

SPECTRUM PHARMACEUTICALS INC

Form 10-Q

August 04, 2011

Table of Contents

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

FORM 10-Q

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2011

**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 July 29, 2011, 53,197,879 shares of the registrant's common stock were outstanding.

**SPECTRUM PHARMACEUTICALS, INC.
FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2011
INDEX**

	Page
<u>PART I FINANCIAL INFORMATION</u>	
<u>ITEM 1. FINANCIAL STATEMENTS (unaudited)</u>	
<u>Condensed Consolidated Balance Sheets as of June 30, 2011 and December 31, 2010</u>	3
<u>Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2011 and 2010</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2011 and 2010</u>	5
<u>Notes to Condensed Consolidated Financial Statements</u>	6
<u>ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	
<u>ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	
<u>ITEM 4. CONTROLS AND PROCEDURES</u>	
<u>PART II OTHER INFORMATION</u>	
<u>ITEM 1A. RISK FACTORS</u>	
<u>ITEM 6. EXHIBITS</u>	
<u>SIGNATURES</u>	
<u>Exhibit 10.36</u>	
<u>Exhibit 10.37</u>	
<u>Exhibit 31.1</u>	
<u>Exhibit 31.2</u>	
<u>Exhibit 32.1</u>	
<u>Exhibit 32.2</u>	
<u>EX-101 INSTANCE DOCUMENT</u>	
<u>EX-101 SCHEMA DOCUMENT</u>	
<u>EX-101 CALCULATION LINKBASE DOCUMENT</u>	
<u>EX-101 LABELS LINKBASE DOCUMENT</u>	
<u>EX-101 PRESENTATION LINKBASE DOCUMENT</u>	
<u>EX-101 DEFINITION LINKBASE DOCUMENT</u>	

Items 1 through 5 of Part II have been omitted because they are not applicable with respect to the current reporting period.

Table of Contents

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

	June 30, 2011	December 31, 2010
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 67,049	\$ 53,557
Marketable securities	37,388	42,117
Accounts receivable, net of allowance for doubtful accounts of \$630 and \$339, respectively	46,471	21,051
Inventories, net	9,399	4,234
Prepaid expenses and other current assets	883	906
Total current assets	161,190	121,865
Investments	14,095	8,569
Property and equipment, net	3,050	3,158
Intangible assets, net	43,962	29,605
Other assets	379	434
TOTAL ASSETS	\$ 222,676	\$ 163,631
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable and other accrued obligations	\$ 56,539	\$ 38,704
Accrued compensation and related expenses	2,816	3,313
Deferred revenue	12,300	12,300
Common stock warrant liability	10,391	3,904
Accrued drug development costs	7,163	5,101
Total current liabilities	89,209	63,322
Capital lease obligations	25	40
Deferred revenue and other credits less current portion	19,290	25,495
Zevalin related contingent obligations	298	298
Total liabilities	108,822	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 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 June 30, 2011 and December 31, 2010, respectively (aggregate liquidation value of \$240)	123	160
Common stock, \$0.001 par value 175,000,000 shares authorized; 52,947,221 and 51,459,284 issued and outstanding at June 30, 2011 and December 31, 2010,	53	51

respectively

Additional paid-in capital	404,273	384,757
Accumulated other comprehensive loss	(176)	(92)
Accumulated deficit	(290,419)	(310,400)
Total stockholders' equity	113,854	74,476
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 222,676	\$ 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)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2011	2010	2011	2010
Revenues:				
Product sales, net	\$ 42,287	\$ 9,268	\$ 82,810	\$ 16,390
License and contract revenue	3,075	3,075	6,150	7,042
Total revenues	\$ 45,362	\$ 12,343	\$ 88,960	\$ 23,432
Operating costs and expenses:				
Cost of product sales (excludes amortization of purchased intangible assets)	8,130	3,592	14,710	6,837
Selling, general and administrative	18,699	13,802	31,450	24,664
Research and development	7,686	6,285	13,516	42,829
Amortization of purchased intangibles	930	930	1,860	1,860
Total operating costs and expenses	35,445	24,609	61,536	76,190
Income (loss) from operations	9,917	(12,266)	27,424	(52,758)
Change in fair value of common stock warrant liability	(1,237)	2,826	(6,487)	4,401
Other income, net	174	(236)	694	(333)
Income (loss) before provision for income taxes	8,854	(9,676)	21,631	(48,690)
Provision for income taxes	(1,650)		(1,650)	
Net income (loss)	\$ 7,204	\$ (9,676)	\$ 19,981	\$ (48,690)
Net income (loss) per share:				
Basic	\$ 0.14	\$ (0.20)	\$ 0.39	\$ (1.00)
Diluted	\$ 0.12	\$ (0.20)	\$ 0.35	\$ (1.00)
Weighted average shares outstanding:				
Basic	52,257,049	49,020,236	51,814,122	48,844,918
Diluted	58,265,264	49,020,236	56,845,371	48,844,918

