SPECTRUM PHARMACEUTICALS INC Form 10-Q August 08, 2006 Table of Contents

# **UNITED STATES**

## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-Q**

(Mark One)

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

For the quarterly period ended June 30, 2006

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 000-28782

# SPECTRUM PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware (State or other jurisdiction of

incorporation or organization)

**157 Technology Drive** 

93-0979187 (I.R.S. Employer

Identification No.)

#### Irvine, California (Address of Principal Executive Offices) (Zip Code) Registrant s Telephone Number, Including Area Code: (949) 788-6700

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No "

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer " Accelerated filer x Non-accelerated filer "

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12B-2 of the Exchange Act). Yes "No x

Indicate the number of shares outstanding of each of the issuer s classes of Common Stock as of the latest practicable date:

Class Common Stock, \$.001 par value **Outstanding at August 4, 2006** 24,485,369

### SPECTRUM PHARMACEUTICALS, INC.

### TABLE OF CONTENTS

	1 460 1100
PART I. <u>FINANCIAL INFORMATION</u>	
ITEM 1. Financial Statements	3
Statement Regarding Financial Information	3
Condensed Consolidated Balance Sheets as of June 30, 2006 and December 31, 2005 (unaudited)	4
Condensed Consolidated Statements of Operations for the three-month and six-month periods ended June 30, 2006 and 2005	
(unaudited)	5
Condensed Consolidated Statements of Cash Flows for the six-month periods ended June 30, 2006 and 2005 (unaudited)	6
Notes to Condensed Consolidated Financial Statements (unaudited)	7
ITEM 2. Management s Discussion and Analysis of Financial Condition and Results of Operations	17
ITEM 3. Quantitative and Qualitative Disclosures About Market Risk	26
ITEM 4. Controls and Procedures	26
PART II. <u>OTHER INFORMATION</u>	
ITEM 1. Legal Proceedings	27
ITEM 1A. Risk Factors	27
ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds	30
ITEM 3. Defaults Upon Senior Securities	31
ITEM 4. Submission of Matters to a Vote of Security Holders	31
ITEM 5. Other Information	31
ITEM 6. <u>Exhibits</u>	33
<u>SIGNATURES</u>	34

Page No.

#### FORM 10-Q

#### For the three-month and six-month periods ended June 30, 2006

#### PART I FINANCIAL INFORMATION

#### **ITEM 1. Financial Statements**

#### **Statement Regarding Financial Information**

The condensed consolidated financial statements of Spectrum Pharmaceuticals, Inc. included herein have been prepared by management, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information normally included in the consolidated financial statements prepared in accordance with accounting principles generally accepted in the United States has been condensed or omitted pursuant to such rules and regulations. However, we believe that the disclosures are adequate to make the information presented not misleading.

We recommend that you read the condensed consolidated financial statements included herein in conjunction with the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2005, filed with the Securities and Exchange Commission on March 15, 2006.

#### **Condensed Consolidated Balance Sheets**

#### (Unaudited)

		lune 30, 2006 1 Thousands,		ember 31, 2005 Share and	
Assets		Per Sh	are Data	)	
Current Assets:					
Cash and cash equivalents	\$	4,226	\$	28,750	
Marketable securities		50,683		34,917	
Accounts Receivable		237		287	
Inventory		109		58	
Prepaid expenses and other current assets		582		373	
Total current assets		55,837		64,385	
Property and equipment, net		608		562	
Other Assets		168		128	
Total assets	\$	56,613	\$	65,075	
Liabilities and Stockholders Equity					
Current Liabilities:					
Accounts payable	\$	1,280	\$	1,220	
Accrued compensation		549		683	
Accrued clinical study costs		2,524		1,925	
Total current liabilities		4,353		3,828	
Deferred rent and deposit		217		241	
Total liabilities		4,570		4,069	
Commitments and Contingencies (Note 4)					
Minority Interest		21		23	
Stockholders Equity:					
Preferred Stock, par value \$0.001 per share, 5,000,000 shares authorized:					
Series B Junior Participating Preferred Stock, 200,000 shares authorized, no shares issued and outstanding (Note 6)					
Series D 8% Cumulative Convertible Voting Preferred Stock, 600 shares authorized, stated value \$10,000 per share, liquidation value \$1,884, issued and outstanding 127 shares at June 30, 2006 and 157					
shares at December 31, 2005		604		747	
Series E Convertible Voting Preferred Stock, 2,000 shares authorized, stated value \$10,000 per share, liquidation value \$3,492, issued and outstanding, 291 shares at June 30, 2006 and December 31, 2005		1,795		1 705	
Common stock, par value \$0.001 per share, 50,000,000 shares authorized (Note 6):		1,795		1,795	
Issued and outstanding, 24,485,370 and 23,503,157 shares at June 30, 2006 and December 31, 2005, respectively		24		24	
Additional paid-in capital		248,662		243,656	
Deferred stock-based compensation		210,002		(783)	
Accumulated other comprehensive income		258		(26)	
Accumulated deficit		(199,321)		(184,430)	

Total stockholders equity	52,022	60,983
Total liabilities and stockholders equity	\$ 56,613	\$ 65,075

The accompanying notes are an integral part of these

condensed consolidated balance sheets.

#### **Condensed Consolidated Statements of Operations**

#### (Unaudited)

	Jun	ee-Months Ended e 30, 2006 a Thousands, 1	F June	e-Months Ended 30, 2005 are and	Jur	x-Months Ended ne 30, 2006 n Thousands, l	Jun	k-Months Ended le 30, 2005 Share and
		Per Sha	re Data)			Per Sha	re Data	)
Revenues	\$		\$	240	\$		\$	240
Operating expenses:								
Cost of product sold				221				221
Research and development		4,028		3,373		7,751		7,082
General and administrative		1,468		1,437		2,863		2,555
Stock-based charges		4,180		36		5,568		694
Total operating expenses		9,676		5,067		16,182		10,552
Loss from operations		(9,676)		(4,827)		(16,182)		(10,312)
Other income, net		658		275		1,289		489
Net loss before minority interest in consolidated subsidiary		(9,018)		(4,552)		(14,893)		(9,823)
Minority interest in net loss of consolidated subsidiary				2		2		4
Net loss	\$	(9,018)	\$	(4,550)	\$	(14,891)	\$	(9,819)
Basic and diluted net loss per share	\$	(0.37)	\$	(0.30)	\$	(0.62)	\$	(0.65)
			۴					
Basic and diluted weighted average common shares			\$					
outstanding	24	4,231,045	15	,353,938	2	3,930,671	1	5,243,965
Supplemental Information								
Stock-based charges - Components:								
Research and development	\$	3,885	\$	16	\$	4,786	\$	654
General and administrative		296		20		782		40
Total stock based charges	\$	4,181	\$	36	\$	5,568	\$	694

The accompanying notes are an integral part of these

condensed consolidated balance sheets.

