

SPECTRUM PHARMACEUTICALS INC

Form 10-Q

August 08, 2012

[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 10-Q**

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

For the quarterly period ended June 30, 2012

.. **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)

Edgar Filing: SPECTRUM PHARMACEUTICALS INC - Form 10-Q

**Delaware**  
(State or other jurisdiction of

incorporation or organization)

**11500 South Eastern Avenue, Suite 240**

**Henderson, Nevada**  
(Address of principal executive offices)

**(702) 835-6300**

(Registrant's telephone number, including area code)

**93-0979187**  
(I.R.S. Employer

Identification No.)

**89052**  
(Zip 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  (Do not check if a smaller reporting company) 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 18, 2012, 60,243,835 shares of the registrant's common stock were outstanding.

**Table of Contents**

**SPECTRUM PHARMACEUTICALS, INC.**

**FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2012**

**INDEX**

	<b>Page</b>
<b>PART I</b>	
	<b><u>FINANCIAL INFORMATION</u></b>
<b>ITEM 1. <u>FINANCIAL STATEMENTS (unaudited)</u></b>	
<u>Condensed Consolidated Balance Sheets as of June 30, 2012 and December 31, 2011</u>	3
<u>Condensed Consolidated Statements of Income for the three and six months ended June 30, 2012 and 2011</u>	4
<u>Condensed Consolidated Statements of Comprehensive Income for the three and six months ended June 30, 2012 and 2011</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2012 and 2011</u>	6
<u>Notes to Condensed Consolidated Financial Statements</u>	7
<b>ITEM 2. <u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u></b>	20
<b>ITEM 3. <u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u></b>	27
<b>ITEM 4. <u>CONTROLS AND PROCEDURES</u></b>	28
<b>PART II</b>	
	<b><u>OTHER INFORMATION</u></b>
<b>ITEM 1A. <u>RISK FACTORS</u></b>	29
<b>ITEM 6. <u>EXHIBITS</u></b>	30
<u>SIGNATURES</u>	31

Item 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 INFORMATION****ITEM 1. Financial Statements****SPECTRUM PHARMACEUTICALS, INC.****Condensed Consolidated Balance Sheets**

(In thousands, except share and per share data)

(Unaudited)

	June 30, 2012	December 31, 2011
<b>ASSETS</b>		
Current Assets:		
Cash and equivalents	\$ 190,154	\$ 121,202
Marketable securities	3,550	40,060
Accounts receivable, net of allowance for doubtful accounts of \$412 and \$471, respectively	84,839	51,703
Inventories, net	7,686	10,762
Prepaid expenses and other current assets	1,800	2,074
Deferred tax assets	10,532	
<b>Total current assets</b>	<b>298,561</b>	<b>225,801</b>
Investments		9,283
Property and equipment, net	2,488	2,681
Intangible assets, net	60,327	41,654
Goodwill	2,389	
Deferred tax assets	20,961	
Other assets	2,846	1,361
<b>TOTAL ASSETS</b>	<b>\$ 387,572</b>	<b>\$ 280,780</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current Liabilities:		
Accounts payable and other accrued obligations	\$ 89,610	\$ 54,771
Accrued compensation and related expenses	3,505	1,788
Deferred revenue	12,300	12,300
Accrued drug development costs	10,610	9,678
<b>Total current liabilities</b>	<b>116,025</b>	<b>78,537</b>
Capital lease obligations		9
Deferred revenue and other credits less current portion	8,329	14,029
Tax liability	169	
Other long-term obligations	298	298
<b>Total liabilities</b>	<b>124,821</b>	<b>92,873</b>
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized:		
Series B junior participating preferred stock, \$0.001 par value; 1,500,000 shares authorized and no shares issued and outstanding	123	123

Edgar Filing: SPECTRUM PHARMACEUTICALS INC - Form 10-Q

Series E convertible voting preferred stock \$0.001 par value and \$10,000 stated value; 2,000 shares authorized; 20 shares issued and outstanding at June 30, 2012 and December 31, 2011 (aggregate liquidation value of \$240)		
Common stock, \$0.001 par value 175,000,000 shares authorized; 59,824,472 and 59,247,483 issued and outstanding at June 30, 2012 and December 31, 2011, respectively	60	59
Additional paid-in capital	463,607	452,761
Accumulated other comprehensive loss	(525)	(227)
Accumulated deficit	(197,271)	(261,883)
Less: Treasury stock at cost; 388,055 and 363,055 shares outstanding at June 30, 2012 and December 31, 2011, respectively	(3,243)	(2,926)
Total stockholders equity	262,751	187,907
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	\$ 387,572	\$ 280,780

See accompanying notes to unaudited condensed consolidated financial statements.

**Table of Contents****SPECTRUM PHARMACEUTICALS, INC.****Condensed Consolidated Statements of Income**

(In thousands, except share and per share data)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
<b>Revenues:</b>				
Product sales, net	\$ 65,627	\$ 42,287	\$ 122,411	\$ 82,810
License and contract revenue	3,075	3,075	6,150	6,150
Total revenues	\$ 68,702	\$ 45,362	\$ 128,561	\$ 88,960
<b>Operating costs and expenses:</b>				
Cost of product sales (excludes amortization of purchased intangible assets)	11,574	8,130	20,247	14,710
Selling, general and administrative	23,347	18,699	41,609	31,450
Research and development	9,583	7,686	18,474	13,516
Amortization of purchased intangibles	1,636	930	2,566	1,860
Total operating costs and expenses	46,140	35,445	82,896	61,536
Income from operations	22,562	9,917	45,665	27,424
Change in fair value of common stock warrant liability		(1,237)		(6,487)
Other income (expense), net	(1,507)	174	(1,369)	694
Income before income taxes	21,055	8,854	44,296	21,631
(Provision) benefit for income taxes	(2,985)	(1,650)	20,316	(1,650)
Net income	\$ 18,070	\$ 7,204	\$ 64,612	\$ 19,981
<b>Net income per share:</b>				
Basic	\$ 0.31	\$ 0.14	\$ 1.10	\$ 0.39
Diluted	\$ 0.29	\$ 0.12	\$ 1.01	\$ 0.35
<b>Weighted average shares outstanding:</b>				
Basic	58,763,700	52,257,049	58,617,530	51,814,122
Diluted	63,387,003	58,265,264	63,666,546	56,845,371

See accompanying notes to unaudited condensed consolidated financial statements.

**Table of Contents****SPECTRUM PHARMACEUTICALS, INC.****Condensed Consolidated Statements of Comprehensive Income**

(In thousands)

(Unaudited)

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2012</b>	<b>2011</b>	<b>2012</b>	<b>2011</b>
Net income	\$ 18,070	\$ 7,204	\$ 64,612	\$ 19,981
Other comprehensive income, net of tax:				
Unrealized loss on securities	(369)	(35)	(301)	(84)
Foreign currency translation adjustment	3		3	
<b>Total comprehensive income</b>	<b>\$ 17,704</b>	<b>\$ 7,169</b>	<b>\$ 64,314</b>	<b>\$ 19,897</b>

See accompanying notes to condensed consolidated financial statements.