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

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

	June 30,	
	2011	2010
Cash Flows From Operating Activities:		
Net income (loss)	\$ 19,981	\$ (48,690)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Amortization of deferred revenue	(6,150)	(7,042)
Depreciation and amortization	2,480	2,136
Stock-based compensation	10,880	4,212
Change in fair value of common stock warrant liability	6,487	(4,401)
Provision for bad debt	291	
Changes in operating assets and liabilities:		
Accounts receivable, net	(25,711)	113
Inventories, net	(5,165)	108
Prepaid expenses and other assets	12	173
Accounts payable and other accrued obligations	7,677	7,072
Accrued compensation and related expenses	(497)	(928)
Accrued drug development costs	2,062	(537)
Landlord contributions to tenant improvements		1,446
Deferred revenue and other credits	(55)	16,935
Net cash provided by (used in) operating activities	12,292	(29,403)
Cash Flows From Investing Activities:		
Maturities of marketable securities	15,157	
Purchases of marketable securities	(15,972)	(4,769)
Purchases of property and equipment	(341)	(1,835)
Net cash used in investing activities	(1,156)	(6,604)
Cash Flows From Financing Activities:		
Proceeds from issuance of common stock from stock option exercises	1,973	690
Proceeds from contributions to ESPP	398	305
Repayment of capital leases	(15)	(14)
Net cash provided by financing activities	2,356	981
Net increase (decrease) in cash and cash equivalents	13,492	(35,026)
Cash and cash equivalents beginning of period	53,557	82,336
Cash and cash equivalents end of period	\$ 67,049	\$ 47,310
Supplemental Disclosure of Cash Flow Information:		
Conversion of preferred stock to common stock	\$ 37	\$

Edgar Filing: SPECTRUM PHARMACEUTICALS INC - Form 10-Q

Common stock issued for Targent milestone	\$	6,230	\$
Targent milestones included in intangible assets and accrued liabilities	\$	10,159	\$

See accompanying notes to unaudited 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 June 30, 2011 and the results of operations and cash flows for the related interim periods ended June 30, 2011 and 2010. The results of operations for the three and six months ended June 30, 2011 are not necessarily indicative of the results that may be expected for the year ending December 31, 2011 or for any other periods.

Significant Accounting Policies

The accounting policies followed by us and other information are contained in the notes to our 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. We have not changed our significant accounting policies as of June 30, 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 June 2011, the FASB issued an accounting standards update that eliminates the option to present components of other comprehensive income as part of the statement of changes in equity and requires an entity to present items of net income and other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. This guidance also requires an entity to present on the face of the financial statements reclassification adjustments from other comprehensive income to net income. This guidance will be effective for fiscal years beginning after December 15, 2011, which will be our fiscal year 2012, with early adoption permitted. We do not expect the adoption of the guidance will have a material impact on our consolidated financial statements.

In May 2011, the FASB issued an accounting standards update that clarifies and amends the existing fair value measurement and disclosure requirements. This guidance will be effective prospectively for interim and annual periods beginning after December 15, 2011, which will be our fiscal year 2012, with early adoption prohibited. We do not expect the adoption of the guidance will have a material impact on our consolidated financial statements.

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 Act 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 June 30, 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 June 30, 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.

Table of Contents

Acquisitions and Collaborations

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

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

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 Canada, 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 our consolidated entities from the consolidated financial statements.

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 periods.

Table of Contents

(in thousands, except share and per share data)		Weighted- Average Shares Outstanding	Earnings Per Share
Three Months Ended June 30, 2011	Net Income	(Denominator)	
Basic earnings per share:	\$ 7,204	52,257,049	\$ 0.14
Diluted earnings per share:			
Dilutive preferred shares		40,000	
Dilutive options		4,384,113	
Incremental shares assumed issued on exercise of in the money warrants		189,446	
Unvested restrictive stock		248,842	
Targent milestone which may be settled in cash or stock		1,145,814	
Diluted earnings per share	\$ 7,204	58,265,264	\$ 0.12
Potentially dilutive securities not included above since they were antidilutive:			
Antidilutive warrants	\$ 1,237	921,686	
Antidilutive options		194,250	
(in thousands, except share and per share data)		Weighted- Average Shares Outstanding	Earnings Per Share
Six Months Ended June 30, 2011	Net Income	(Denominator)	
Basic earnings per share:	\$ 19,981	51,814,122	\$ 0.39
Diluted earnings per share:			
Dilutive preferred shares		40,000	
Dilutive options		3,767,162	
Incremental shares assumed issued on exercise of in the money warrants		160,709	
Unvested restrictive stock		219,109	
Targent milestone which may be settled in cash or stock		844,269	
Diluted earnings per share	\$ 19,981	56,845,371	\$ 0.35
Potentially dilutive securities not included above since they were antidilutive:			