#### **Condensed Consolidated Statements of Cash Flows**

#### (Unaudited)

	Six-Months Ended June 30, 2006 (In Thousand	Jur	x-Months Ended 1e 30, 2005 Share and
	Per	Share Data	ı)
Cash Flows From Operating Activities:			
Net loss	\$ (14,891)	\$	(9,819)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	96		120
Amortization of deferred stock-based compensation	2,252		100
Fair value of common stock issued in connection with drug license	3,316		594
Minority interest in subsidiary	(2)		(4)
Changes in operating assets and liabilities:	50		(11)
(Increase) decrease in Accounts Receivable	50		(41)
(Increase) decrease in Inventory	(51)		16
(Increase) decrease in other assets	(209)		161
Increase (decrease) in accounts payable and accrued expenses	720		1,839
Increase (decrease) in accrued compensation and related taxes	(134)		(432)
Increase (decrease) in other non-current liabilities	(24)		69
Net cash used in operating activities	(8,877)		(7,397)
Cash Flows From Investing Activities:			
Sales of marketable securities			35,965
Purchases of marketable securities	(15,522)		(104)
Purchases of property and equipment	(142)		(50)
Net cash provided by (used in) investing activities	(15,664)		35,811
Cash Flows From Financing Activities:			
Proceeds from issuance of common stock and warrants			750
Proceeds from exercise of warrants	17		1,052
Proceeds from exercise of stock options			5
Net cash provided by financing activities	17		1,807
	(24.524)		20.221
Net increase (decrease) in cash and cash equivalents	(24,524)		30,221
Cash and cash equivalents, beginning of period	28,750		3,241
Cash and cash equivalents, end of period	\$ 4,226	\$	33,462
Supplemental Cash Flow Information:			
Interest paid	\$ 3	\$	
Income taxes paid	\$ 1	\$	1
Schodule of Non-Cosh Investing and Financing Astivition			
Schedule of Non-Cash Investing and Financing Activities: Preferred stock dividends paid with common stock	\$ 55	\$	63
referred stock dividends paid with common stock	φ 55	φ	05

Fair value of common stock issued in connection with drugs licensed	\$ 3,316	\$ 594
Fair value of options and warrants issued to consultants for services	\$ 407	\$ 110
Fair value of restricted stock granted employees and directors	\$ 338	
Fair value of stock issued to match employee 401(k) contributions	\$ 75	

The accompanying notes are an integral part of these

condensed consolidated balance sheets.

#### Notes to Condensed Financial Statements

#### June 30, 2006

#### (Unaudited)

#### 1. Business and Basis of Presentation

#### Business

Spectrum Pharmaceuticals, Inc., or the Company, is a specialty pharmaceutical company engaged in the business of acquiring, developing and commercializing prescription drugs for various indications. While we directly own certain patent rights, the drugs we are currently developing, which are focused on the treatment of cancer and other unmet medical needs, are in-licensed from third parties whereby we acquired rights to develop and commercialize those compounds in territories specified in the respective agreements.

#### **Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements are prepared on a consistent basis in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals and consolidation and elimination entries) considered necessary for a fair presentation have been included. Operating results for the three-month and six-month periods ended June 30, 2006 are not necessarily indicative of the results that may be expected for the year ending December 31, 2006. The balance sheet at December 31, 2005 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by GAAP for complete financial statements. For further information, refer to the consolidated financial statements and footnotes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2005.

Certain quarterly amounts have been reclassified to conform to the current period presentation.

#### 2. Summary of Significant Accounting Policies and Estimates

#### **Principles of Consolidation**

The consolidated financial statements include the accounts of the Company and of our wholly owned and majority owned subsidiaries. As of June 30, 2006, we had three subsidiaries: NeoJB LLC (NeoJB), 80% owned, organized in Delaware in April 2002; Spectrum Pharmaceuticals GmbH, wholly owned, incorporated in Switzerland in April 1997; and NeoGene Technologies, Inc. (NeoGene), an inactive subsidiary, 88.4% owned, incorporated in California in October 1999. We have eliminated all significant intercompany accounts and transactions.

Investments by outside parties in our consolidated subsidiary are recorded as Minority Interest in Consolidated Subsidiary in our accounts, and stated net after allocation of income and losses in the subsidiary.

We operate in one business segment, that of acquiring, developing and commercializing prescription drug products. The business has not matured to the point that disaggregated segment information would be meaningful. Accordingly, the accompanying financial statements are reported in the aggregate including all our activities in one segment.

Certain prior year amounts have been reclassified to conform to the current year presentation.

#### Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States 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. Our most significant assumptions are employed in estimates used in determining values of financial instruments and accrued obligations, as well as in estimates used in applying the revenue recognition policy and estimating stock-based charges. 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.

In estimating the fair value of stock-based compensation, we use the quoted market price of our common stock for stock awards, and the Black-Scholes Option Pricing Model for stock options and warrants. We estimate future volatility based on past volatility of our common stock; and we estimate the expected length of the option on several criteria, including the vesting period of the grant, and the expected volatility. In estimating the fair value of restricted common stock we issue in connection with licensing transactions, we apply a discount for marketability restrictions of more than one year, calculated after considering past volatility of our common stock as well as the term of restriction and the cost of risk free capital for a period that is comparable with the term of the restriction on the shares.

#### Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, marketable securities, accounts receivable, accounts payable and accrued liabilities, as reported in the balance sheets, are considered to approximate fair value given the short term maturity and/or liquidity of these financial instruments.

#### Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities primarily consist of bank checking deposits, short-term treasury securities, and institutional money market funds, corporate debt and equity, municipal obligations, including market auction debt securities, government agency notes, and certificates of deposit. We classify highly liquid short-term investments, with insignificant interest rate risk and maturities of 90 days or less at the time of acquisition, as cash and cash equivalents. Other investments, which do not meet the above definition of cash equivalents, are classified as either held-to-maturity or available-for-sale marketable securities, in accordance with the provisions of Financial Accounting Standards Board (FASB) Statement No. 115, Accounting for Certain Investments in Debt and Equity Securities. Investments that we intend to hold for more than one year are classified as long-term investments.