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

(In thousands)

(Unaudited)

	<b>Six Months Ended June 30,</b>	
	<b>2012</b>	<b>2011</b>
<b>Cash Flows From Operating Activities:</b>		
Net income	\$ 64,612	\$ 19,981
Adjustments to reconcile net income to net cash provided by operating activities:		
Amortization of deferred revenue	(6,150)	(6,150)
Depreciation and amortization	4,043	2480
Stock-based compensation	6,097	10,880
Deferred income tax benefit	(31,493)	
Change in fair value of common stock warrant liability		6,487
Provision for (recovery of) bad debt	(31)	291
Provision for inventory obsolescence	437	
Foreign currency remeasurement loss	1,354	
Excess tax benefits from share-based compensation	(2,181)	
Changes in operating assets and liabilities:		
Accounts receivable, net	(33,105)	(25,711)
Inventories, net	2,639	(5,165)
Prepaid expenses and other assets	(950)	12
Accounts payable and other accrued obligations	36,409	7,677
Accrued compensation and related expenses	1,717	(497)
Accrued drug development costs	932	2,062
Deferred revenue and other credits	619	(55)
<b>Net cash provided by operating activities</b>	<b>44,949</b>	<b>12,292</b>
<b>Cash Flows From Investing Activities:</b>		
Sales and maturities of marketable securities	57,797	15,157
Purchases of marketable securities	(11,944)	(15,972)
Purchases of property and equipment	(302)	(341)
Purchases of available for sale securities	(622)	
Acquisition of ZEVALIN Rights	(25,435)	
<b>Net cash provided by (used in) investing activities</b>	<b>19,494</b>	<b>(1,156)</b>
<b>Cash Flows From Financing Activities:</b>		
Proceeds from issuance of common stock from stock option exercises	2,523	1,973
Proceeds from contributions to ESPP	372	398
Payments to acquire treasury stock	(317)	
Repurchase of shares to satisfy minimum tax withholding for restricted stock vesting	(326)	
Repayment of capital leases	(9)	(15)
Excess tax benefits from share-based compensation	2,181	
<b>Net cash provided by financing activities</b>	<b>4,424</b>	<b>2,356</b>
Effect of exchange rates on cash	85	



Edgar Filing: SPECTRUM PHARMACEUTICALS INC - Form 10-Q

Net increase in cash and cash equivalents	68,952	13,492
Cash and cash equivalents beginning of period	121,202	53,557
Cash and cash equivalents end of period	\$ 190,154	\$ 67,049
Supplemental Disclosure of Cash Flow Information:		
Conversion of preferred stock to common stock	\$	\$ 37
Common stock issued for Targent milestone	\$	\$ 6,230
Targent milestones included in intangible assets and accrued liabilities	\$	\$ 10,159
Inventory liability assumed in acquisition	\$ 580	\$

See accompanying notes to condensed consolidated financial statements.

---

**Table of Contents**

**SPECTRUM PHARMACEUTICALS, INC.**

**Notes to Condensed Consolidated Financial Statements**

**(Unaudited)**

**1. Business and Basis of Presentation**

**Business**

Spectrum Pharmaceuticals, Inc. (Spectrum, the Company, we, our, or us) is a biotechnology company with fully integrated commercial and development operations, with a primary focus in oncology and hematology. Our strategy is comprised of acquiring, developing and commercializing a broad and diverse pipeline of late-stage clinical and commercial products. We currently market two oncology drugs - FUSILEV® (levoleucovorin) for Injection in the U.S. and ZEVALIN® (ibrutinomab tiuxetan) Injection for intravenous use, for which we have worldwide rights. We also have a diversified pipeline of product candidates in advanced-stage Phase 2 and Phase 3 studies. 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.

**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 condensed consolidated financial statements include our accounts and our wholly-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated. 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, 2012 and the results of operations and cash flows for the related interim periods ended June 30, 2012 and 2011. The results of operations for the three and six months ended June 30, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012 or for any other periods. The unaudited financial statements should be read in conjunction with our audited financial statements for the year ended December 31, 2011, included in the Annual Report on Form 10-K filed with the SEC.

**Significant Accounting Policies**

The accounting policies followed by us and other information are contained in the notes to the Company's audited consolidated financial statements for the year ended December 31, 2011 included in our Annual Report on Form 10-K filed on March 2, 2012 with the SEC. We have not changed our significant accounting policies as of June 30, 2012. 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 2, 2012.

**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 the consolidated entities from the condensed consolidated financial statements.

**Segment and Geographic Information**

We operate in one reportable segment: acquiring, developing and commercializing prescription drug products. We evaluate all revenues by product in the aggregate given the similarity of product, production processes, customers, distribution methods and regulatory environment. Accordingly, we report the accompanying condensed consolidated financial statements in the aggregate, including all of our activities in one reportable segment.

**Use of Estimates**

## Edgar Filing: SPECTRUM PHARMACEUTICALS INC - Form 10-Q

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 Financial Accounting Standards Board (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 became effective for fiscal years beginning after December 15, 2011. In December 2011, the FASB issued an accounting standards update that defers the presentation requirement for other comprehensive income reclassifications on the face of the financial statements. We adopted the provisions of the guidance in the first quarter of 2012 and elected to present items of net income and other comprehensive income in two separate but consecutive 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 became effective prospectively for interim and annual periods beginning after December 15, 2011. We adopted the provisions of the guidance in the first quarter of 2012. The adoption did not have a material impact on our consolidated financial statements.

**Acquisitions and Collaborations**

For all in-licensed products, we perform an analysis to determine whether we hold a variable interest or interests that give us a controlling financial interest in a variable interest entity. On the basis of our interpretations and conclusions, we determine whether the acquisition falls under the purview of variable interest entity accounting and if so, consider the necessity to consolidate the acquisition. As of June 30, 2012, we determined there were no variable interest entities required to be consolidated other than our Canadian affiliate, Spectrum Pharma Canada.

We also perform an analysis to determine if the inputs and/or processes acquired in an acquisition qualify as a business. On the basis of our interpretations and conclusions, we determine if the in-licensed products qualify as a business and whether to account for such products as a business combination or an asset acquisition. The excess of the purchase price over the fair value of the net assets acquired can only be recognized as goodwill in a business combination.