Edgar Filing: SPECTRUM PHARMACEUTICALS INC - Form 10-Q

Antidilutive warrants	\$	6,487	603,944
Antidilutive options			1,855,750

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

As of June 30, 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 \$118.5 million and \$104.2 million as of June 30, 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	Gross	Estimated		Marketable Security		
	Amortized	Unrealized	Unrealized	fair	Cash	Current	Long
	Cost	Gains	Losses	Value			Term
June 30, 2011							
Cash and cash equivalents	\$ 67,049	\$	\$	\$ 67,049	\$ 67,049	\$	\$
Bank CDs (including restricted certificate of deposit of \$500)	29,984			29,984		15,889	14,095
Money market currency funds	20,748			20,748		20,748	
U.S. Government securities	751			751		751	
Other securities (included in other assets)	26		18	8			8
Total investments	\$ 118,558	\$	\$ 18	\$ 118,540	\$ 67,049	\$ 37,388	\$ 14,103
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
Money market currency funds	15,488			15,488		15,488	
U.S. Government securities	2,909			2,909		2,909	
	2,304			2,304		2,304	

Corporate debt securities								
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 June 30, 2011 are classified in the table below in one of the three categories of the fair value hierarchy described below:

	Fair Value Measurements			Total
	Level 1	Level 2	Level 3	
2011				
Assets:				
Cash and cash equivalents	\$ 67,049	\$	\$	\$ 67,049
Bank CDs		29,984		29,984
Money market currency funds		20,748		20,748
U.S. Government securities		751		751
Cash and cash equivalents and marketable securities	67,049	51,483		118,532
Other securities	8			8
	\$ 67,057	\$ 51,483	\$	\$ 118,540
Liabilities:				
Common stock warrant liability			10,391	10,391
	\$	\$	\$ 10,391	\$ 10,391

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 six months ended June 30, 2011:

	Fair Value Measurements of Common Stock Warrants Using Significant Unobservable Inputs (Level 3) (\$ in 000 s)
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	6,487
Balance at June 30, 2011	\$ 10,391

During the six months ended June 30, 2011, the fair value of common stock warrants increased approximately \$6.5 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 June 30, 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. Intangible Assets

Intangible assets consist of the following:

	June 30, 2011	December 31, 2010
	(\$ in 000 s)	
Zevalin intangibles	\$ 41,900	\$ 41,900
Fusilev intangibles	16,388	
	58,288	41,900
Less: accumulated amortization	(14,326)	(12,295)
	\$ 43,962	\$ 29,605

During the three and six months ended June 30, 2011, Zevalin intangible amortization of \$930,000 and \$1.9 million, respectively, are included in amortization of purchased intangibles. In addition, during the three months ended June 30, 2011, \$171,000 is included in cost of goods sold related to Fusilev Targent milestones.

Table of Contents**5. Inventories**

Inventories, net of allowances consisted of the following:

	June 30, 2011	December 31, 2010
	(\$ in 000 s)	
Raw materials	\$ 1,294	\$ 962
Work-in-process	2,361	
Finished goods	5,744	3,272
	\$ 9,399	\$ 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.

6. Accounts payable and accrued obligations

Accounts payable and other accrued obligations consisted of the following:

	June 30, 2011	December 31, 2010
	(\$ in 000 s)	
Trade payables	\$ 10,601	\$ 8,734
Allowance for rebates	12,914	14,474
Accrued product royalty	15,509	4,026
Allowance for returns	3,000	2,000
Accrued data and distribution fees	3,298	1,874
Allowance for chargebacks	460	350
Accrued income taxes	1,650	
Other accrued obligations	9,107	7,246
	\$ 56,539	\$ 38,704

7. 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 June 30, 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. The change in the valuation allowance was primarily due to a corresponding change in a deferred tax asset that we determined required a valuation allowance.

Table of Contents

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.