#### Concentrations of Credit Risk, Supplier and Customer

All of our cash, cash equivalents and marketable securities are invested at three major financial institutions. To a limited degree these investments are insured by the Federal Deposit Insurance Corporation (FDIC) and by third party insurance. 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 credit worthiness of the underlying issuer. We believe that such risks are mitigated because we invest only in investment grade securities. We have not incurred any significant credit risk losses related to such investments.

#### Inventory

Inventory is stated at the lower of cost (first-in, first-out method) or market. As of June 30, 2006, inventory consisted of primarily finished dosage form of our drug product carboplatin injection. The lower of cost or market is determined based on net realizable value after appropriate consideration is given to obsolescence, excessive levels, deterioration, and other factors.

#### Patents and Licenses

We own or license all the intellectual property that forms the basis of our business model. We expense all licensing and patent application costs as they are incurred.

#### **Revenue Recognition**

License fees representing non-refundable payments received upon the execution of license agreements are recognized as revenue upon execution of the license agreements where we have no significant future performance obligations and collectibility of the fees is assured. Milestone payments, which are generally based on developmental or regulatory events, are recognized as revenue when the milestones are achieved, collectibility is assured, and we have no significant future performance obligations in connection with the milestones. In those instances where we have collected fees or milestone payments but have ongoing future obligations related to the development of the drug product, revenue recognition is deferred and amortized ratably over the period of our future obligations.

Revenue from sales of product is recognized upon shipment of product when title and risk of loss have transferred to the customer, and provisions for estimates, including promotional adjustments, price adjustments, returns, and other potential adjustments are reasonably determinable. Such revenue is recorded, net of such estimated provisions, at the minimum amount of the customer s obligation to us. We state the related accounts receivable at net realizable value, with any allowance for doubtful accounts charged to general operating expenses.

#### **Research and Development**

Research and development expenses are comprised of the following types of costs incurred in performing research and development activities: personnel expenses, facility costs, contract services, licensing fees and milestone payments, costs of clinical trials, laboratory supplies and drug products, and allocations of corporate costs. We expense all research and development activity costs in the period incurred.

#### Basic and Diluted Net Loss Per Share

In accordance with FASB Statement No. 128, *Earnings Per Share*, we calculate basic and diluted net loss per share using the weighted average number of common shares outstanding during the periods presented, and adjust the amount of net loss, used in this calculation, for preferred stock dividends declared during the period.

We incurred a net loss in each period presented, and as such, did not include the effect of potentially dilutive common stock equivalents in the diluted net loss per share calculation, as their effect would be anti-dilutive for all periods. Potentially dilutive common stock equivalents would include the common stock issuable upon the conversion of preferred stock and the exercise of warrants and stock options that have conversion or exercise prices below the market value of our common stock at the measurement date. As of June 30, 2006 and 2005, all potentially dilutive common stock equivalents amounted to approximately 15 million and 11 million shares, respectively.

The following data show the amounts used in computing basic loss per share for the three-month and six-month periods ended June 30, 2006 and 2005.

	]	ee-Months Ended e 30, 2006 (In	Jun	ee-Months Ended e 30, 2005 nds, Except Sh	Ju	x-Months Ended 1e 30, 2006 d Per Share Da	Jun	-Months Ended e 30, 2005
Net loss	\$	(9,018)	\$	(4,550)	\$	(14,891)	\$	(9,819)
Less:								
Preferred dividends paid in cash or stock		(26)		(32)		(55)		(63)
Income available to common stockholders used in computing basic earnings per share	\$	(9,044)	\$	(4,582)	\$	(14,946)	\$	(9,882)
Weighted average shares outstanding	24	4,231,045	1:	5,353,938	2	3,930,671	15	5,243,965

Basic and diluted net loss per share	\$ (0.37)	\$ (0.30)	\$ (0.62)	\$ (0.65)

#### Accounting for Stock-Based Employee Compensation

In December 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123(R), *Share-Based Payment*. This pronouncement amends SFAS No. 123, *Accounting for Stock-Based Compensation*, and supersedes Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*. SFAS No. 123(R) requires that companies account for awards of equity instruments issued to employees under the fair value method of accounting and recognize such amounts in their statements of operations. We adopted SFAS No. 123(R) on January 1, 2006, using the modified prospective method and, accordingly, have not restated the consolidated statements of operations for periods prior to January 1, 2006. Under SFAS No. 123(R), we are required to measure compensation cost for all stock-based awards at fair value on the date of grant and recognize compensation expense in our consolidated statements of operations over the service period that the awards are expected to vest. As permitted under SFAS No. 123(R), we have elected to recognize compensation cost for all options with graded vesting on a straight-line basis over the vesting period of the entire option.

Prior to January 1, 2006, we accounted for stock-based compensation, as permitted by FASB Statement No. 123, *Accounting for Stock-Based Compensation*, under the intrinsic value method described in Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations. Under the intrinsic value method, no stock-based employee compensation cost is recorded when the exercise price is equal to, or higher than, the market value of the underlying common stock on the date of grant. We recognized stock-based compensation expense for all grants to consultants and for those grants to employees where the exercise prices were below the market price of the underlying stock at the measurement date of the grant.

The following table illustrates the effect on net loss and loss per share if we had applied the fair value recognition provisions of FASB Statement No. 123, *Accounting for Stock-Based Compensation*, to stock-based employee compensation, using the straight-line method, for periods prior to January 1, 2006.

	Three-Months Ended June 30, 2005 (In Thousands, 1	Six-Months Ended June 30, 2005 Except Share and
	Per Sha	re Data)
Net loss, as reported	\$ (4,550)	\$ (9,819)

Deduct: Total stock-based employee compensation expense determined under fair value		
based method for all awards, net of related tax effects	(797)	(2,779)
Pro forma net loss	\$ (5,347)	\$ (12,598)
Loss per share:		
Basic and diluted as reported	\$ (0.30)	\$ (0.65)

### Comprehensive Loss

The net loss reflected on our Consolidated Statements of Operations substantially represents the total comprehensive loss for the periods presented.