**Basic and Diluted Earnings per Share**

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

(in thousands, except share and per share data)	Net Income	Weighted-Average Shares Outstanding (Denominator)	Earnings Per Share
<b>Three Months Ended June 30, 2012</b>			
Basic earnings per share:	\$ 18,070	58,763,700	\$ 0.31
Diluted earnings per share:			
Dilutive preferred shares		40,000	
Dilutive options		4,069,118	
Incremental shares assumed issued on exercise of in the money warrants		251,578	
Unvested restricted stock		262,607	
Diluted earnings per share	\$ 18,070	63,387,003	\$ 0.29
Potentially dilutive securities not included above since they were antidilutive:			

Antidilutive options

301,708

**Table of Contents**

(in thousands, except share and per share data)	Net Income	Weighted-Average Shares Outstanding (Denominator)	Earnings Per Share
<b>Three Months Ended June 30, 2011</b>			
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	
Target 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)	Net Income	Weighted-Average Shares Outstanding (Denominator)	Earnings Per Share
<b>Six Months Ended June 30, 2012</b>			
Basic earnings per share:	\$ 64,612	58,617,530	\$ 1.10
Diluted earnings per share:			
Dilutive preferred shares		40,000	
Dilutive options		4,483,596	
Incremental shares assumed issued on exercise of in the money warrants		269,403	
Unvested restrictive stock		256,017	
Diluted earnings per share	\$ 64,612	63,666,546	\$ 1.01
Potentially dilutive securities not included above since they were antidilutive:			
Antidilutive options		155,750	
(in thousands, except share and per share data)	Net Income	Weighted-Average Shares Outstanding (Denominator)	Earnings Per Share
<b>Six Months Ended June 30, 2011</b>			
Basic earnings per share:	\$ 19,981	51,814,122	\$ 0.39
Diluted earnings per share:			
Dilutive preferred shares		40,000	

Edgar Filing: SPECTRUM PHARMACEUTICALS INC - Form 10-Q

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:

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

**Table of Contents****2. Licensing Rights of ZEVALIN Outside the U.S.**

On April 1, 2012, through a subsidiary, Spectrum Pharmaceuticals Cayman, L.P., we completed the acquisition of licensing rights to market ZEVALIN (ZEVALIN Rights) outside of the U.S. from Bayer Pharma AG or Bayer. Pursuant to the terms of the Agreement, Spectrum acquired all rights including marketing, selling, intellectual property and access to existing inventory of ZEVALIN from Bayer. We currently market ZEVALIN in the U.S. and this agreement expands our commercial efforts to the rest of the world. ZEVALIN is currently approved in more than 40 countries outside the U.S. for the treatment of B-cell non-Hodgkin lymphoma, including countries in Europe, Latin America and Asia. Under the terms of the agreement, Spectrum obtained marketing rights, patents, and access to existing inventory of ZEVALIN from Bayer. In consideration for the rights granted under the Agreement, concurrent with the closing, Spectrum paid Bayer a one-time fee of Euro 19 million or US \$25.4 million and will pay Bayer royalties based on a percentage of net sales of the licensed products in all territories worldwide except the U.S. Under the agreement, we also acquired access to existing inventory of ZEVALIN and concurrent with the closing, entered into certain ancillary agreements including but not limited to a transition services agreement to transition the business.

The acquisition of ZEVALIN Rights has been accounted for as a business combination using the acquisition method of accounting which requires, among other things, that assets acquired and liabilities assumed be recognized at their fair values as of the purchase date and be recorded on the balance sheet regardless of the likelihood of success of the related product or technology. The process for estimating the fair values of identifiable intangible assets involves the use of significant estimates and assumptions, including estimating future cash flows and developing appropriate discount rates. Transaction costs are not included as a component of consideration transferred and were expensed as incurred. The ZEVALIN Rights related transaction costs expensed for the three and six months ended June 30, 2012 were \$687,384.

**Consideration Transferred**

The acquisition-date fair value of the consideration transferred consisted of the following items (\$ in thousands):

Cash consideration for ZEVALIN Rights	\$ 25,435
Total liabilities assumed	580
<b>Total purchase consideration</b>	<b>\$ 26,015</b>

**Fair Value Estimate of Assets Acquired and Liabilities Assumed**

The total purchase consideration is allocated to ZEVALIN Rights net tangible and intangible assets based on their estimated fair values as of the closing date. The allocation of the total purchase price to the net assets acquired and included in our condensed consolidated balances sheet is as follows (\$ in thousands):

ZEVALIN product line/marketing rights	\$ 19,810
Customer relationships	3,680
<b>Identified intangible assets</b>	<b>23,490</b>
Goodwill	2,525
<b>Total fair value of assets</b>	<b>\$ 26,015</b>

The fair value of the acquired marketing rights and customer relationships intangible assets was estimated using the income approach. The income approach uses valuation techniques to convert future amounts to a single present amount (discounted). The Company's measurement is based on the value indicated by current market expectations about those future amounts. The fair value considered the Company's estimates of future incremental earnings that may be achieved by the promotion and distribution contract intangible assets, and included estimated cash flows of approximately 22 years and a discount rate of 14% to 26%.

Goodwill is calculated as the excess of the consideration transferred over the net assets recognized and represents the future economic benefits arising from other assets acquired that could not be individually identified and separately recognized. Specifically, the goodwill recorded as part



## Edgar Filing: SPECTRUM PHARMACEUTICALS INC - Form 10-Q

of the acquisition of ZEVALIN Rights includes benefits that the Company believes will result from expanding geographical sales internationally and any intangible assets that do not qualify for separate recognition. Goodwill is not amortized and is not deductible for tax purposes.

These identified intangible assets are being amortized over the estimated useful life of 10 years. Included in amortization of purchased intangibles expense in the accompanying statement of income for the three and six months ended June 30, 2012 is \$706,000 related to the amortization of these intangibles.

**Table of Contents****3. Cash, Equivalents and Marketable Securities**

As of June 30, 2012, we held substantially all of our 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. We maintain cash balances in excess of federally insured limits in reputable financial institutions. To a limited degree, the Federal Deposit Insurance Corporation and third parties 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 limit investing in long-term maturity instruments.

Cash, equivalents and investments in marketable securities, including long term bank certificates of deposits, totaled \$194.0 million and \$170.6 million as of June 30, 2012 and December 31, 2011, respectively. Long term bank certificates of deposit include a \$500,000 restricted certificate of deposit that collateralizes tenant improvement obligations to the lessor of our principal offices. The following is a summary of such investments (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated fair Value	Cash	Marketable Security Current	Long Term
<b>June 30, 2012</b>							
Cash and equivalents	\$ 190,154	\$	\$	\$ 190,154	\$ 190,154	\$	\$
Bank CDs (including restricted certificate of deposit of \$500)	2,951			2,951		2,951	
Money market currency funds	599			599		599	
U.S. Government securities							
Other securities (included in other assets)	657		362	295			295
<b>Total investments</b>	<b>\$ 194,361</b>	<b>\$</b>	<b>\$ 362</b>	<b>\$ 193,999</b>	<b>\$ 190,154</b>	<b>\$ 3,550</b>	<b>\$ 295</b>
<b>December 31, 2011</b>							
Cash and equivalents	\$ 121,202	\$	\$	\$ 121,202	\$ 121,202	\$	\$
Bank CDs (including restricted certificate of deposit of \$500)	27,845			27,845		18,562	9,283
Money market currency funds	14,485			14,485		14,485	
U.S. Government securities	7,013			7,013		7,013	
Other securities (included in other assets)	35		29	6			6
<b>Total investments</b>	<b>\$ 170,580</b>	<b>\$</b>	<b>\$ 29</b>	<b>\$ 170,551</b>	<b>\$ 121,202</b>	<b>\$ 40,060</b>	<b>\$ 9,289</b>

As of June 30, 2012, none of the securities had been in a continuous unrealized loss position longer than one year.