8. 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 agreements contain 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 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.

Table of Contents

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 June 2011, we amended the Agreement to, among other things, revise the target indications of additional clinical trials, extend certain milestone dates, and to modify certain payment obligations and expense allocation provisions.

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 regulatory events as well as for certain sales levels for Fusilev within a calendar year. In connection with the achievement of the FDA approval milestone in April 2011, we issued an aggregate amount of 733,715 shares of common stock to certain of Targent's stockholders, as directed by Targent. We capitalized \$6.3 million associated with this milestone as intangible assets during the three months ended June 30, 2011 which is being amortized over the estimated useful life of 8.7 years.

In addition, in the event that aggregate net sales of Fusilev, as defined in the agreement, exceed \$40 million and or \$100 million during any calendar year, we are to pay to Targent \$5 million in cash or the common stock equivalent thereof for each milestone. These milestone payments are in effect only with respect to the first calendar year in which aggregate net Sales combined exceed such amount and not with respect to any subsequent calendar year in which aggregate net Sales of the products combined exceed such amounts. As of June 30, 2011, we achieved the first sales milestone of \$40 million and have the option of paying \$5 million in cash or common stock equivalent thereof. This payment is subject to direction from Targent. In the event we determine to pay this milestone in stock, it will equate to 577,367 shares. Included in cost of goods sold expense for the quarter ended June 30, 2011 is \$171,000 related to the amortization of these milestones.

As of June 30, 2011, we determined that it is probable that our aggregate Net Sales of Fusilev will exceed \$100 million for the fiscal year ended December 31 2011, and recorded the liability for the milestone payment of \$5 million under Accounts payable and other accrued obligations and corresponding intangible assets to be amortized over the estimated useful life.

Service Agreements

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

At each period end, we accrue for all costs of goods and services received, with such accruals based on factors such as estimates of work performed, patient enrollment, completion of patient studies and other events. Generally, we are in a position to accelerate, slow down or discontinue any or all of the projects that we are working on at any given point in time. Should we decide to discontinue and/or slow down the work on any project, the associated costs for those projects would be limited to the extent of the work completed. Generally, we are able to terminate these contracts due to the discontinuance of the related project(s) and can thus avoid paying for the services that have not yet been rendered and our future purchase obligations would reduce accordingly.

Employment Agreement

We have entered into an employment agreement with Dr. Rajesh C. Shrotriya, our President and Chief Executive Officer, which expires January 2, 2012. The employment agreement automatically renews for subsequent one-year calendar term unless either party gives written notice of such party's intent not to renew the agreement at least 90 days prior to the commencement of the new term. The employment agreement requires Dr. Shrotriya to devote his full working time and effort to our business and affairs during the term of the agreement. The employment agreement provides for a minimum annual base salary with annual increases, periodic bonuses and option grants as determined by the Compensation Committee of our Board of Directors.

Table of Contents**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.

9. 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 six months ended June 30, 2011:

	Common Stock Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2010	4,192,312	\$ 6.45
Issued		
Exercised		
Forfeited		
Expired		
Outstanding, at June 30, 2011	4,192,312	\$ 6.45
Exercisable, at June 30, 2011	4,142,312	\$ 6.48

Approximately 3.7 million of the outstanding warrants are scheduled to expire by September 15, 2011, of which 206,476 warrants were exercised in July 2011.

Share-Based Compensation

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
	(\$ in 000 s)			
Research and development	\$ 495	\$ 801	\$ 899	\$ 1,858
Selling, general and administrative	6,321	936	9,981	2,354
Total share based compensation expense	\$ 6,816	\$ 1,737	\$ 10,880	\$ 4,212

Table of Contents**Stock Options**

During the three and six month periods ended June 30, 2011, the Compensation Committee of our Board of Directors granted stock options at exercise prices equal to 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 period ended June 30, 2011 and 2010 were estimated at approximately \$7.67 and \$4.49, respectively using the Black-Scholes option pricing model with the following assumptions:

	Six-months ended June 30,	
	2011	2010
Divided yield	0.00%	0.00%
Expected volatility	70.86%	71.01%
Risk free interest rate	1.76%	2.37%
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 and six months ended June 30, 2011, our share-based charge in connection with the expensing of stock options was approximately \$3.2 million and \$6.1 million, respectively. During the three and six months ended June 30, 2010, our 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, 2011, there was approximately \$14.2 million of unrecognized stock-based compensation cost related to stock options which we expect to recognize over a weighted average period of approximately 2.67 years.

