

SPECTRUM PHARMACEUTICALS INC  
Form 10-Q  
November 03, 2006

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

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 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)

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

**157 Technology Drive**  
**Irvine, California**  
(Address of Principal Executive Offices)

**92618**  
(Zip Code)

Registrant's Telephone Number, Including Area Code: (949) 788-6700

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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 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  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

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

| Class                          | Outstanding at November 2, 2006 |
|--------------------------------|---------------------------------|
| Common Stock, \$.001 par value | 25,093,480                      |

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**SPECTRUM PHARMACEUTICALS, INC.**

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**FORM 10-Q**

**For the three-month and nine-month periods ended September 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)

|   | September 30, 2006                                 | December 31, 2005 |
|---|--|-------------------|
|   | (In Thousands,<br>Except Share and Per Share Data) |                   |
| <b>Assets</b>   |  |                   |
| Current Assets:   |  |                   |
| Cash and cash equivalents   | \$ 4,263   | \$ 28,750         |
| Marketable securities   | 46,189   | 34,917            |
| Accounts Receivable   | 1,214  | 287               |
| Inventory   |  | 58                |
| Prepaid expenses and other current assets   | 293  | 373               |
| Total current assets  | 51,959   | 64,385            |
| Property and equipment, net   | 578  | 562               |
| Other Assets  | 197  | 128               |
| Total assets  | \$ 52,734  | \$ 65,075         |
| <b>Liabilities and Stockholders' Equity</b>   |  |                   |
| Current Liabilities:  |  |                   |
| Accounts payable  | \$ 2,596   | \$ 1,220          |
| Accrued compensation  | 672  | 683               |
| Accrued clinical study costs  | 3,049  | 1,925             |
| Total current liabilities   | 6,317  | 3,828             |
| Deferred revenue and other credits  | 1,066  | 241               |
| Total liabilities   | 7,383  | 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, 1,000,000 shares authorized, no shares issued and outstanding  |  |                   |
| Series D 8% Cumulative Convertible Voting Preferred Stock, 600 shares authorized, stated value \$10,000 per share, liquidation value \$1,524, issued and outstanding 127 shares at September 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 September 30, 2006 and December 31, 2005                          |  |                   |
|   | 1,795  | 1,795             |
| Common stock, par value \$0.001 per share, 100,000,000 shares authorized:   |  |                   |
| Issued and outstanding, 24,485,369 and 23,503,157 shares at September 30, 2006 and December 31, 2005, respectively  |  |                   |
|   | 24   | 24                |
| Additional paid-in capital  | 249,375  | 243,656           |
| Deferred stock-based compensation   |  | (783 )            |
| Accumulated other comprehensive income  | 255  | (26 )             |
| Accumulated deficit   | (206,723 )   | (184,430 )        |
| Total stockholders' equity  | 45,330   | 60,983            |
| Total liabilities and stockholders' equity  | \$ 52,734  | \$ 65,075         |

The accompanying notes are an integral part of these condensed consolidated balance sheets.



## Condensed Consolidated Statements of Operations

(Unaudited)

|  | Three-Months<br>Ended<br>September 30, 2006        | Three-Months<br>Ended<br>September 30, 2005 | Nine-Months<br>Ended<br>September 30, 2006         | Nine-Months<br>Ended<br>September 30, 2005 |
|--|--|---|--|--|
|  | (In Thousands,<br>Except Share and Per Share Data) |   | (In Thousands,<br>Except Share and Per Share Data) |  |
| <b>Revenues</b>  |  |   |  |  |
| Licensing fees   | \$   | \$ 56                                       | \$   | \$ 56                                      |
| Product sales  | 92   | 128   | 92   | 368  |
| Total revenues   | \$ 92  | \$ 184                                      | \$ 92  | \$ 424                                     |
| <b>Operating expenses:</b>                                   |  |   |  |  |
| Cost of product sold   | \$ 97  | \$ 103                                      | \$ 97  | \$ 324                                     |
| Research and development                                     | 5,803  | 3,252                                       | 13,554   | 10,319                                     |
| General and administrative                                   | 1,516  | 2,152                                       | 4,379  | 4,721                                      |
| Stock-based charges  | 738  | 169   | 6,306  | 863  |
| Total operating expenses                                     | 8,154  | 5,676                                       | 24,336   | 16,227                                     |
| Loss from operations   | (8,062 )   | (5,492 )                                    | (24,244 )  | (15,803 )                                  |
| Other income, net  | 660  | 264   | 1,949  | 754  |
| Net loss before minority interest in consolidated subsidiary | (7,402 )   | (5,228 )                                    | (22,295 )  | (15,049 )                                  |
| Minority interest in net loss of consolidated subsidiary     |  |   | 2  | 4  |
| <b>Net loss</b>  | <b>\$ (7,402 )</b>                                 | <b>\$ (5,228 )</b>                          | <b>\$ (22,293 )</b>                                | <b>\$ (15,045 )</b>                        |
| Basic and diluted net loss per share                         | \$ (0.30 )   | \$ (0.32 )                                  | \$ (0.93 )   | \$ (0.96 )                                 |
| Basic and diluted weighted average common shares outstanding | 24,485,369   | 16,666,960                                  | 23,934,749   | 15,723,509                                 |
| <b>Supplemental Information</b>                              |  |   |  |  |
| <b>Stock-based charges - Components:</b>                     |  |   |  |  |
| Research and development                                     | \$ 447   | \$ 147                                      | \$ 5,233   | \$ 801                                     |
| General and administrative                                   | 291  | 22  | 1,073  | 62   |
| Total stock based charges                                    | \$ 738   | \$ 169                                      | \$ 6,306   | \$ 863                                     |