**Table of Contents****4. 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, 2012 and December 31, 2011 are classified in the table below in one of the three categories of the fair value hierarchy described below:

	Fair Value Measurements (\$ in 000 s)			Total
	Level 1	Level 2	Level 3	
<b>June 30, 2012</b>				
Assets:				
Cash and equivalents	\$ 190,154	\$	\$	\$ 190,154
Bank CDs (including restricted certificate of deposit of \$500)		2,951		2,951
Money market currency funds		599		599
Cash and equivalents, and marketable securities and investments	190,154	3,550		193,704
Deferred compensation investments, including life insurance cash surrender value		2,059		2,059
Other securities	295			295
	\$ 190,449	\$ 5,609	\$	\$ 196,058
Liabilities:				
Deferred executive compensation liability		1,496		1,496
	\$	\$ 1,496	\$	\$ 1,496

	Fair Value Measurements (\$ in 000 s)			Total
	Level 1	Level 2	Level 3	
<b>December 31, 2011</b>				
Assets:				
Cash and equivalents	\$ 121,202	\$	\$	\$ 121,202
Bank CDs (including restricted certificate of deposit of \$500)		27,845		27,845
Money market currency funds		14,485		14,485
U.S. Government securities		7,013		7,013
Cash and equivalents, marketable securities and investments	121,202	49,343		170,545
Deferred compensation investments		972		972
Other securities	6			6
	\$ 121,208	\$ 50,315	\$	\$ 171,523
Liabilities:				
Deferred executive compensation liability		969		969
	\$	\$ 969	\$	\$ 969

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:

## Edgar Filing: SPECTRUM PHARMACEUTICALS INC - Form 10-Q

*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.

**Table of Contents**

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

A majority of our financial assets have been classified as Level 2. These assets have been initially valued at the transaction price and subsequently valued utilizing third party pricing services. The pricing services use many observable market inputs to determine value, including reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates and other industry and economic events. We validate the prices provided by our third party pricing services by understanding the models used, obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming those securities trade in active markets.

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.

**5. Intangible Assets and Goodwill**

Intangible assets consist of the following:

	June 30, 2012	December 31, 2011
	(\$ in 000 s)	
ZEVALIN intangibles US	\$ 41,900	\$ 41,900
ZEVALIN intangibles ZEVALIN Rights	22,220	
Fusilev intangibles	16,778	16,778
	80,898	58,678
Less: accumulated amortization	(20,571)	(17,024)
	\$ 60,327	\$ 41,654

During the three months ended June 30, 2012 and 2011, ZEVALIN intangible amortization of \$1.6 million and \$930,000, respectively, is included in amortization of purchased intangibles. In addition, during the three months ended June 30, 2012 and 2011, \$493,000 and \$171,000 is included in cost of goods sold related to Fusilev Targent milestones achieved in 2011.

During the six months ended June 30, 2012 and 2011, ZEVALIN intangible amortization of \$2.6 million and \$1.8 million, respectively, is included in amortization of purchased intangibles. In addition, during the six months ended June 30, 2012 and 2011, \$986,000 and \$171,000, respectively, is included in cost of goods sold related to Fusilev Targent milestones achieved in 2011. There were no comparable amounts for the six months ended June 30, 2011.

Future amortization of intangible assets is as follows:

Years Ending December 31	
2012	\$ 4,329
2013	8,658
2014	8,658
2015	8,658
2016	8,658
Thereafter	21,366



**Table of Contents****Goodwill**

Changes in the carrying amount of goodwill through June 30, 2012 were as follows:

	<b>June 30, 2012</b>
	(\$ in 000 s)
Balance at December 31, 2011	\$
Acquisition of ZEVALIN Rights	2,525
Foreign exchange translation effects	(136)
	\$ 2,389

**6. Inventories**

Inventories, net of allowances consisted of the following:

	<b>June 30, 2012</b>	<b>December 31, 2011</b>
	(\$ in 000 s)	
Raw materials	\$ 1,730	\$ 1,213
Work-in-process	3,563	4,726
Finished goods	2,393	4,823
	\$ 7,686	\$ 10,762

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.

**7. Accounts payable and accrued obligations**

Accounts payable and other accrued obligations consisted of the following:

	<b>June 30, 2012</b>	<b>December 31, 2011</b>
	(\$ in 000 s)	
Trade payables	\$ 20,942	\$ 9,805
Allowance for rebates	17,982	8,114
Accrued product royalty	8,223	11,003
Allowance for returns	3,500	4,000
Accrued data and distribution fees	8,900	5,866
Accrued GPO administrative fees	2,013	2,562
Inventory management fee	2,750	1,380
Accrued income taxes	3,974	1,409
Allowance for chargebacks	8,600	950
Other accrued obligations	12,726	9,682
	\$ 89,610	\$ 54,771

## 8. Income Taxes

On an interim basis, we estimate that the anticipated annual effective tax rate for the provision for income taxes will be 20.45% and have recorded a quarterly income tax provision in accordance with this anticipated annual rate. The annual effective rate is below the statutory rate principally as a result of tax benefits expected to be realized from the release of our valuation allowance against domestic deferred tax assets based upon projected current year earnings. 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. When we establish or reduce the valuation allowance against the deferred tax asset the provision for income taxes will increase or decrease, respectively, in the period such determination is made.



## **Table of Contents**

Based on the weight of both positive and negative evidence, we concluded that it is more likely than not that our domestic net deferred tax assets will be realized, and therefore, during the quarter ended March 31, 2012 we began the process of releasing our domestic valuation allowance. Through June 30, 2012, we released approximately \$24 million of our domestic valuation allowance as of January 1, 2012 as a discrete tax benefit. The remaining \$22 million domestic valuation allowance as of January 1, 2012 will be released as a result of projected current year earnings and is a component in the calculation of our estimated 20.45% annual effective tax. We released approximately \$22 million as part of the projected annual effective tax rate and released the remaining \$24 million of the domestic valuation allowance as a discrete item through June 30, 2012. We maintain a valuation allowance against our foreign net deferred tax assets.

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.

## **9. Commitments and Contingencies**

### **Facility Lease**

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

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

### **Licensing Agreements**

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

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

In October 2008, we signed an exclusive development and commercialization collaboration agreement with Allergan for apaziquone. Under the terms of the agreement, Allergan paid us an up-front non-refundable \$41.5 million at closing and will make additional payments of up to \$304 million based on the achievement of certain development, regulatory and commercialization milestones. In June 2011, we amended the agreement with Allergan to, among other things, revise the target indications of additional clinical trials, and extend certain milestone dates, and to modify certain payment obligations and expense allocation provisions. 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 \$18.6 million. The potential milestones will be based on the achievement of certain regulatory and commercialization milestones.



---

## **Table of Contents**

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 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 connection with the achievement of the first sales milestone of \$40 million in May 2011 we issued 577,367 shares of common stock to certain of Targent's stockholders (which was equivalent value to approximately \$5 million in cash), as directed by Targent. In September 2011, we achieved the second and final sales milestone of \$100 million and paid \$5 million in cash for an aggregate with the first sales milestone of \$10.0 million. We capitalized the \$10.0 million associated with these milestones as intangible assets. These intangible assets are being amortized over the estimated useful life of 8.6 years. As of December 2011, we have met all of the contractual milestones related to FUSILEV.

