease expiring June 30, 2016. The lease agreement contains certain scheduled rent increases which are accounted for on a straight-line basis.

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.

In October 2008, we signed an exclusive development and commercialization collaboration agreement with Allergan for apaziquone. Under the terms of the agreement, Allergan paid us an up-front non-refundable \$41.5 million at closing and will make additional payments of up to \$304 million based on the achievement of certain development, regulatory and commercialization milestones. In November 2009, we entered into a collaboration agreement with Handok Pharmaceuticals of Korea for the development and commercialization of apaziquone for the treatment of non-muscle invasive bladder cancer in North and South Korea. Under the terms of the Handok collaboration agreement, Handok paid us an up-front payment of \$1.0 million and is required to pay potential milestone payments of approximately \$19.0 million. The potential milestones will be based on the achievement of certain regulatory and commercialization milestones.

In March 2006, we entered into an Asset Purchase Agreement with Targent, Inc. As part of the consideration for the purchase of certain assets, we agreed to pay milestone payments to Targent upon the achievement of certain sales levels for Fusilev within a calendar year. In the event that aggregate Net Sales of Fusilev, as defined in the agreement, exceed \$40 million during any calendar year, we are to pay to Targent \$5 million in cash or the common stock equivalent thereof. This milestone payment is in effect only with respect to the first calendar year in which aggregate Net Sales combined exceed such amount. As of March 31, 2011, we determined that it is probable that our aggregate Net Sales of Fusilev will exceed \$40 million for the fiscal year ended December 31, 2011, and recorded the liability under Accounts payable and other accrued obligations and corresponding intangible asset under Other assets to be amortized over the estimated useful life.

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.



**Table of Contents**

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.

**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 three months ended March 31, 2011:

	<b>Common Stock Warrants</b>	<b>Weighted Average Exercise Price</b>
Outstanding at December 31, 2010	4,192,312	\$ 6.45
Issued		
Exercised		
Forfeited		
Expired		
Outstanding, at March 31, 2011	4,192,312	\$ 6.45
Exercisable, at March 31, 2011	4,142,312	\$ 6.48

Approximately 3.7 million of the outstanding warrants are scheduled to expire by September 14, 2011.

**Table of Contents****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 month period ended March 31, is as shown below:

	<b>Three Months Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
	(\$ in 000 s)	
Research and development	\$ 404	\$ 1,058
Selling, general and administrative	3,660	1,417
Total share based compensation expense	\$ 4,064	\$ 2,475

**Stock Options**

During the three month period ended March 31, 2011, 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 three month period ended March 31, 2011 and 2010 were estimated at approximately \$4.10 and \$2.87, respectively using the Black-Scholes option pricing model with the following assumptions:

	<b>Three-months ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
Divided yield	0.00%	0.00%
Expected volatility	70.46%	75.52%
Risk free interest rate	2.11%	2.50%
Expected life (years)	4.93	5.00

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.

During the three months ended March 31, 2011 and 2010, our share-based charge in connection with the expensing of stock options was approximately \$2.8 million and \$1.8 million, respectively. As of March 31, 2011, there was approximately \$6.8 million of unrecognized stock-based compensation cost related to stock options which we expect to recognize over a weighted average period of approximately 3.03 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 period ended March 31, 2011 and 2010, the share-based charge in connection with the expensing of restricted stock awards was approximately \$931,000 and \$511,000, respectively. As of March 31, 2011, there was approximately \$2.8 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 2.57 years.

**401(k) Plan Matching Contribution**

During the three month period ended March 31, 2011, we issued 21,714 shares of common stock as our match of approximately \$149,000 on the 401(k) contributions of our employees. During the three month period ended March 31, 2010, we issued 37,688 shares of common stock as our match of approximately \$171,000 on the 401(k) contributions of our employees.



**Table of Contents****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 March 31, 2011, Purchase Plan participant contributions of \$174,981 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 March 31, 2011, 233,998 shares have been issued under the Purchase Plan.