#### 3. Products and Strategic Alliances

Basic and diluted pro forma

As of June 30, 2006, we had nine proprietary drugs under development: satraplatin, levofolinic acid (LFA), EOquin , elsamitrucin, ozarelix (formerly SPI-153), lucanthone, RenaZorb , SPI-1620 and SPI-205 and through the date of this report we have filed multiple Abbreviated New Drug Applications, or ANDAs, with the U.S. Food and Drug Administration, or FDA, including those for ciprofloxacin and fluconazole tablets, and carboplatin injection, which

(0.35)

\$

\$

(0.83)

have been approved by the FDA. We are developing our proprietary drugs for the treatment of a variety of cancers and other unmet medical needs.

In general, we direct and pay for all aspects of the drug development process, and consequently incur the risks and rewards of drug development, which is an inherently uncertain process. To mitigate such risks we enter into alliances where we believe that our partners can provide strategic advantage in the development, manufacturing or distribution of our drugs. In such situations, the alliance partners may share in the risks and rewards of the drug development and commercialization.

#### **Business** Alliances

Our business alliances are described in detail in our Annual Report on Form 10-K for the year ended December 31, 2005. The following represents an update for significant developments during 2006.

<u>Par Pharmaceutical Companies Inc.</u>: In February 2006, we entered into a strategic alliance with Par Pharmaceutical Companies, Inc., or Par, one of the largest generics companies in the United States, to distribute generic drugs for which we have filed ANDAs, including sumatriptan succinate injection. We expect that we will receive FDA approval for several ANDAs during the next eighteen months. Pursuant to the terms of the agreement, we will receive payments upon regulatory approval of certain ANDAs filed by us. The agreement also provides for a share of the profits from the sale by Par of our generic products. In addition, Par agreed to provide financial and legal support, including the payment of all legal expenses going forward, for the ongoing patent challenge for sumatriptan succinate injection. Within twenty-four months of the effective date of the agreement, we have the right to request Par to make an equity investment in the Company, which is subject to due diligence and the negotiation of definitive documents at that time. Not counting our share of any profits from sales of the generic drugs, we could receive an aggregate of over \$10 million under the agreement if the equity investment is made and all the regulatory milestones are achieved.

#### Products under development

The following is a brief update of the most advanced products under development as of June 30, 2006:

<u>Satraplatin</u>: Satraplatin is an orally administered chemotherapeutic agent that is being studied for treating hormone refractory prostate cancer. A phase 3 clinical trial being conducted by our development partner, GPC Biotech AG, or GPC Biotech, was proceeding in accordance with plans, and a rolling submission of a New Drug Application, or NDA, with the FDA has commenced. We expect final data from the phase 3 trial in the Fall, and completion of the NDA filing in the fourth quarter of 2006.

*Levofolinic acid (LFA):* In April 2006, we completed the acquisition of all of the oncology drug assets of Targent, Inc. The principal asset in the transaction was a license agreement between Targent and Merck Eprova AG, a Swiss corporation, whereby we acquired an exclusive license to use regulatory filings related to levofolinic acid, or LFA, and a non-exclusive license under certain patents and know-how related to LFA to develop, make, have made, use, sell and have sold LFA in the field of oncology in North America. LFA is the pure active isomer of calcium leucovorin, a component of standard of care 5-fluorouracil, or 5-FU, containing regimens for the treatment of colorectal cancer and other malignancies, for which a new drug application is on file with the FDA. We expect to respond in the first quarter 2007 to certain chemistry and manufacturing questions raised by the FDA during the review of the application.

<u>EOquin</u>: EOquin, a synthetic drug which is activated by certain enzymes present in higher amounts in cancer cells than in normal tissues, is currently being developed for superficial bladder cancer. Enrollment in a phase 2 clinical trial has been completed and patients are in follow-up. In early 2006, we held a pre-IND and end of phase 2 meeting with the FDA and recently filed an IND with the FDA, with the view to initiating phase 3 trials in the United States in late 2006 to evaluate EOquin in superficial bladder cancer after completion of a 20-patient pilot study which has recently begun.

<u>Ozarelix</u>: Ozarelix, a fourth generation LHRH (Luteinizing Hormone Releasing Hormone, also known as GnRH or Gonadotropin Releasing Hormone) antagonist is under evaluation for its intended initial indications, hormone-dependent prostate cancer and benign prostatic hypertrophy. Phase 2 clinical trials in each of those indications are proceeding in Europe in accordance with plans.

#### 4. Commitments and Contingencies

#### Facility and Equipment Leases

As of June 30, 2006, we were obligated under a facility lease and several operating equipment leases. We have sub-leased a portion of our facility through September 2007, with a renewal option through the remaining term of our underlying lease.

Minimum lease commitments, and minimum contractual sublease income for each of the next five years and thereafter, under the property and equipment operating leases, are as follows:

		Sub	-Lease
Year ending December 31:	Lease Commitments	Comn	nitments
	Amounts In	Thousan	ds
2006 (Remainder of Year)	\$ 232	\$	114
2007	\$ 474	\$	171
2008	\$ 494	\$	
2009	\$ 253	\$	
Thereafter	\$ 5	\$	
	\$ 1,458	\$	285

#### **Licensing Agreements**

Each of our proprietary drug product candidates is being developed pursuant to license agreements, which provide us with rights to certain territories to, among other things, develop, sublicense, and sell the drugs. With regard to one of our proprietary drug product candidates, satraplatin, we have out-licensed our rights to GPC Biotech. We are required to use commercially reasonable efforts to develop the drugs, are generally responsible for all development, patent filing and maintenance costs, sales, marketing and liability insurance costs, and are contingently obligated to make milestone payments to the licensors if we successfully reach development and regulatory milestones specified in the agreements. In addition, we are obligated to pay royalties and milestone payments based on net sales, if any, after marketing approval is obtained from regulatory authorities. We have no similar milestone or other payment obligations in connection with our generic drug products.

The potential contingent development and regulatory milestone obligations under all our licensing agreements, are generally tied to progress through the FDA approval process, which approval significantly depends on positive clinical trial results. The following list is typical of milestone events: commencement of phase 3 clinical trials, filing of new drug applications in the United States, Europe and Japan, and approvals from those regulatory agencies.