In February 2010, we entered into a licensing and collaboration agreement with TopoTarget, for the development and commercialization of belinostat, pursuant to which TopoTarget and the Company agreed to a collaboration for the development and commercialization of belinostat. The agreement provides that we have the exclusive right to make, develop and commercialize belinostat in North America and India, with an option for China. The agreement also grants TopoTarget a co-promote option if and only if we do not maintain a minimum number (subject to adjustment for certain events outside of our control) of field personnel (as defined in the agreement) for a certain number of years post-approval of the PTCL indication.

In consideration for the rights granted to us under the license and collaboration agreement with TopoTarget, we paid TopoTarget an up-front fee of \$30.0 million in 2010 which is recorded as research and development expense in the accompanying condensed consolidated financial statements. In addition, we will pay up to \$313 million and one million shares of Spectrum common stock based on the achievement of certain development, regulatory and sales milestones, as well as certain royalties on net sales of belinostat. Under the terms of the agreement, all development, including studies, will be conducted under a joint development plan and in accordance with a mutually agreed upon target product profile provided that we have final decision-making authority for all developmental activities in North America and India (and China upon exercise of the option for China) and TopoTarget has final decision-making authority for all developmental activities in all other jurisdictions. We will assume all responsibility for and future costs of the ongoing registrational PTCL trial while TopoTarget will assume all responsibility for and future costs of the ongoing Phase 2 CUP trial. We and TopoTarget will conduct future planned clinical trials pursuant to the joint development plan, of which we will fund 70% of the development costs and TopoTarget will fund 30% of the development costs.

Under the terms of the agreement, we will each pay 50% of the costs for chemical, pharmaceutical and other process development related to the manufacturing of the product that are incurred with a mutually agreed upon budget in the joint development plan. TopoTarget is responsible for supplying us with both clinical and commercial product.

In late January 2012, we entered into a co-development and commercialization agreement with Hanmi Pharmaceutical Company, or Hanmi, for SPI-2012, formerly known as LAPS-GCSF, a drug for the treatment of chemotherapy induced neutropenia based on Hanmi's proprietary LAPSCOVERY Technology. In consideration for the rights granted to us under the co-development and commercialization agreement with Hanmi, we paid Hanmi a fee which is included in research and development expense in the accompanying condensed consolidated financial statements because the technology has not yet achieved regulatory approval. We expect to initiate Phase 2 trials in collaboration with Hanmi in 2012. Under the terms of the agreement, we will share the costs and expenses of the study although we will have primary responsibility for them. If SPI-2012 is ultimately commercialized by us, we will have worldwide rights except for Korea, China and Japan upon payment of fees and milestone payments related to further development, regulatory approvals and sales targets.

## **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 be reduced accordingly.



**Table of Contents****Employment Agreement**

We have entered into an employment agreement with Dr. Rajesh C. Shrotriya, our President and Chief Executive Officer, which expires January 2, 2013. The employment agreement automatically renews for subsequent one-year calendar terms unless either party gives written notice of such party's intent not to renew the agreement at least 90 days prior to the commencement of the new term. The employment agreement requires Dr. Shrotriya to devote his full working time and effort to our business and affairs during the term of the agreement. The employment agreement provides for a minimum annual base salary with annual increases, periodic bonuses and option grants as determined by the Compensation Committee of our Board of Directors.

**Litigation**

We are involved with various legal matters arising in the ordinary course of our business. We make provisions for liabilities when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. Such provisions are reviewed at least quarterly and adjusted to reflect the impact of any settlement negotiations, judicial and administrative rulings, advice of legal counsel, and other information and events pertaining to a particular case. Litigation is inherently unpredictable. 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 condensed consolidated results of operations, cash flows or financial condition.

**10. Stockholder's Equity****Treasury Stock**

On June 13, 2011, our Board of Directors authorized the repurchase of up to \$25 million of our outstanding common stock through the end of 2012. During the six months ended June 30, 2012, we repurchased 25,000 shares of our common stock for a purchase price of \$317,000 bringing the aggregate purchases to date to \$3.2 million or 388,055 shares. There were no repurchases of our common stock during the six months ended June 30, 2011.

Repurchased shares have been recorded as treasury shares and will be held until the Company's Board of Directors designates that these shares be retired or used for other purposes.

**Warrant Activity**

We have issued warrants to purchase shares of our common stock to investors as part of financing transactions, or in connection with services rendered by consultants. Our outstanding warrants expire on varying dates through June 2015. Below is a summary of warrant activity during the three months ended June 30, 2012:

	Common Stock Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2011	445,000	\$ 5.04
Issued		
Exercised		
Forfeited		
Expired		
Outstanding, at June 30, 2012	445,000	\$ 5.04
Exercisable, at June 30, 2012	420,000	\$ 5.11

**Table of Contents****Share-Based Compensation**

We record share-based employee compensation expense for all equity-based programs, including stock options, restricted stock grants, 401(k) plan matching and our employee stock purchase plan. The fair value of share-based awards is estimated at the grant date and the portion that is ultimately expected to vest is recognized as compensation expense over the requisite service period. Total expense recorded for the three month periods ended June 30, 2012 and 2011 is as shown below:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
	(\$ in 000 s)			
Research and development	\$ 397	\$ 495	\$ 788	\$ 899
Selling, general and administrative	2,685	6,321	5,309	9,981
Total share based compensation expense	\$ 3,082	\$ 6,816	\$ 6,097	\$ 10,880

**Stock Options**

During the six month period ended June 30, 2012, the Compensation Committee of our Board of Directors granted stock options at exercise prices equal to or greater than the closing price of our common stock on the trading day prior to the grant date. The weighted average grant date fair value of stock options granted during the six month period ended June 30, 2012 and 2011 were estimated at approximately \$7.57 and \$4.55, respectively using the Black-Scholes option pricing model with the following assumptions:

	Six-months ended June 30,	
	2012	2011
Divided yield	0.00%	0.00%
Expected volatility	72.1%	70.86%
Risk free interest rate	0.40%	1.76%
Expected life (years)	4.50	4.93

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, 2012, our share-based compensation in connection with the expensing of stock options was approximately \$1.3 million and \$2.6 million, respectively. 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.

As of June 30, 2012, there was approximately \$7.2 million of unrecognized stock-based compensation cost related to stock options which we expect to recognize over a weighted average period of approximately 2.09 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, 2012, the share-based compensation in connection with the expensing of restricted stock awards was approximately \$1.3 million and \$2.5 million, respectively. 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.

## Edgar Filing: SPECTRUM PHARMACEUTICALS INC - Form 10-Q

As of June 30, 2012, there was approximately \$5.4 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 2.33 years.

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

During the six month period ended June 30, 2012, we issued 26,154 shares of common stock as our match of approximately \$333,500 on the 401(k) contributions of our employees. During the six month period ended June 30, 2011, we issued 36,624 shares of common stock as our match of approximately \$287,000 on the 401(k) contributions of our employees.

**Table of Contents****Employee Stock Purchase Plan**

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

A total of 5,000,000 shares of common stock are authorized for issuance under the Purchase Plan, and as of June 30, 2012, 364,254 shares have been issued under the Purchase Plan.