**Common Stock Reserved for Future Issuance**

As of March 31, 2011, approximately 13.8 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	40,000
Exercise of stock options	9,596,685
Exercise of warrants	4,192,312
<b>Total shares of common stock reserved for future issuances</b>	<b>13,828,997</b>

**9. Subsequent Event**

Effective April 22, 2011, our board of directors adopted a Long-Term Retention and Management Incentive Plan.

**Table of Contents**

**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, continues, or variations thereon or similar terminology (although not all forward-looking statements contain these words). Such forward-looking statements are based on the reasonable 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, 2010, 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 approval 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;

**Table of Contents**

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, 2010 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. 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, or PTCL, under a strategic collaboration with TopoTarget A/S or TopoTarget.

## **Table of Contents**

The following is an update of our business strategy for 2011, as described in our Annual Report on Form 10-K for the year ended December 31, 2010 filed with the SEC.

***Maximizing the growth potential of our marketed drugs, Zevalin and Fusilev.*** Our near-term outlook largely depends on sales and marketing successes for our two marketed drugs. For Zevalin, we stabilized sales in 2009, increased sales in 2010 and believe we can continue to grow sales in 2011 and beyond. For Fusilev, which we launched in August 2008, we were able to benefit from broad utilization in community clinics and hospitals and recognized a dramatic increase in sales during 2010 due to a shortage of generic leucovorin. While we cannot predict how long the shortage may continue, our focus has been to obtain approval for Fusilev in advanced metastatic colorectal cancer. As part of its review of our supplemental new drug application, or sNDA, for metastatic colorectal cancer, the FDA requested additional data to which we submitted a response on October 29, 2010. The FDA formally accepted the submission and we received approval on April 29, 2011.

For both Zevalin and Fusilev, we initiated and continue to stage appropriate infrastructure expansions and additional initiatives to facilitate broad customer reach and to address other market requirements, as appropriate. We have formed a dedicated commercial organization comprised of highly experienced and motivated sales representatives, account managers, and a complement of other support marketing personnel to manage the sales and marketing of these drugs. In addition our scientific department supports field activities through various MDs, PhDs and other medical science liaison personnel.

***Optimizing our development portfolio and maximizing the asset values of its components.*** While over the recent few years, we have evolved from a development-stage to a commercial-stage pharmaceutical company, we have maintained a highly focused development portfolio. Our strategy with regard to our development portfolio is to focus on late-stage drugs and to develop them rapidly to the point of regulatory approval. We plan to develop some of these drugs ourselves or with our subsidiaries and affiliates, or secure collaborations such that we are able to suitably monetize these assets.

We have assembled a drug development infrastructure that is comprised of highly experienced and motivated MDs, PhDs, clinical research associates and a complement of other support personnel to rapidly develop these drugs. During 2009, this team achieved our goal of completing enrollment in the two Phase 3 apaziquone trials (with more than 1,600 patients enrolled) and expect to finish evaluation of the last patient in 2011. We expect to file a NDA in 2012. We expect to continue to maximize the value of apaziquone through further developmental efforts and initiation of additional trials.

With regard to our anti-cancer drug belinostat, a novel HDAC inhibitor, we have to date opened more than 100 sites and continue to enroll patients in the registrational pivotal trial. We expect to complete enrollment in mid-to-late second half of 2011, and file a NDA in 2012. Belinostat has received Fast Track designation from FDA, which means, if the FDA agrees, we can start filing a rolling new-drug application even before the clinical package is ready, beginning with the filing of pre-clinical data and CMC before the end of this year

We have several other exciting compounds in earlier stages of development in our portfolio. Based upon a criteria-based portfolio review, we are in the process of streamlining our pipeline drugs, allowing for greater focus and integration of our development and commercial goals.

***Expanding our pipeline of late stage and commercial drugs through licensing and business development.***

It is our goal to identify new strategic opportunities that will create strong synergies with our currently marketed drugs and identify and pursue partnerships for out-licensing certain of our drugs in development. To this end, we will continue to explore strategic collaborations as these relate to drugs that are either in advanced clinical trials or are currently on the market. We believe that such opportunistic collaborations will provide synergies with respect to how we deploy our internal resources. In this regard, we intend to identify and secure drugs that have significant growth potential either through enhanced marketing and sales efforts or through pursuit of additional clinical development. In January 2011, we signed a letter of agreement with Viropro, Inc., for the development of a biosimilar version of the monoclonal antibody drug rituximab. Biosimilars, or follow-on biologics, are terms used to describe officially-approved subsequent versions of innovator biopharmaceutical products made by a different sponsor following patent and exclusivity expiry.