Given the uncertainty of the drug development process, we are unable to predict with any certainty when any of the milestones will occur and, accordingly, the milestone payments represent contingent obligations that will be recorded as expense when the milestone is achieved. In connection with the development of in-licensed drug products, we anticipate certain milestones will be achieved over the next eighteen months. If the anticipated milestones are achieved, we will likely become obligated to issue approximately 500,000 restricted shares of our common stock and pay up to approximately \$5 million in cash during the eighteen-month period. If all of our contingent milestones were achieved, our potential contingent cash development and regulatory milestone obligations, aggregating approximately \$52 million as of June 30, 2006, would be due approximately as follows: \$5 million in less than 1 year; \$6 million between 1 and 3 years; \$2 million between 3 and 5 years; and \$39 million after 5 years.

If we reach a milestone, it will likely occur prior to revenues being generated from the related compound. However, in connection with the milestone obligations related to satraplatin, each of our contingent future payment obligations is generally matched by a corresponding, greater payment milestone obligation of GPC Biotech to us.

#### Service Agreements

In connection with the research and development of our drugs, we have entered into contracts with numerous third party service providers, such as clinical trial centers, clinical research organizations, data monitoring centers, and with drug formulation, development and testing laboratories. The financial terms of these agreements vary and generally obligate us to pay in stages, depending on achievement of certain events specified in the agreements, such as contract execution, reservation of service or production capacity, actual performance of service, or the successful accrual and dosing of patients. As of each period end, we accrue for all non-cancelable installment amounts that we are likely to become obligated to pay.

#### **Employment Agreements**

We have entered into employment agreements with two of our Executive Officers, Dr. Shrotriya, Chief Executive Officer, and Dr. Lenaz, Chief Scientific Officer, expiring December 31, 2006 and July 1, 2007, respectively. The employment agreements automatically renew for a one-year term unless either party gives written notice at least 90 days prior to the commencement of the next year of such party s intent not to renew the agreement. The agreements require each executive to devote his full working time and effort to the business and affairs of the Company during the term of the agreement. The agreements provide for an annual base salary with annual increases, periodic bonuses and option grants as determined by the Compensation Committee of our Board of Directors.

Each officer s employment may be terminated by us with or without cause, as defined in the agreement. The agreements provide for certain guaranteed severance payments and benefits if the officer s employment is terminated without cause, if the officer s employment is terminated due to a change in control or is adversely affected due to a change in control and the officer resigns or if the officer decides to terminate his employment due to a disposition of a significant amount of assets or business units. The guaranteed severance payment includes a payment equal to the officer s annual base salary and other cash compensation, and approved bonus. The officer is also entitled to two years medical, dental and other benefits following termination. In addition, all options held by the officer s employment is being terminated for the reason that the shared expectations of the officer and the board are not being met, then the options currently held by the officer will vest in accordance with their terms for up to one year after the date of termination, with the right to exercise those options, when they vest, for approximately thirteen months after the date of termination. The agreements also provide that, upon his retirement, all options held by the officer will become fully vested.

#### Litigation

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

At June 30, 2006, we were in litigation with GlaxoSmithKline as a result of filing an ANDA for sumatriptan succinate injection, which is marketed by GlaxoSmithKline under the brand name Imitrex<sup>®</sup>. Pursuant to our February 2006 agreement with Par, Par agreed to provide financial and legal support, including the payment of all legal expenses going forward, for this patent challenge.

#### 5. Stockholders Equity

#### **Common Stock**

In connection with the acquisition, in April 2006, of all the oncology assets of Targent, Inc., we issued to Targent and its stockholders an aggregate amount of 600,000 shares of Spectrum common stock, with a fair value of \$2.7 million as of the transaction closing date, all of which amount representing purchased research and

development, has been charged to expense at the closing of the transaction. Targent is eligible to receive additional payments of shares of Spectrum common stock and/or cash upon achievement of certain regulatory and sales milestones, if any. At our option, cash payments specified in the agreement may be paid in shares of Spectrum common stock having a value determined as provided in the asset purchase agreement, equal to the cash payment amount.

In June 2006, we issued to Altair Nanotechnologies, Inc. 140,000 restricted shares of Spectrum common stock, representing partly payment of a milestone pursuant to the license agreement for RenaZorb , and partly additional amounts for transfer of technology related to formulation improvements to RenaZorb developed by Altair. The fair value of the stock, \$574,000, was recorded as a stock-based charge for the six-month period ended June 30, 2006.

#### Common Stock Reserved for Future Issuance

As of June 30, 2006, approximately 15 million shares of common stock were issuable upon conversion or exercise of rights granted under prior financing arrangements and stock options and warrants, as follows:

Conversion of Series D preferred shares	537,479
Conversion of Series E preferred shares	582,000
Exercise of stock options	4,039,042
Exercise of warrants	9,944,363
Total shares of common stock reserved for future issuances	15,102,884

#### **Stock-Based** Compensation

At June 30, 2006, we had three stock incentive plans: the 1991 Stock Incentive Plan (1991 Plan), the 1997 Stock Incentive Plan (1997 Plan) and the 2003 Amended and Restated Incentive Award Plan (2003 Plan), (collectively, the Plans). We are not granting any more options pursuant the 1991 and 1997 Plans. The 2003 Plan authorizes the grant, in conjunction with all of our other plans, of various forms of stock-based awards including incentive and non-statutory stock options, stock purchase rights, stock appreciation rights, and restricted and unrestricted stock awards, for the purchase of up to a total of 30% of our issued and outstanding stock at the time of grant. As of June 30, 2006, approximately 3.0 million incentive awards were available for grant under the 2003 Plan. Stock-based awards vest over periods of up to four years and have a ten-year life.

Below is a summary of activity, for all of our stock incentive plans, during the six-month period ended June 30, 2006:

#### Stock Options:

During the six-month period ended June 30, 2006, the Compensation Committee granted stock options at exercise prices equal to or greater than the quoted price of our common stock on the grant dates. The weighted average grant date fair value of stock options granted during the six-month period ended June 30, 2006, was estimated at approximately \$3.01, using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%; expected volatility of 83.70%; risk free interest rate of 4.63%; and an expected life of five years.

				Aggregate Intrinsic
	Common Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Term (In Years)	Value (In Thousands)
Outstanding at beginning of period	3,661,682	\$ 6.98	(in Fours)	(III I III Justifius)
Granted	445,500	\$ 4.36		
Exercised		\$		
Forfeited	(44,650)	\$ 4.92		
Expired	(23,490)	\$ 7.00		

Outstanding, at the end of period	4,039,042	\$ 6.72	7.20	\$ 1,405
Vested and expected to vest, at end of period	3,968,208	\$ 6.73	7.18	\$ 1,405
Exercisable, at the end of period	2,622,363	\$ 7.19	6.64	\$ 1,404

The aggregate intrinsic value in the table above represents the total difference between the Company s closing common stock price on June 30, 2006 and the exercise price, multiplied by the number of all in-the-money options, that would have been received by the option holders had all option holders exercised their options on June 30, 2006. This amount changes based on the fair market value of the Company s common stock.