**Common Stock Reserved for Future Issuances**

As of June 30, 2012, approximately 10.0 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	9,511,943
Exercise of warrants	445,000
Total shares of common stock reserved for future issuances	9,996,943

**11. 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 market capitalization target over a specified period of time of \$750 million (the Initial Capitalization Target ) and/or \$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 be exercised 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. At June 30, 2012 there is \$147,000 of unrecognized expense that will be amortized over the respective Service Life. Included in selling, general and administrative expense was \$484,200 of compensation expense for the six months ended June 30, 2012.



## 12. Deferred Compensation Plan

On September 2, 2011, the Board of Directors approved the Spectrum Pharmaceuticals, Inc. Deferred Compensation Plan (the Plan). The Plan is intended to comply with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended. The Plan will be administered by the Compensation Committee of the board of directors, or a designee or designees of the Compensation Committee. The Plan is intended to be an unfunded plan which is maintained primarily to provide deferred compensation benefits for a select group of our employees including management, as selected by the Plan administrator (the Participants). Under the Plan, we will provide the Participants with the opportunity to make annual elections to defer up to a specified amount or percentage of their eligible cash compensation, as established by the Plan administrator, and we have the option to make discretionary contributions. At June 30, 2012, deferrals and contributions totaling \$1.5 million are included in deferred revenue and other credits in the accompanying condensed consolidated balance sheet.

---

**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 the negative thereof 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, 2011, 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;

## Edgar Filing: SPECTRUM PHARMACEUTICALS INC - Form 10-Q

competition in the marketplace for our drugs;

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

actions by the FDA and other regulatory agencies, including international agencies;

securing positive reimbursement for our products;

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

the impact of legislative or regulatory reform of the healthcare industry and the impact of recently enacted healthcare reform legislation;

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 which 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.

---

## **Table of Contents**

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, 2011 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 hematology and 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<sup>®</sup> and FUSILEV<sup>®</sup> 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 affairs, 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.

The following is an update of our business strategy for 2012, as described in our Annual Report on Form 10-K for the year ended December 31, 2011 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 and continue to work on growing the ZEVALIN brand and are working to expand indications for use through additional trials. Effective April 2, 2012, with the acquisition of licensing rights from Bayer Pharma AG, we began the sales of ZEVALIN outside of the U.S. For FUSILEV, we are working to expand usage in colorectal cancer. We have initiated and continue to build appropriate infrastructure 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.

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 beginning in the second half of 2010 due to a shortage of generic leucovorin. While generic leucovorin supplies and utilization have been negatively impacted by this shortage, we cannot predict how long the shortage may continue or the extent of the impact the shortage may ultimately have on FUSILEV utilization. In April of 2011, we received two FDA approvals for FUSILEV. The first FDA approval was for the use of FUSILEV in combination with 5-fluorouracil in the palliative treatment of patients with advanced metastatic colorectal cancer. The second FDA approval was for a Ready-To-Use formulation, or RTU, of FUSILEV. We are now actively engaged in marketing FUSILEV for use in advanced metastatic colorectal cancer and have engaged a focused commercial sales organization to work with our commercial group to support efforts to grow FUSILEV sales.

***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 safely and expeditiously 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 develop these drugs. In April 2012, we announced that the single instillation Phase 3 clinical trials for apaziquone did not meet their primary endpoint and a meeting with the FDA is under consideration. For patients with more invasive and aggressive bladder cancer, we continue to study patients in multiple instillation studies.

With regard to our anti-cancer drug belinostat, a novel HDAC inhibitor, we have to date opened more than 100 sites. We completed enrollment in September 2011, and expect to file a NDA in late 2012 or early 2013. Belinostat has received Fast Track designation from the 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

## Edgar Filing: SPECTRUM PHARMACEUTICALS INC - Form 10-Q

of pre-clinical data and Chemistry Manufacturing and Control.

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.

---

## **Table of Contents**

***Expanding our pipeline of development stage and commercial drugs through business development activities.*** 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 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, regulatory and sales 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 business development efforts outlined above.

***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 beginning in 2009 and continuing through 2012. This policy includes the pursuit of dilutive and non-dilutive funding options, prudent expense management, and the achievement of critical synergies within our operations in order to maintain a reasonable burn rate. 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 rely 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 dilutive and 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 to be realized 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, 2012, are approximately \$197.3 million. We reported a net profit in 2011 and we have continued profitable operations through the first half of 2012. We remain dependent upon revenues from our two commercial drugs, specifically FUSILEV and ZEVALIN. Our long-term strategy is to continue to generate profits from the sale and licensing of our drug products.

While we believe that the approximately \$193.7 million in cash, equivalents and investments, which includes long term marketable securities (after payment of \$25.4 million for the purchase of the ZEVALIN Rights), we had available on June 30, 2012 will allow us to fund our current planned operations for at least the next twelve to eighteen months, we may, however, seek to obtain additional capital through the sale of debt or equity securities, if necessary, especially in conjunction with opportunistic acquisitions or license of drugs. We may be unable to obtain such additional capital when needed, or on terms favorable to us or our stockholders, if at all. If we raise additional funds by issuing equity securities, the percentage ownership of our stockholders will be reduced, stockholders may experience additional dilution or such equity securities may provide for rights, preferences or privileges senior to those of the holders of our common stock. If additional funds are raised through the issuance of debt securities, the terms of such securities may place restrictions on our ability to operate our business. If and when appropriate, just as we have done in the past, we may pursue non-dilutive financing alternatives as well.

Our expenditures for research and development or R&D consist of direct product specific costs (such as up-front license fees, milestone payments, active pharmaceutical ingredients, clinical trials, patent related legal costs, and product liability insurance, among others) and non-product specific, or indirect, costs (such as personnel costs, rent, and utilities, among others). During the six month period ended June 30, 2012, our total research and development expenditure, including indirect expenditures, was approximately \$18.5 million (net of \$5.4 million

received from Allergan).

---

## **Table of Contents**

Our primary focus areas for the foreseeable future, and the programs that are expected to represent a significant part of our R&D expenditures, are the on-going registrational clinical trials of apaziquone and belinostat and additional clinical studies in supporting the expanded utilization of our FDA products (ZEVALIN and FUSILEV). While we are currently focused on advancing these key product development programs, we continually evaluate our R&D programs of other pipeline products in response to the scientific and clinical success of each product candidate, as well as an ongoing assessment as to the product candidate's commercial potential. Our anticipated net use of cash for R&D in the fiscal year ending December 31, 2012, excluding the cost of in-licensing or acquisitions of additional drugs, if any, is expected to range between approximately \$38 and \$42 million.

Under our various existing licensing agreements, we are contingently obligated to make various regulatory and business milestone payments. In connection with the development of certain in-licensed drug products, we anticipate the occurrence of certain of these milestones during 2012. Upon successful achievement of these milestones, we will likely become obligated to pay up to approximately \$5.6 million during the next twelve months, payable in cash or stock at our discretion.

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.