Terms of the agreement call for a nominal upfront payment and additional payments based on certain development and regulatory milestones should the Company elect to continue development efforts. We believe our in-licensing of belinostat, a novel histone deacetylase, or HDAC, inhibitor, is demonstrative of such licensing and business development efforts outlined above.



**Table of Contents**

***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 capital markets environment during 2009, 2010 and continuing in 2011. This policy includes the pursuit of non-dilutive funding options, prudent expense management, and the achievement of critical synergies within our operations in order to maintain a reasonable burn rate. Even with the continued build-up in operational infrastructure to facilitate the marketing of our two commercial drugs, we intend to be fiscally prudent in any expansion we undertake. In terms of revenue generation, we plan to become more reliant on sales from currently marketed drugs and intend to pursue out-licensing of select pipeline drugs in select territories, as discussed above. When appropriate, we may pursue other sources of financing, including non-dilutive financing alternatives. While we are currently focused on advancing our key drug development programs, we anticipate that we will make regular determinations as to which other programs, if any, to pursue and how much funding to direct to each program on an ongoing basis, based on clinical success and commercial potential, including termination of our existing development programs, especially if we do not expect value being driven from continued development.

***Further enhancing the organizational structure to meet our corporate objectives.*** We have highly experienced staff in pharmaceutical operations, clinical development, regulatory and commercial functions who previously held positions at both small to mid-size biotech companies, as well as large pharmaceutical companies. We have strengthened the ranks of our management team, and will continue to pursue talent on an opportunistic basis. Finally, we remain committed to running a lean and efficient organization, while effectively leveraging our critical resources.

**Financial Condition**

***Liquidity and Capital Resources***

Our cumulative losses, since inception in 1987 through March 31, 2011, are approximately \$297.6 million. We may incur additional losses for at least the next few years, as we implement our growth strategy of commercializing marketed drugs, while continuing to develop our portfolio of late-stage drug products. Our long-term strategy 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 revenue from out-licensing our other drug products.

While we believe that the approximately \$89.0 million in cash, cash equivalents and investments, which includes long term marketable securities, we had available on March 31, 2011 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 at all. 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 additional funds are raised through the issuance of debt securities, the terms of such securities may place restrictions on our ability to operate our business. If and when appropriate, just as we have done in the past, we may pursue non-dilutive financing alternatives as well.

**Table of Contents**

Zevalin sales growth is largely dependent on the adoption of Zevalin for use as part of first-line therapy for follicular NHL and continued use in its initial indication. As discussed earlier, during 2010 and through March 31, 2011, our sales of Fusilev grew considerably over prior years because of a shortage of generic leucovorin. We are unable to predict how long this current shortage may last. On April 29, 2011 we received approval from the U.S. Food and Drug Administration (FDA) for the use of FUSILEV® (levoleucovorin) in combination with 5-fluorouracil in the palliative treatment of patients with advanced metastatic colorectal cancer. This new, expanded indication supplements the original 2008 FDA approval of FUSILEV. This approval will allow us to actively market Fusilev for use in the treatment of colorectal cancer. We are unable to reasonably estimate when, if ever, we will realize sustainable net profit from sales of these two products or any of our other products, if they are approved by the FDA.

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 three-month period ended March 31, 2011, our total research and development expenditure, including indirect expenditures, was approximately \$5.8 million (net of \$1.7 million received from Allergan).

Our primary focus areas for the foreseeable future, and the programs that are expected to represent a significant part of our R&D are the on-going registrational clinical trials of apaziquone and belinostat and additional clinical studies in supporting the expanded utilization of our FDA products (ZEVALIN and FUSILEV). While we are currently focused on advancing these key product development programs, we continually evaluate our R&D programs of other pipeline products 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 R&D in the fiscal year ending December 31, 2011, excluding the cost of in-licensing or acquisitions of additional drugs, if any, is expected to range between approximately \$30 and \$40 million.