The accompanying notes are an integral part of these condensed consolidated balance sheets.

## Condensed Consolidated Statements of Cash Flows

(Unaudited)

|   | Nine-Months<br>Ended<br>September 30, 2006         | Nine-Months<br>Ended<br>September 30, 2005 |
|---|--|--|
|   | (In Thousands,<br>Except Share and Per Share Data) |  |
| <b>Cash Flows From Operating Activities:</b>                                |  |  |
| Net loss  | \$ (22,293 )                                       | \$ (15,045 )                               |
| Adjustments to reconcile net loss to net cash used in operating activities: |  |  |
| Depreciation and amortization   | 145  | 175  |
| Amortization of deferred stock-based compensation                           | 2,990  | 269  |
| 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:                                |  |  |
| Increase in Accounts Receivable   | (927 )   | (155 )                                     |
| Decrease in Inventory   | 58   | 81   |
| Decrease in other assets  | 80   | 239  |
| Increase in accounts payable and accrued expenses                           | 2,536  | 3,098                                      |
| Decrease in accrued compensation and related taxes                          | (11 )  | (426 )                                     |
| Increase in other non-current liabilities                                   | 825  | 66   |
| Net cash used in operating activities                                       | (13,283 )  | (11,108 )                                  |
| <b>Cash Flows From Investing Activities:</b>                                |  |  |
| (Purchases) sales of marketable securities, net                             | (11,060 )  | 35,861                                     |
| Purchases of property and equipment   | (161 )   | (126 )                                     |
| Net cash provided by (used in) investing activities                         | (11,221 )  | 35,735                                     |
| <b>Cash Flows From Financing Activities:</b>                                |  |  |
| Proceeds from issuance of common stock                                      |  | 40,117                                     |
| Proceeds from exercise of warrants  | 17   | 1,052                                      |
| Repurchase of Warrants  |  | (420 )                                     |
| Proceeds from exercise of stock options                                     |  | 5  |
| Net cash provided by financing activities                                   | 17   | 40,754                                     |
| Net increase (decrease) in cash and cash equivalents                        | (24,487 )  | 65,381                                     |
| Cash and cash equivalents, beginning of period                              | 28,750   | 3,241                                      |
| Cash and cash equivalents, end of period                                    | \$ 4,263   | \$ 68,622                                  |
| <b>Supplemental Cash Flow Information:</b>                                  |  |  |
| Interest paid   | \$ 3   | \$   |
| Income taxes paid   | \$ 1   | \$ 1                                       |
| <b>Schedule of Non-Cash Investing and Financing Activities:</b>             |  |  |
| Preferred stock dividends paid with common stock                            | \$ 55  | \$ 95                                      |
| Fair value of common stock issued in connection with drug license           | \$ 3,316   | \$ 594                                     |
| Fair value of options and warrants issued to consultants for services       | \$ 237   | \$ 693                                     |
| Fair value of restricted stock granted employees and directors              | \$ 338   |  |
| Fair value of stock issued to match employee 401k contributions             | \$ 75  |  |

The accompanying notes are an integral part of these condensed consolidated balance sheets.



**Notes to Condensed Financial Statements**

**September 30, 2006**

**(Unaudited)**

**1. Business and Basis of Presentation**

***Business***

Spectrum Pharmaceuticals, Inc., or the Company, is a 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 nine-month periods ended September 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 September 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

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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.

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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. 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 September 30, 2006 and 2005, all potentially dilutive common stock equivalents amounted to approximately 15 million shares.