During the six-month period ended June 30, 2006, the stock-based charge in connection with the expensing of stock options was \$2.1 million. As of June 30, 2006, there was \$4.8 million of unrecognized stock-based compensation cost related to stock options which is expected to be recognized over a weighted average period of 1.30 years.

#### Restricted Stock:

	Restricted Stock Awards	Av Gra	eighted verage unt date r Value
Nonvested at beginning of period	115,000	\$	4.26
Granted	80,000	\$	4.23
Vested	(48,750)	\$	4.25
Forfeited		\$	
Nonvested, at the end of period	146,250	\$	4.25

The fair value of restricted stock awards is the quoted market price of our stock on the grant date, 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 six-month period ended June 30, 2006, the stock-based charge in connection with the expensing of restricted stock awards was \$194,000. As of June 30, 2006, there was \$512,000 of unrecognized stock-based compensation cost related to nonvested restricted stock awards, which is expected to be recognized over a weighted average period of 2.51 years.

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

In June 2006, we issued 17,709 shares of common stock as the Company s match of 75,000 on the 401(k) contributions of its employees accrued in 2005.

#### Warrants Activity

We typically issue warrants to purchase shares of our common stock to investors as part of a financing transaction, or in connection with services rendered by placement agents and consultants. Our outstanding warrants expire on varying dates through September 2013. Below is a summary of warrant activity during the six-month period ended June 30, 2006. The weighted average grant date fair value of stock options granted during the six-month period ended June 30, 2006, was estimated at approximately \$3.55, using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%; expected volatility of 80.04%; risk free interest rate of 5.21%; and an expected life of five years.

	Common Stock Warrants	Weighted Average Exercise Price	
Outstanding at beginning of period	9,920,703	\$	7.20
Granted	50,000	\$	5.25
Exercised	(5,750)	\$	3.00
Forfeited		\$	
Expired	(20,590)	\$	(163.98)
Outstanding, at the end of period	9,944,363	\$	6.87
Exercisable, at the end of period	9,824,363	\$	6.89

#### 6. Subsequent Events

On July 6, 2006, our stockholders approved an amendment to our Certificate of Incorporation to increase the authorized number of shares of our common stock from 50 million shares to 100 million shares. The amendment was filed with the Delaware Secretary of State on July 7, 2006. Further, on July 7, 2006, we amended the Certificate of Designation of Rights, Preferences and Privileges of Series B Junior Participating Preferred Stock filed with the Delaware Secretary of State on December 18, 2000 to increase the authorized number of Series B Junior Participating Preferred Stock from 200,000 shares to 1,000,000.

On August 4, 2006, we agreed to terminate the supply agreement dated April 16, 2002, by and between J.B. Chemicals & Pharmaceuticals Ltd., or JBCPL, and NeoJB LLC, or NeoJB, an 80% owned subsidiary, whereby in addition to certain named products we also had the right of first refusal on products sold by JBCPL in the U.S. In place of the supply agreement, we have agreed to enter into a new supply agreement between the Company and JBCPL for four specified products, including ciprofloxacin and fluconazole tablets, to be supplied by JBCPL. In addition, pursuant to a share subscription agreement, JBCPL agreed to purchase 120,000 restricted shares of our common stock for \$1 million subject to approval by the appropriate regulatory authorities in India. We have agreed to file a registration statement with the Securities and Exchange Commission to register the shares after they have been issued.

#### 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, and Section 21E of the Securities Exchange Act of 1934, as amended, in reliance upon the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding our future product development activities and costs, the revenue potential (licensing, royalty and sales) of our product candidates, the safety and efficacy of our drug products, the timing and likelihood of achieving development milestones and product revenues, the sufficiency of our capital resources, and other statements containing forward-looking words, such as, believes, may, could, will. expects, intends, estimates. anticipates. continues. Such forward-looking statements are based on the beliefs of the Company's management as well as assumptions made by and information currently available to the Company s 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 below, including under Risk Factors . These factors include, but are not limited to:

our ability to successfully develop, obtain regulatory approvals for and market our products;

our ability to generate and maintain sufficient cash resources to fund in our business;

our ability to enter into strategic alliances with partners for manufacturing, development and commercialization;

our ability to identify new product candidates;

the timing or results of pending or future clinical trials;

competition in the marketplace for our generic drugs;

actions by the FDA and other regulatory agencies;

demand and market acceptance for our approved products; and

the effect of changing economic conditions.

We do not plan to update any such forward-looking statements and expressly disclaim any duty to update the information contained in this report except as required by law.

You should read the following discussion of the financial condition and results of our operations in conjunction with the condensed financial statements and the notes to those financial statements included in Item 1 of Part 1 of this report.

#### Overview

Spectrum Pharmaceuticals, Inc. is a specialty pharmaceutical company engaged in the business of acquiring, developing and commercializing prescription drugs for various indications. While we directly own certain patent rights, the drugs we are currently developing, which are focused

#### Table of Contents

plans.

on the treatment of cancer and other unmet medical needs, are in-licensed from third parties whereby we acquired rights to develop and commercialize those compounds in territories specified in the agreements. We are also actively seeking FDA approval for marketing generic versions of branded drugs whose patent protection has either already expired, or is scheduled to expire in the foreseeable future. We currently have three generic products approved by the FDA for marketing in the United States, ciprofloxacin tablets, fluconazole tablets, and carboplatin injection. In addition, we have a few neurology compounds that we may out-license to third parties for further development.

New drug development is an inherently uncertain, lengthy and expensive process. We focus our research and development efforts principally on clinical stage drug candidates, for which the primary expenses relate to the conduct of clinical trials necessary to demonstrate to the satisfaction of the FDA, and other regulatory authorities in the United States and other countries, that the products are both safe and effective in their respective indications and that they can be produced by a validated consistent manufacturing process. The number, size, scope and timing of the clinical trials necessary to bring a product candidate to development completion and commercialization cannot readily be determined at an early stage, nor, given the timelines of the trials extending over periods of years, can future costs be estimated with precision. While generic drug development is also subject to approval by regulatory authorities, the costs and timelines of development completion and commercialization can be significantly shorter, and compared to new drug development, relatively less uncertain and less expensive.