Further, 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. Additionally, we entered into a collaboration agreement with TopoTarget, whereby, commencing February 2, 2010, TopoTarget bears, for belinostat, 100% of the CUP trial costs and 30% of other development costs unrelated to the PTCL study.

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 \$16.4 million for the three months ended March 31, 2011. The principal components of such cash usage was net income in the period of \$12.8 million adjusted for net non-cash credits of \$7.5 million, offset primarily by a \$31.1 million increase in accounts receivable due to the increase in product sales.

**Table of Contents*****Net Cash used in Investing Activities***

Net cash provided by investing activities, \$342,000 during the three months ended March 31, 2011, was primarily due to the net \$522,000 maturities of marketable securities partially offset by a \$180,000 increase in property and equipment acquisitions.

***Net Cash provided by Financing Activities***

Net cash provided by financing activities, \$1.3 million for the three months ended March 31, 2011, primarily relates to proceeds from the issuance of common stock as a result of the exercise of stock options.

**Results of Operations*****Three months ended March 31, 2011 and 2010***

***Net Revenues.*** Net revenues increased \$32.5 million, or 293%, to \$43.6 million in the three months ended March 31, 2011 from \$11.1 million in the three months ended March 31, 2010. We recognized \$40.5 million from product sales, of which \$34.6 million related to sales of FUSILEV (each net of estimates for promotional, price and other adjustments, including adjustment of the allowance for product returns) and \$5.9 million related to sales of ZEVALIN. Product revenues recorded in the three months ended March 31, 2010 were \$7.1 million, of which \$618,000 related to sales of FUSILEV and \$6.5 million related to sales of ZEVALIN. Revenues from the sales of FUSILEV have increased due to a supply disruption of leucovorin. Sales of FUSILEV grew significantly in the third and fourth quarter of 2010 which have continued in the first quarter of 2011. We are unable to determine how long the current disruption in supplies of generic leucovorin will last. We are in the process of qualifying additional suppliers of Fusilev, however, until this process is complete, we cannot predict our ability to manufacture sufficient quantities to meet fluctuating commercial demand. During the three months ended March 31, 2011 and 2010, we also recognized \$3.1 million 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.*** Cost of product sales increased \$3.3 million to \$6.6 million in the three months ended March 31, 2011 from \$3.2 million in the three months ended March 31, 2010. The increase in total cost of sales relates to an increase in product revenues.

***Selling, General and Administrative.*** Selling, general and administrative expenses increased \$1.9 million, or 17%, to \$12.8 million, in the three months ended March 31, 2011 from \$10.9 million in the three months ended March 31, 2010. The increase is due primarily to an increase of \$2.2 million in stock compensation expense. We expect selling, general and administrative expenses for the remainder of 2011 to continue at a pace similar to the first three months of 2011.

***Research and Development.*** Research and development expenses decreased \$30.7 million, or 84%, to \$5.8 million, in the three months ended March 31, 2011 from \$36.5 million in the three months ended March 31, 2010. The decrease is primarily due to the \$30.0 million upfront payment for the licensing of belinostat incurred in the first quarter of 2010. We expect research and development expenses to range between approximately \$30 and \$40 million for 2011, excluding the cost of in-licensing or acquisitions of additional drugs, if any.

***Amortization of Purchased Intangibles.*** We incurred a non-cash charge of \$930,000 for the three months ended March 31, 2011 and 2010 due to the amortization of intangibles from the acquisition of ZEVALIN.

***Change in Fair Value of Common Stock Warrant Liability.*** We recorded a loss of \$5.3 million for the change in the fair value of the warrant obligations during the three month period ended March 31, 2011 compared to income of \$1.6 million in the same period of 2010.

**Table of Contents**

**Other Net Income.** The principal components of other income of \$520,000 and (\$97,000) during the three month periods ended March 31, 2011 and 2010, 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.

**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 three months ended March 31, 2011 and 2010, the following is a roll forward of the provisions for return, discounts and rebates and chargebacks allowances and estimated doubtful account allowances.