On April 4, 2012 we entered into a definitive agreement to acquire all of the outstanding shares of Allos Therapeutics, Inc. for \$1.82 per share in cash plus one Contingent Value Right (CVR). This CVR entitled Allos stockholders to an additional payment of \$0.11 per share in cash if certain European regulatory approval and commercialization milestones for FOLOTYN<sup>®</sup> were achieved. Effective as of June 21, 2012, the conditions for the CVR can no longer be met and, therefore, we will not be obligated to make such additional payment in the future if the transaction is consummated. The upfront portion of the transaction is valued at up to \$206 million on a fully-diluted basis, and \$108 million net of Allos' cash balance at the end of 2011. We currently intend to finance the acquisition with a combination of cash on hand and a revolving credit line. Pursuant to the terms of the agreement, we commenced a tender offer to purchase all of the outstanding shares of Allos, which tender offer is still pending.

### ***Net Cash Provided by Operating Activities***

Net cash provided by operating activities was \$44.9 million for the first six months of 2012 which includes net income in the period of \$64.6 million adjusted for net non-cash credits of \$27.9 million of which, \$31.5 million relates to a deferred income tax benefit.

### ***Net Cash Provided by Investing Activities***

Net cash provided by investing activities of \$19.5 million for the first six months of 2012 was primarily due to the maturities of marketable securities partially offset by the \$25.4 million purchase of the ZEVALIN Ex US rights and the \$622,000 purchase of available for sale securities.

### ***Net Cash Provided by Financing Activities***

Net cash provided by financing activities of \$4.4 million for the first six months of 2012, primarily relates to the \$2.5 million in proceeds from the issuance of common stock as a result of the exercise of 531,355 stock options, \$2.2 million in excess tax benefits from share-based compensation and \$372,000 in purchases of shares under our Employee Stock Purchase Plan. These proceeds were partially offset by the \$326,000 repurchase of shares to satisfy minimum tax withholding for the vesting of restricted stock and the \$317,000 purchase of treasury stock.

## **Results of Operations**

### ***Three months ended June 30, 2012 and 2011***



## Edgar Filing: SPECTRUM PHARMACEUTICALS INC - Form 10-Q

**Total Revenues.** Total revenues increased \$23.3 million, or 51.5%, to \$68.7 million in the three months ended June 30, 2012 from \$45.4 million in the three months ended June 30, 2011. We recognized \$65.6 million from product sales, of which \$56.6 million related to sales of FUSILEV (each net of estimates for promotional, price and other adjustments, including adjustment of the allowance for product returns) and \$9.0 million related to worldwide sales of ZEVALIN. Product revenues recorded in the three months ended June 30, 2011 were \$42.3 million, of which \$33.9 million related to sales of FUSILEV and \$8.4 million related to sales of ZEVALIN. Revenues from the sales of FUSILEV have increased due to FDA approval of FUSILEV for use in the treatment of advanced metastatic colorectal cancer received on April 29, 2011 and a supply disruption of generic leucovorin. During the three month periods ended June 30, 2012 and 2011, 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 \$16.0 million upfront payment we received from Nippon Kayaku and Handok in the first quarter of 2010.

## **Table of Contents**

**Cost of Product Sales.** Cost of product sales increased \$3.4 million or 42.4% to \$11.6 million in the three months ended June 30, 2012 from \$8.1 million in the three months ended June 30, 2011. The increase in total cost of sales relates primarily to an increase in product revenues.

**Selling, General and Administrative.** Selling, general and administrative expenses increased \$4.6 million, or 24.9% to \$23.3 million, in the three months ended June 30, 2012 from \$18.7 million in the three months ended June 30, 2011. The increase is due primarily to:

\$2.7 million increase in compensation and associated benefits, of which \$2.2 million of the increase is attributable to sales and marketing expenses as a result of the expansion of our sales force. We expect sales and marketing activities will increase as we invest in additional commercial resources to increase market expansion of both ZEVALIN and FUSILEV.

\$2.7 million in legal and professional fees related to the Allos tender offer and \$687,000 transaction costs related to the Bayer agreement licensing rights to market ZEVALIN outside the U.S.

\$563,000 increase for transitional services related to sales of ZEVLIN outside the U.S.

\$1.4 million increase in advertising, branding, printing, marketing and promotion

\$360,000 increase in professional services

These increases were partially offset by:

\$3.6 million decrease in non-cash stock compensation expense primarily related to the management incentive plan

**Research and Development.** Research and development expenses increased \$1.9 million, or 24.7%, to \$9.6 million, in the three months ended June 30, 2012 from \$7.7 million in the three months ended June 30, 2011. The increase is primarily due to an increase of \$755,000 for drug product, \$594,000 increase in on-going clinical trials and \$799,000 increase in compensation and associated benefits.

We expect research and development expenses to range between approximately \$38 and \$42 million for 2012, excluding the cost of in-licensing or acquisitions of additional drugs, if any.

**Amortization of Purchased Intangibles.** We incurred a non-cash charge of \$1.6 million and \$930,000 for the three months ended June 30, 2012 and 2011, respectively, due to the amortization of intangibles from the acquisition of ZEVALIN and the rights to market ZEVALIN outside the U.S.

**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 2011. No warrants recorded as a liability were outstanding in 2012.

**Other Net Income (Loss).** The principal components of other income (loss) of (\$1.5 million) and \$174,000 during the three month periods ended June 30, 2012 and 2011, respectively, consisted primarily of an increase in currency exchange rate losses related to the acquisition of ZEVALIN Rights partially offset by \$58,000 of net interest income earned on outstanding bank balances. 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 \$3.0 million in 2012 as compared to \$1.7 million recorded in the three months ended June 30, 2011.

The \$3.0 million charge for income taxes during the three months ended June 30, 2012 was due to the generation of \$21.1 million of pretax income during the quarter ended June 30, 2012. The tax expense for the quarter was below the statutory rate as a result of recognizing \$3.2

## Edgar Filing: SPECTRUM PHARMACEUTICALS INC - Form 10-Q

million of additional research and experimentation credit carryovers following the completion of an analysis of prior year credits during the quarter.

### Results of Operations

#### *Six months ended June 30, 2012 and 2011*

**Total Revenues.** Total revenues increased \$39.6 million, or 44.5%, to \$128.6 million in the six months ended June 30, 2012 from \$89.0 million in the six months ended June 30, 2011. We recognized \$122.4 million from product sales, of which \$107.8 million related to sales of FUSILEV (each net of estimates for promotional, price and other adjustments, including adjustment of the allowance for product returns) and \$14.6 million related to sales of ZEVALIN. Product revenues recorded in the six months ended June 30, 2011 were \$82.8 million, of which \$68.6 million related to sales of FUSILEV and \$14.3 million related to sales of ZEVALIN. Revenues from the sales of FUSILEV have increased due to FDA approval of FUSILEV for use in the treatment of advanced metastatic colorectal cancer received on April 29, 2011 and a supply disruption of generic leucovorin. During each of the six months periods ended June 30, 2012 and 2011, we also recognized \$6.2 million of licensing revenues from the amortization of a \$41.5 million upfront payment we received from Allergan in 2008, and \$16.0 million upfront payment we received from Nippon Kayaku and Handok in the first quarter of 2010.

## **Table of Contents**

**Cost of Product Sales.** Cost of product sales increased \$5.5 million or 37.6% to \$20.2 million in the six months ended June 30, 2012 from \$14.7 million in the six months ended June 30, 2011. The increase in total cost of sales relates primarily to an increase in product revenues.