#### **Business Outlook**

Our primary business focus for 2006, and beyond, will be to continue to acquire, develop and commercialize a portfolio of marketable prescription drug products with a mix of near-term and long-term revenue potential. As of the date of filing this report, we had nine proprietary drug product candidates under development: satraplatin, levofolinic acid, or LFA, EOquin , elsamitrucin, ozarelix, lucanthone, RenaZorb , SPI-1620 and SPI-205. Key developments anticipated in 2006 and early 2007 are:

Satraplatin: Funding for worldwide satraplatin clinical trials is being borne entirely by our co-development partner GPC Biotech and its new sublicensee, Pharmion Corporation. Patient accrual in a phase 3 clinical trial (SPARC (Satraplatin and Prednisone Against Refractory Cancer) trial) was completed in December 2005. The independent Data Monitoring Board, or DMB, performed an interim analysis of the phase 3 data in the second quarter of 2006. The DMB analyzed the efficacy data as assessed by the blinded, independent end point review panel on the first 354 progression-free survival events, available overall survival data, and the safety data from the first 593 patients who have been randomized in the trial and have completed at least one cycle of treatment. After reviewing the data, the DMB reported that the design and conduct of the trial remain sound. In addition, the DMB determined that the trial had also passed the pre-defined futility analysis. As anticipated, the DMB recommended that the trial should continue as planned, and therefore, the trial continues as planned. GPC Biotech and Spectrum Pharmaceuticals remain blinded to the study data. Final study results are expected in the Fall. In December 2005, a rolling NDA filing with the FDA was commenced. Completion of the full NDA filing is expected by the end of 2006.

*Levofolinic acid (LFA):* In April 2006, we completed the acquisition of all of the oncology drug assets of Targent, Inc. The key drug acquired is LFA, the pure active isomer of calcium leucovorin, a component of standard of care 5-fluorouracil, or 5-FU, containing regimens for the treatment of colorectal cancer and other malignancies, for which a new drug application is on file with the FDA. We expect to respond to certain chemistry and manufacturing questions raised by the FDA during the review of the application in the first quarter 2007.

<u>EOquin</u>: In early 2006, we held a pre-IND and end of phase 2 meeting with the FDA and recently filed an IND with the FDA, with the view to initiating phase 3 trials in the United States before the end of 2006 to evaluate EOquin in superficial bladder cancer, after completion of a 20-patient pilot study which recently commenced.

<u>Ozarelix</u>: We expect final results from the hormone-dependent prostate cancer (HDPC) and benign prostatic hypertrophy (BPH) phase 2 trials in the fourth quarter of 2006. Based on those results we will determine the next regulatory and clinical steps. Also, we plan to initiate a study in healthy female volunteers for endometriosis in Europe in the second half of 2006. A license and collaboration agreement has been signed with Nippon Kayaku for the Japanese oncology market, for which Spectrum is entitled to receive fifty percent of the upfront, milestone and royalty payments.

We plan to continue to fund the development of lucanthone, elsamitrucin, RenaZorb, SPI-1620 and SPI-205.

We expect to continue to evaluate additional promising drug product candidates for acquisition or license.

We have recorded only modest revenues to date from generic product sales, due primarily to our late entry into the market for each of our approved generic drugs. We are unable at this time to reliably estimate recurring revenues or profits from these generic products in the foreseeable future. We have observed significant price declines in the

marketplace for each of our marketed products, due to the FDA s approval of several competing ANDAs, and the resultant glut of product introduced on and after the generic product launch dates. We continue to explore sales opportunities for our products. If we are successful in our patent challenge for sumatriptan succinate injection, and obtain 180-day marketing exclusivity as the only FDA approved generic version of this product, the resulting revenues could be significant. We recently entered into a strategic alliance with Par Pharmaceutical Companies, Inc., or Par, for the marketing of our current as well as certain future generic drugs. In addition, Par shall provide financial and legal support, including payment of legal expenses going forward, for the litigation regarding sumatriptan succinate injection. With three generic drugs already approved and additional approvals expected this year, we hope to see success from the sale of these drugs in the next twelve months.

#### **Financial Condition**

#### Liquidity and Capital Resources

Our current business operations do not generate sufficient operating cash to finance the clinical development of our drug product candidates. Our cumulative losses, since inception in 1987, through June 30, 2006, have exceeded \$190 million. We expect to continue to incur significant additional losses as we implement our growth strategy of developing marketable drug products for at least the next several years unless they are offset, if at all, by licensing revenues under our out-license agreement with GPC Biotech or from the out-license of any of our other proprietary products and any profits from the sale of generic products.

We believe that the approximately \$55 million in cash, cash equivalents and marketable securities that we had on hand as of June 30, 2006, will allow us to fund our current planned operations for at least the next twelve months. Our long-term strategy is to generate profits from the sale and licensing of our propriety drug products. In the next several years, we anticipate supplementing our cash position with licensing and royalties revenues under our out-license agreement with GPC Biotech, licensing revenues from out-licensing our other proprietary products and milestone payments and profits from the sale of our generic products by Par. Under the agreement with Par, not counting our share of the profits from sales of the generic drugs, the Company could receive an aggregate of over \$10 million under the agreement if a specified equity investment is made and the necessary regulatory approvals are obtained. If GPC Biotech successfully completes the filing of the NDA as planned, we will realize licensing revenues in late 2006 from licensing milestones specified in the agreement.

However, if we are unable to generate the necessary revenues to finance our operations long-term, we may have to seek additional capital through the sale of our equity. Our operations have historically been financed by the issuance of capital stock. To this effect, we have a shelf registration statement with approximately \$32 million available for the sale of our securities. In addition, we could receive a significant amount of cash from the exercise of outstanding warrants and options, if the price of our common stock appreciates. It is generally difficult to fund pharmaceutical research and development via borrowings due to the significant expenses involved, lack of revenues sufficient to service debt and the significant inherent uncertainty as to results of research and the timing of those results.

As described elsewhere in this report, including in Item 1A under Risk Factors, our drug development efforts are subject to the considerable uncertainty inherent in any new drug development. Due to the uncertainties involved in progressing through clinical trials, and the time and cost involved in obtaining regulatory approval and in establishing collaborative arrangements, among other factors, we cannot reasonably estimate the timing and ultimate aggregate cost of developing each of our drug product candidates, and are similarly unable to reasonably estimate when, if ever, we will realize material net cash inflows from our proprietary drug product candidates. Accordingly, the following discussion of our current assessment of the need for cash to fund our operations may prove too optimistic and our assessment of expenditures may prove inadequate.