Restricted Stock

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

During the three and six month periods ended June 30, 2011, the share-based charge in connection with the expensing of restricted stock awards was approximately \$249,000 and \$1.2 million, respectively. During the three and six month periods ended June 30, 2010, the share-based charge in connection with the expensing of restricted stock awards was approximately \$200,000 and \$800,000, respectively.

As of June 30, 2011, there was approximately \$2.3 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 2.32 years.

401(k) Plan Matching Contribution

During the three and six month period ended June 30, 2011, we issued 14,909 and 36,624 shares of common stock as our match of approximately \$138,000 and \$287,000 on the 401(k) contributions of our employees. During the three and six month period ended June 30, 2010, we issued 36,991 and 74,679 shares of common stock as our match of approximately \$100,000 and \$200,000 on the 401(k) contributions of our employees.

Employee Stock Purchase Plan

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

Table of Contents

A total of 5,000,000 shares of common stock are authorized for issuance under the Purchase Plan, and as of June 30, 2011, 302,232 shares have been issued under the Purchase Plan.

Common Stock Reserved for Future Issuances

As of June 30, 2011, approximately 15.0 million shares of our common stock, when fully vested, were issuable upon conversion or exercise of rights granted under prior financing arrangements, stock options and warrants, as follows:

Conversion of Series E preferred shares	40,000
Exercise of stock options	10,759,198
Exercise of warrants	4,192,312
Total shares of common stock reserved for future issuances	14,991,510

10. Long-Term Retention and Management Incentive Plan

Effective April 22, 2011, our Board of Directors adopted a Long-Term Retention and Management Incentive Plan (the Incentive Plan) to provide equity and cash incentives for our principal executive officer, principal financial officer and certain other named executive officers. The Incentive Plan rewards long-term corporate performance, with a goal of helping to align the total compensation of the participants with the interests of our stockholders. The Incentive Plan provides that, upon the occurrence of certain events, defined as a \$750 million (the Initial Capitalization Target) and/or a \$1 billion market capitalization target (the Subsequent Capitalization Target), each participant will be entitled to receive stock awards under our 2009 Incentive Award Plan, as amended, and cash awards upon a change in control. The Incentive Plan will terminate on April 22, 2016, the fifth anniversary of its effective date. The number of shares available for issuance under the Incentive Plan will not exceed 1,039,500 shares.

The fair value of each stock award under the Incentive Plan was estimated on the date of the grant using the Monte Carlo valuation model and assumes that the Initial Capitalization Target will be achieved at 13 months and the Subsequent Capitalization Target will be achieved at 20 months (collectively referred to as the Service Life), from the effective date. The key inputs used to estimate the awards' fair value include the following:

Term of Incentive Plan	5 Years
Estimated trading days from grant to end of market condition period	1,260
Average stock price on date of grant	\$ 9.29
Number of common shares outstanding proximate to grant date	52,041,781
Maximum number of options expected to exercise during term	8,397,094
Expected annual stock volatility	65.0%
Expected return on common equity	15%

The fair value of these equity awards was determined to be approximately \$8.1 million and will be amortized over the respective Service Life. Included in selling, general and administrative expense was \$3.1 million of compensation expense for the three months ended June 30, 2011.

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 variation 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;

Table of Contents

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;

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, 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, 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 is to obtain utilization of Fusilev as part of the treatment regimens for advanced metastatic colorectal cancer. The FDA formally approved our supplemental new drug application for Fusilev's use in the treatment of advanced metastatic colorectal cancer 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 with third parties 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 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.

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. Under the agreement, we paid a nominal upfront payment and are required to make additional payments

based on certain development and regulatory milestones should we elect to continue development efforts. We believe our in-licensing of belinostat, a novel histone deacetylase, or HDAC, inhibitor, is also 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 June 30, 2011, are approximately \$290.5 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.

We believe that the approximately \$118.5 million in cash, cash equivalents and investments, which includes long term marketable securities, we had available on June 30, 2011 will allow us to fund our current planned operations for at least the next twelve to eighteen months. However, we may 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 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.

Table of Contents

Zevalin sales growth is largely dependent on the adoption of Zevalin for use as part of first-line therapy for follicular non-Hodgkin's lymphoma, or NHL and continued use in its initial indication. As discussed earlier, during 2010 and through June 30, 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 enables us to actively market Fusilev for use in the treatment of advanced metastatic colorectal cancer.

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 six-month period ended June 30, 2011, our total research and development expenditure, including indirect expenditures, was approximately \$13.5 million (net of \$3.4 million received from Allergan).