**Selling, General and Administrative.** Selling, general and administrative expenses increased \$10.2 million, or 32.3%, to \$41.6 million in the six months ended June 30, 2012 from \$31.5 million in the six months ended June 30, 2011. The increase is due primarily to:

\$6.1 million increase in compensation and associated benefits, of which \$4.7 million of the increase is attributable to sales and marketing expenses as a result of the expansion of our sales force. We expect sales and marketing activities will increase as we invest in additional commercial resources to increase market expansion of both ZEVALIN and FUSILEV.

\$2.6 million increase in advertising, branding, printing, marketing and promotion

\$3.4 million in legal and professional fees related to the Allos tender offer and \$687,000 transaction costs related to the Bayer agreement licensing rights to market ZEVALIN outside the U.S.

\$967,000 increase in professional fees

\$506,000 increase in regulatory fees

\$563,000 increase for transitional services related to sales of ZEVLIN outside the U.S.

These increases were partially offset by:

\$4.7 million decrease in non-cash stock compensation expense primarily due to the management incentive plan expenses.

**Research and Development.** Research and development expenses increased \$5.0 million, or 36.7%, to \$18.5 million, in the six months ended June 30, 2012 from \$13.5 million in the six months ended June 30, 2011. The increase is primarily due to:

\$3.3 million increase for drug product and a payment related to the co-development and commercialization agreement with Hamni Pharmaceutical Company for SPI-2012,

\$1.5 million increase in compensation and associated benefits.

We expect research and development expenses to range between approximately \$38 and \$42 million for 2012, excluding the cost of in-licensing or acquisitions of additional drugs, if any.

**Amortization of Purchased Intangibles.** We incurred a non-cash charge of \$2.6 million and \$1.9 million for the six months ended June 30, 2012 and 2011, respectively, due to the amortization of intangibles from the acquisition of ZEVALIN Rights to market ZEVALIN outside the U.S.

**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 2011. No warrants recorded as a liability were outstanding in 2012.

**Other Net Income.** The principal components of other income (loss) of (\$1.3 million) and \$694,000 during the six month periods ended June 30, 2012 and 2011, respectively, consisted primarily of an increase in currency exchange rate losses partially offset by \$132,000 of net interest

## Edgar Filing: SPECTRUM PHARMACEUTICALS INC - Form 10-Q

income earned on outstanding bank balances. 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/Benefit for Income Taxes.** We recorded a benefit for income taxes of \$20.3 million in 2012 as compared to a provision of \$1.7 million recorded in the six months ended June 30, 2011.

Based on the weight of both positive and negative evidence, we concluded that it is more likely than not that the domestic net deferred tax assets will be realized, and therefore, we have released our domestic valuation allowance during the quarter ended March 31, 2012. We released approximately \$22 million as part of the projected annual effective tax rate and released the remaining \$24 million of the domestic valuation allowance as a discrete item through June 30, 2012. We maintained a valuation allowance against our foreign net deferred tax assets as we continue to conclude it is not more likely than not that the foreign net deferred tax assets will be realized.

The annual effective rate for fiscal 2012 is below the statutory rate principally as a result of tax benefits expected to be realized from the release of our valuation allowance against domestic deferred tax assets based upon projected current year earnings. The year to date tax benefit of \$20.3 million in 2012 is primarily the result of a \$24 million discrete tax benefit recognized during the quarter ended March 31, 2012 related to the release of our valuation allowance on domestic deferred tax assets.

**Table of Contents****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 income 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, 2012 and 2011, 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)					
<b>Period ended June 30, 2012:</b>						
Balances at beginning of the period	\$ 1,942	\$ 8,114	\$ 4,000	\$ 5,866	\$ 471	\$ 20,393
Add provisions/(recovery):	25,607	21,192	(490)	8,511	(30)	54,790
Less: Credits or actual allowances:	(17,771)	(11,324)	(10)	(5,477)	(29)	(34,611)
Balances at the close of the period	\$ 9,778	\$ 17,982	\$ 3,500	\$ 8,900	\$ 412	\$ 40,572
<b>Period ended June 30, 2011:</b>						
Balances at beginning of 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

Amounts recorded as allowances on our condensed consolidated balance sheets for 2012 and 2011 are reflected in the table above. The basis and methods of estimating these allowances, used by management, are described below.

**Chargebacks, discounts and rebates**

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

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

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

## Edgar Filing: SPECTRUM PHARMACEUTICALS INC - Form 10-Q

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 amounts have not been material to the financial statements.

## **Table of Contents**

### ***Product returns allowances***

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

### ***Distribution and Data Fees***

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

### ***Doubtful Accounts***

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

### ***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

Fair value of acquired assets

Research and development

Fair value measurements



Amortization and impairment of intangible assets

Share-based compensation

During the six months ended June 30, 2012, 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, 2011 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 capital, 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.

## **Table of Contents**

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, 2012 and 2011, 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, 2012 or 2011, any decline in the fair value of our investments would not be material in the context of our condensed 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.

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.

### **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, 2012, 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, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Table of Contents**

**PART II OTHER INFORMATION**

**ITEM 1A. RISK FACTORS**

Except as set forth below, 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, 2011 as filed with the SEC. The risk factor titled *We are subject to risks associated with doing business internationally* in our Form 10-K is amended and restated in its entirety to read as follows:

*Expansion into international markets is important to our long-term success, and our inexperience in international operations increases the risk that our international expansion efforts will not be successful.*

We currently maintain offices outside of the United States and have sales personnel or independent consultants in several countries. Additionally, we conduct clinical trials and manufacture our drug products internationally. We have limited experience operating in foreign jurisdictions and are rapidly building our international operations. Managing a global organization is difficult, time consuming and expensive. Our inexperience in operating our business outside of the United States increases the risk that any international expansion efforts that we may undertake will not be successful. In addition, conducting international operations subjects us to new risks that we have not generally faced in the United States, many of which are beyond our control. These risks include, among other things:

challenges caused by distance, language and cultural differences;

maintaining compliance with foreign legal requirements, including employment law;

unexpected changes in foreign regulatory requirements, including quality standards and other certification requirements;

potentially adverse tax consequences, including the complexities of foreign value added tax systems and restrictions on the repatriation of earnings;

tariffs, customs, duties and other trade barriers;

increased financial accounting and reporting burdens and complexities;

changing economic conditions in countries where our products are manufactured;

exchange rate risks;

product liability, intellectual property and other claims;

reduced or varied protection for intellectual property rights in some countries;

political and social instability;

new export license requirements; and

difficulties in managing and staffing foreign operations.

Operating in international markets also requires significant management attention and financial resources. The investment and additional resources required to establish operations and manage growth in other countries may not produce the desired levels of revenue or profitability, which could have an adverse effect on our business, financial condition and results of operations.

**Table of Contents**

**ITEM 6. EXHIBITS**

<b>Exhibit Number</b>	<b>Description</b>
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.

+ Filed herewith.

\* 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.

By: /s/ Brett L. Scott

Date: August 8, 2012

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

**Table of Contents**

**INDEX TO EXHIBITS**

<b>Exhibit Number</b>	<b>Description</b>
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.

+ Filed herewith.

\* 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.