	<b>Chargebacks and Discounts</b>	<b>Rebates</b>	<b>Returns</b>	<b>Data and Distribution Fees</b>	<b>Doubtful accounts</b>	<b>Total</b>
	(\$ in 000 s)					
<b>Period ended March 31, 2011:</b>						
Balances at beginning of the period	\$ 675	\$ 14,474	\$ 2,000	\$ 1,874	\$ 339	\$ 19,362
Add provisions:	1,718	3,388	1,207	1,527	105	7,945
Less: Credits or actual allowances:	(1,120)	(10,888)	(7)	(1,288)		(13,303)
Balances at the close of the period	\$ 1,273	\$ 6,974	\$ 3,200	\$ 2,113	\$ 444	\$ 14,004
<b>Period ended March 31, 2010:</b>						
Balances at beginning of period	\$ 860	\$	\$ 1,176	\$ 213	\$ 150	\$ 2,399
Add provisions:	353		128	90	259	830
Less: Credits or actual allowances:	(114)		(55)	(213)	(54)	(436)
Balances at the close of the period	\$ 1,099	\$	\$ 1,249	\$ 90	\$ 355	\$ 2,793

Amounts recorded as allowances on our condensed consolidated balance sheets for 2011 and 2010 are reflected in the table above. The basis and methods of estimating these allowances, used by management, are described below.

**Chargebacks, discounts and rebates**

Chargebacks represent a provision against gross accounts receivable and related reduction to gross revenue. A chargeback is the difference between the price the wholesale customer, in our case the wholesaler or distributor, pays

(the wholesale acquisition cost, or WAC) and the price (contracted price) that a contracted customer (e.g., a Group Purchasing Organization, or GPO, member) pays for a product. We accrue for chargebacks in the relevant period on the presumption that all units of product sold to members of the GPOs will be 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;

**Table of Contents**

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

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 the Company 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.

We record Medicaid and Medicare rebates based on estimates for such expense. However, such amount have not been material to the financial statements.

***Product returns allowances***

Customers are typically permitted to return products within thirty days after shipment, if incorrectly shipped or not ordered, and within a window of time six months before and twelve months after the expiration of product dating, subject to certain restocking fees and preauthorization requirements, as applicable. 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 experience of our management with selling similar oncology products. We record an allowance for future returns by debiting revenue, thereby reducing gross revenues and crediting a reserve for returns to other accrued liabilities.

***Distribution and Data Fees***

Distribution and data fees are paid to authorized wholesalers and specialty distributors of Fusilev as a percentage of WAC for products sold. The services provided include contract administration, inventory management, product sales reporting by customer, returns for clinics and hospitals. We accrue distribution and data fees based on a percentage of Fusilev revenues that are set and governed by distribution agreements.

***Doubtful Accounts***

An allowance for doubtful accounts is estimated based on the customer payment history and a review by management of the aging of the accounts receivables as of the balance sheet date. We accrue for 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 estimate the accrual for such doubtful receivables or write the receivable off.

**Table of Contents**

**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.

**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 three months ended March 31, 2011, 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, 2010 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, (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 investing in highly liquid, highly rated instruments and not investing in long-term maturity instruments.

In response to the dislocation in the credit markets since the latter part of 2007, in early 2008 we converted substantially all of our investments, including all of our market auction debt securities, into highly liquid and safe instruments. Our investments, as of March 31, 2011 and 2010, were primarily in money market accounts, short-term corporate bonds, certificate of deposits, 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 our instruments are held in accounts segregated from the assets of the institutions. However, due to the current extremely volatile financial and credit markets and liquidity crunch faced by many banking institutions, the financial viability of these institutions, and the safety and liquidity of our funds, are being constantly monitored.

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

**Table of Contents**

**ITEM 4. CONTROLS AND PROCEDURES**

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

As required by Exchange Act Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Acting Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of March 31, 2011, the end of the period covered by this quarterly report. Based on the foregoing, our Chief Executive Officer and Acting Chief Financial Officer concluded that our disclosure controls and procedures, as of the end of the period covered by this report, were effective.

There has been no change in our internal control over financial reporting during the quarter ended March 31, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**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, 2010 as filed with the SEC.



**Table of Contents**

**ITEM 6. EXHIBITS**