Our primary focus areas for the foreseeable future, and the programs that we expect to represent a significant part of our research and development are the on-going registrational clinical trials of apaziquone and belinostat and additional clinical studies in supporting the expanded utilization of our FDA approved products (ZEVALIN and FUSILEV). While we are currently focused on advancing these key product development programs, we continually evaluate our research and development programs with respect to other pipeline products in response to the scientific and clinical successes 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 research and development 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 provided by Operating Activities

Net cash provided by operating activities was \$12.3 million for the six months ended June 30, 2011. The principal components of such cash provided by operations was net income in the period of \$19.9 million plus net non-cash credits of \$14.0 million, offset primarily by a \$25.7 million increase in accounts receivable as a result of increased product sales.

Table of Contents

Net Cash used in Investing Activities

Net cash used in investing activities, \$1.2 million during the six months ended June 30, 2011, was primarily due to the net \$815,000 purchases of marketable securities partially offset by a \$341,000 increase in property and equipment acquisitions.

Net Cash provided by Financing Activities

Net cash provided by financing activities, \$2.4 million for the six months ended June 30, 2011, primarily relates to proceeds from the issuance of common stock as a result of the exercise of stock options and purchases of shares under our Employee Stock Purchase Plan.

Results of Operations

Three months ended June 30, 2011 and 2010

Revenues. Revenues increased \$33.0 million, or 268%, to \$45.4 million in the three months ended June 30, 2011 from \$12.3 million in the three months ended June 30, 2010. We recognized \$42.3 million from product sales, of which \$33.9 million related to sales of FUSILEV and \$8.4 million related to sales of ZEVALIN (each net of estimates for promotional, price and other adjustments, including adjustment of the allowance for product returns). Product revenues recorded in the three months ended June 30, 2010 were \$9.3 million, of which \$2.4 million related to sales of FUSILEV and \$6.9 million related to sales of ZEVALIN. Revenues from the sales of FUSILEV have increased due to a supply disruption of generic leucovorin and FDA approval of FUSILEV for use in the treatment of advanced metastatic colorectal cancer received on April 29, 2011. Sales of FUSILEV grew significantly in the third and fourth quarter of 2010 and have continued through June 2011. We are unable to determine how long the current disruption in supplies of generic leucovorin will last. During the three months ended June 30, 2011 and 2010, we also recognized \$3.1 million of licensing revenues from the amortization of a \$41.5 million upfront payment we received from Allergan in 2008, and a \$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 \$4.5 million to \$8.1 million in the three months ended June 30, 2011 from \$3.6 million in the three months ended June 30, 2010. The increase in total cost of product sales relates to an increase in product revenues and start up costs incurred for new suppliers.

Selling, General and Administrative. Selling, general and administrative expenses increased \$4.9 million, or 36%, to \$18.7 million, in the three months ended June 30, 2011 from \$13.8 million in the three months ended June 30, 2010. The increase is due primarily to an increase of \$4.8 million in stock compensation expense, of which \$3.1 million relates to the long-term retention and management incentive plan adopted during the June 2011 quarter. We expect that expenses associated with sales and marketing activities will increase as we invest in additional commercial resources to increase market expansion of FUSILEV for its recently approved indication in colorectal cancer.

Research and Development. Research and development expenses increased \$1.4 million, or 22%, to \$7.7 million, in the three months ended June 30, 2011 from \$6.3 million in the three months ended June 30, 2010. The increase is primarily due to on-going clinical trials. We expect research and development expenses to range between approximately \$30 and \$40 million for the year ending December 31, 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 June 30, 2011 and 2010 due to the amortization of intangibles from the acquisition of ZEVALIN.

Table of Contents

Change in Fair Value of Common Stock Warrant Liability. We recorded a loss of \$1.2 million for the change in the fair value of the warrant obligations during the three month period ended June 30, 2011 compared to income of \$2.8 million in the same period of 2010. The change in fair value of the common stock warrant liability was primarily the result of the change in our stock price over the same period of time. Approximately 3.7 million of the outstanding warrants are scheduled to expire by September 14, 2011, of which 206,476 warrants were exercised in July 2011

Other Net Income. The principal components of other income of \$174,000 and (\$236,000) during the three month periods ended June 30, 2011 and 2010, respectively, 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.

Provision for Income Taxes. We recorded a provision for income taxes of \$1.7 million during the three months ended June 30, 2011 due to our profitability. No similar expense was recorded in 2010 as we were in a loss position.