Our expenditures for research and development and general and administrative expenses consist of direct product specific costs and non-product specific, or indirect, costs. The following describes our current assessment of direct, or product specific development costs, such as upfront license fees, milestone payments, active pharmaceutical ingredient, clinical trials, patent related legal costs, and product liability insurance, among others, for each significant proprietary product, and generics as a group, currently under development. These costs are subject to uncertainties inherent in new drug development. Additionally, we may shift our cash resources between products. Therefore, what we actually spend to develop a particular product may not fall within the estimated range and the estimated ranges may change from quarter to quarter based upon changes in priorities or strategy and/or the results of the development. While we do not receive any funding from third parties for research and development we conduct, our estimated costs could be mitigated should we enter into co-development agreements for any of our drug product candidates.

<u>Satraplatin</u>: The costs of conducting clinical trials worldwide are being borne entirely by our co-development partner GPC Biotech and its sublicensee, Pharmion Corporation. While we have licensed the development of satraplatin to GPC Biotech, we are not obligated to reimburse GPC Biotech for development costs they incur or to refund any license or milestone payments we receive.

<u>Levofolinic acid (LFA)</u>: In April 2006, we acquired the rights to the NDA filing pending at the FDA. During the six-month period ended June 30, 2006, excluding indirect costs, we spent approximately \$0.6 million on the development of LFA. In order to complete the NDA filing to the satisfaction of the FDA, we anticipate that over the next twelve months we may incur development costs up to approximately \$2 million.

<u>EQuuin</u>: During the six-month period ended June 30, 2006, excluding indirect costs, we spent approximately 0.8 million on the development of EQuuin . Estimated expenditures for the next twelve months are subject to considerable uncertainty, and are largely dependent on the outcome of continuing discussions with the FDA regarding our planned phase 3 clinical trial. We anticipate that over the next twelve months we could incur development costs up to approximately 6 million.

<u>Ozarelix</u>: During the six-month period ended June 30, 2006, excluding indirect costs, we spent approximately \$0.6 million on the development of ozarelix. Estimated expenditures for the next twelve months are subject to considerable uncertainty, and are largely dependent on the results from the analysis of the complete phase 2 study data, expected in the fourth quarter of 2006, and the initiation of a study in healthy female volunteers for endometriosis in Europe in the second half of this year. We anticipate that over the next twelve months we could incur development costs up to approximately \$6 million.

<u>Elsamitrucin</u>: During the six-month period ended June 30, 2006, excluding indirect costs, we incurred approximately \$0.3 million on the development of elsamitrucin. Estimated expenditures for the next twelve months are subject to considerable uncertainty, and are largely dependent on positive results from the analysis of the phase 2 study data as well as other pilot combination studies.

*Lucanthone*: During the six-month period ended June 30, 2006, excluding indirect costs, we incurred approximately \$0.3 million on the development of lucanthone. Estimated expenditures for the next twelve months are subject to considerable uncertainty, and are largely dependent on the timing of the continuation of the phase 2 clinical trial.

<u>RenaZorb</u>: During the six-month period ended June 30, 2006, excluding indirect costs, we incurred less than \$250,000 on the development of RenaZorb. Estimated expenditures for the next twelve months are subject to considerable uncertainty, and are largely dependent on the results of our preclinical work and the initiation of any clinical trials.

<u>SPI-1620</u>: During the six-month period ended June 30, 2006, excluding indirect costs, we incurred approximately \$0.7 million on the development of SPI-1620. Estimated expenditures for the next twelve months are subject to considerable uncertainty, and are largely dependent on the results of our preclinical work and the initiation of any clinical trials.

<u>SPI-205</u>: During the six-month period ended June 30, 2006, excluding indirect costs described earlier, we incurred less than \$250,000 on the development of SPI-205. Estimated expenditures for the next twelve months are subject to considerable uncertainty, and are largely dependent on the results of our preclinical work and the initiation of any clinical trials.

<u>Generic Drugs</u>: During the six-month period ended June 30, 2006, excluding indirect costs, we incurred approximately \$0.6 million for the advancement of our generic drugs, including costs for products for which we anticipate filing ANDAs in the future. In addition to the foregoing 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 our research and development expenditures would likely increase.

Under our various existing licensing agreements, we are contingently obligated to make milestone payments. In connection with the development of certain in-licensed drug products, we anticipate the occurrence of certain of these milestones over the next eighteen months. Upon successful achievement of these milestones, we will likely become obligated to pay up to approximately \$5 million in cash and issue approximately 500,000 shares of our common stock during the eighteen-month period.

#### Net Cash used in Operating Activities

During the six-month period ended June 30, 2006, the net cash used in operations was approximately \$8.9 million, net of interest income of approximately \$1.3 million.

Based on our current plans and the scope of our activities, our anticipated use of cash for operations over the next twelve months, excluding the cost of in-licensing any additional drug products, is expected to average between approximately \$5 million and \$7.5 million per quarter. Our cash expenses may increase or decrease beyond this range depending on the results of the ongoing clinical trials and research and development activity.

#### Net Cash provided by and used for Investing Activities

While cash preservation is our primary investment goal, in order to maximize the interest yield on our investments, we invest our cash in a variety of investments pending its use in our business. During the six-month period ended June 30, 2006, we reinvested our funds with Lehman Brothers acting as primary cash manager. This reinvestment resulted in the net conversion of approximately \$15 million of cash and cash equivalents into marketable securities.

#### Net Cash provided by and used for Financing Activities

During the six-month period ended June 30, 2006, we received approximately \$17,000 from the exercise of an outstanding warrant for 5,750 shares of our common stock.

#### **Results of Operations**

#### Results of Operations for the three-month period ended June 30, 2006 Compared to the three-month period ended June 30, 2005

For the three-month period ended June 30, 2006, we incurred a net loss of approximately \$9.0 million compared to a net loss of approximately \$4.6 million in the three-month period ended June 30, 2005. The increase of approximately \$4.4 million in the net loss was primarily due to increases in stock-based charges resulting from the adoption, effective January 1, 2006, of SFAS 123(R), and the issuance of common stock to Targent, Inc. in connection with the acquisition