Six months ended June 30, 2011 and 2010

Revenues. Revenues increased \$65.5 million, or 280%, to \$89.0 million in the six months ended June 30, 2011 from \$23.4 million in the six months ended June 30, 2010. We recognized \$82.8 million from product sales, of which \$68.6 million related to sales of FUSILEV and \$14.3 million related to sales of ZEVALIN (each net of estimates for promotional, price and other adjustments, including adjustment of the allowance for product returns). Product revenues recorded in the six months ended June 30, 2010 were \$16.4 million, of which \$3.0 million related to sales of FUSILEV and \$13.4 million related to sales of ZEVALIN. Revenues from the sales of FUSILEV have increased due to a supply disruption of generic leucovorin. Sales of FUSILEV grew significantly in the third and fourth quarter of 2010 which have continued through June 2011. We are unable to determine how long the current disruption in supplies of generic leucovorin will last. During the six months ended June 30, 2011 and 2010, we also recognized \$6.2 million and \$7.0 million, respectively, of licensing revenues from the amortization of a \$41.5 million upfront payment we received from Allergan in 2008, and a \$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 \$7.9 million to \$14.7 million in the six months ended June 30, 2011 from \$6.8 million in the six months ended June 30, 2010. The increase in total cost of product sales relates to an increase in product revenues and start up costs incurred for new suppliers.

Selling, General and Administrative. Selling, general and administrative expenses increased \$6.8 million, or 28%, to \$31.5 million, in the six months ended June 30, 2011 from \$24.7 million in the six months ended June 30, 2010. The increase is due primarily to an increase of \$7.6 million in stock compensation expense, of which \$3.1 million relates to the long-term retention and management incentive plan partially offset by a decrease in trade show and meeting expenses of approximately \$800,000.

Research and Development. Research and development expenses decreased \$29.3 million, or 68%, to \$13.5 million, in the six months ended June 30, 2011 from \$42.8 million in the six months ended June 30, 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.

Amortization of Purchased Intangibles. We incurred a non-cash charge of \$1.9 million for the six months ended June 30, 2011 and 2010 due to the amortization of intangibles from the acquisition of ZEVALIN.

Table of Contents

Change in Fair Value of Common Stock Warrant Liability. We recorded a loss of \$6.5 million for the change in the fair value of the warrant obligations during the six month period ended June 30, 2011 compared to income of \$4.4 million in the same period of 2010. The change in fair value of the common stock warrant liability was primarily the result of the change in our stock price over the same period of time.

Other Net Income. The principal components of other net income of \$694,000 and (\$333,000) during the six months ended June 30, 2011 and 2010, respectively, 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.

Provision for Income Taxes. We recorded a provision for income taxes of \$1.7 million during the six months ended June 30, 2011 due our profitability. No similar expense was recorded in 2010 as we were in a loss position.

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 months ended June 30, 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.

	Chargebacks and Discounts	Rebates	Returns	Data and Distribution Fees	Doubtful accounts	Total
	(\$ in 000 s)					
Period ended June 30, 2011:						
Balances at beginning of the period	\$ 675	\$ 14,474	\$ 2,000	\$ 1,874	\$ 339	\$ 19,362
Add provisions:	3,026	9,360	1,048	3,226	291	16,951
Less: Credits or actual allowances:	(2,378)	(10,920)	(48)	(1,802)		(15,148)
Balances at the close of the period	\$ 1,323	\$ 12,914	\$ 3,000	\$ 3,298	\$ 630	\$ 21,165
Period ended June 30, 2010:						
Balances at beginning of period	\$ 860	\$	\$ 1,176	\$ 213	\$ 150	\$ 2,399
Add provisions:	499	1,849	735	386	415	3,884
Less: Credits or actual allowances:	(180)		(247)	(213)	(54)	(694)
Balances at the close of the period	\$ 1,179	\$ 1,849	\$ 1,664	\$ 386	\$ 511	\$ 5,589

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.

Table of Contents

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;
- (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, discount structures and payment terms 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 has 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.

Table of Contents

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.

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 six months ended June 30, 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 June 30, 2011 and 2010, were primarily in money market accounts, short-term corporate bonds, certificates of deposit, 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. Because of our ability to generally redeem these investments at par on short notice and without penalty, we believe that 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, 2011 or 2010, any decline in the fair value of our investments would not be material in the context of our consolidated 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.

Table of Contents

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.

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 June 30, 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 June 30, 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 other than the following:

Table of Contents

Risks Related to Our Business

Our drug product Fusilev may not be more cost-effective than competing drugs and otherwise may not have any competitive advantage, which could hinder our sales.

Fusilev is a novel folate analog formulation and the pharmacologically active isomer (the levo-isomer) of the racemic compound calcium leucovorin, a product approved for the same indications our product is approved for. Leucovorin has been sold as a generic product on the market for a number of years. There are generic companies that currently sell the product and therefore Fusilev competes against a low-cost alternative.

Fusilev is part of a treatment regimen that may change or may become the subject of shortages.

Fusilev is offered as part of a treatment regimen, and that regimen may suffer supply shortages or otherwise change to exclude Fusilev, which would negatively impact Fusilev revenue.

Our revenue from Fusilev sales may not be sustainable and our customer concentration is significant

Most of the Fusilev revenue the Company recorded in the past resulted from the leucovorin drug shortage, the depth of which we cannot predict. Even with approval for colorectal cancer achieved in 2011, there is no surety that Fusilev will be adopted by the medical community nor is there assurance that sales will be sustainable. Our customer concentration of Fusilev is high. Sales to Customer A for the years ended December 31, 2010, 2009 and 2008 were 45.7%, 27.1%, and 35.7% respectively, of our total consolidated gross product sales. If our relationship with our top distributors is impaired our sales of Fusilev would be negatively impacted.

If we are unable to sustain and expand the approved usage of Fusilev, the product's operating results may be harmed, which could adversely affect our financial and operating results.

Fusilev was approved by the FDA on April 29, 2011 for use in combination with 5-FU-containing regimens in the treatment of advanced metastatic colorectal cancer. While we believe the greatest potential use of this product is in this indication, we may not recognize the full anticipated value of our investment in the product and our financial and operating results could be adversely affected.

We may face difficulties in achieving broader market acceptance of Fusilev if we do not invest significantly in our sales and marketing infrastructure.

Implementation of the sales and marketing strategy for Fusilev, and the efforts to expand approved usage of Fusilev, will require a continued significant investment of financial and other resources by us for the foreseeable future and may not ultimately increase Fusilev sales or allow us to realize the anticipated benefits from our investment in the product. Additionally, our efforts to establish an effective commercial team for Fusilev will require significant commitments of both financial and management resources by us, and may not ultimately be successful due a variety of factors.

Table of Contents

ITEM 6. EXHIBITS

Exhibit Number	Description
10.36*	Long-Term Retention and Management Incentive Plan.
10.37#	Amendment to License, Supply and Distribution Agreement, dated June 13, 2011, by among the Company Allergan Sales, LLC, Allergan USA, Inc. and Allergan, Inc.
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.
101.1+	XBRL Instance Document.
101.2+	XBRL Taxonomy Extension Schema Document.
101.3+	XBRL Taxonomy Extension Calculation Linkbase Document.
101.4+	XBRL Taxonomy Extension Definition Linkbase Document.
101.5+	XBRL Taxonomy Extension Label Linkbase Document.
101.6+	XBRL Taxonomy Extension Presentation Linkbase Document.

* Indicates a management contract or compensatory plan or arrangement.

Confidential portions omitted and filed separately with the U.S. Securities and Exchange Commission pursuant to Rule 24b-2 promulgated under the Securities Exchange Act of 1934, as amended.

+ The XBRL information is being furnished and not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any registration statement under the Securities Act of 1933, as amended.

Table of Contents

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 3, 2011

By: /s/ Brett L. Scott
Brett L. Scott
Senior Vice President, Acting Chief Financial
Officer
(Authorized Signatory and Principal Financial
and
Accounting Officer)

Table of Contents

INDEX TO EXHIBITS

Exhibit Number	Description
10.36*	Long-Term Retention and Management Incentive Plan.
10.37#	Amendment to License, Supply and Distribution Agreement, dated June 13, 2011, by among the Company Allergan Sales, LLC, Allergan USA, Inc. and Allergan, Inc.
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.
101.1+	XBRL Instance Document.
101.2+	XBRL Taxonomy Extension Schema Document.
101.3+	XBRL Taxonomy Extension Calculation Linkbase Document.
101.4+	XBRL Taxonomy Extension Definition Linkbase Document.
101.5+	XBRL Taxonomy Extension Label Linkbase Document.
101.6+	XBRL Taxonomy Extension Presentation Linkbase Document.

* Indicates a management contract or compensatory plan or arrangement.

Confidential portions omitted and filed separately with the U.S. Securities and Exchange Commission pursuant to Rule 24b-2 promulgated under the Securities Exchange Act of 1934, as amended.

+ The XBRL information is being furnished and not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any registration statement under the Securities Act of 1933, as amended.