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

|  | Three-Months<br>Ended<br>September 30, 2006     | Three-Months<br>Ended<br>September 30, 2005 | Nine-Months<br>Ended<br>September 30, 2006 | Nine-Months<br>Ended<br>September 30, 2005 |
|--|---|---|--|--|
|  | (In Thousands, Except Share and Per Share Data) |   |  |  |
| Net loss   | \$ (7,402 )                                     | \$ (5,228 )                                 | \$ (22,293 )                               | \$ (15,045 )                               |
| Less:  |   |   |  |  |
| Preferred dividends paid in cash or stock  | (26 )   | (32 )                                       | (81 )                                      | (95 )                                      |
| Income available to common stockholders used in computing basic earnings per share | \$ (7,428 )                                     | \$ (5,260 )                                 | \$ (22,374 )                               | \$ (15,140 )                               |
| <b>Weighted average shares outstanding</b>   | 24,485,369                                      | 16,666,960                                  | 23,934,749                                 | 15,723,509                                 |
| Basic and diluted net loss per share   | \$ (0.30 )                                      | \$ (0.32 )                                  | \$ (0.93 )                                 | \$ (0.96 )                                 |

**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

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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.

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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<br>Ended<br>September 30, 2005        | Nine-Months<br>Ended<br>September 30, 2005 |
|---|--|--|
|   | (In Thousands,<br>Except Share and Per Share Data) |  |
| Net loss, as reported   | \$ (5,228 )  | \$ (15,045 )                               |
| Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects | (803 )   | (3,582 )                                   |
| Pro forma net loss  | \$ (6,031 )  | \$ (18,627 )                               |
| Loss per share:   |  |  |
| Basic and diluted as reported   | \$ (0.32 )   | \$ (0.96 )                                 |
| Basic and diluted pro forma   | \$ (0.36 )   | \$ (1.19 )                                 |
| <b><i>Comprehensive Loss</i></b>  |  |  |

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

We are developing our proprietary drugs for the treatment of a variety of cancers and other unmet medical needs. As of September 30, 2006, we had several proprietary drugs under development, and through the date of this report we have filed multiple, and received approval for some, Abbreviated New Drug Applications, or ANDAs, with the U.S. Food and Drug Administration, or FDA.

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.

*Par Pharmaceutical Companies Inc.*: 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. 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 an at least 50% 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 for the ongoing patent challenge for sumatriptan succinate injection.

*J.B. Chemicals & Pharmaceuticals Ltd.*: In August 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.

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*Products under development*

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

Satraplatin: Satraplatin is an orally administered chemotherapeutic agent that is being studied for the treatment of hormone refractory prostate cancer in a phase 3 clinical trial. In September 2006, we announced positive results from the trial, which is being conducted by our development partner, GPC Biotech AG, or GPC Biotech. A rolling submission of a New Drug Application, or NDA, with the FDA had commenced in December 2005, and is expected to complete in the fourth quarter of 2006. Acceptance of the NDA by the FDA will trigger a milestone payment from GPC Biotech to us.

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 to market levofolinic acid, or 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. Calcium leucovorin is also used after the administration of high-dose methotrexate in treating certain malignancies. A NDA for LFA has been filed with the FDA for the osteosarcoma indication. We expect to respond in early 2007 to certain chemistry and manufacturing questions raised by the FDA during the review of the application.

EOquin : 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 (non-invasive) bladder cancer. Earlier in 2006, we held a pre-IND and end of phase 2 meeting with the FDA and have filed an IND with the FDA, with the view to initiating phase 3 trials in the United States in the next few months to evaluate EOquin in superficial (non-invasive) bladder cancer after completion of a 20-patient pilot study which has recently begun and approval of a special protocol assessment by the FDA.

Ozarelix: 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 (BPH). Evaluation of the data from the Phase 2 clinical trials in each of those indications is proceeding. We recently announced preliminary data from these trials, and anticipate commencing a phase 3 clinical trial in BPH in 2007. The successful conclusion of a phase 2 trial, such that the data support the commencement of a phase 3 trial, triggers a milestone payment to Aeterna Zentaris, from whom we licensed ozarelix. Accordingly, we accrued approximately \$1.3 million for such potential payment.

Aeterna Zentaris recently entered into a licensing and collaboration agreement, with a third party, for the development and marketing of ozarelix in Japan, and received certain upfront payments. Under the terms of our license agreement with Aeterna Zentaris, we are entitled to receive fifty percent of the upfront and milestone payments and royalties Aeterna Zentaris receives for such rights in Japan. As of September 30, 2006, we have recorded, as deferred revenue, an estimate of our share of these upfront payments. Such deferred revenue will be amortized to income in accordance with our revenue recognition policy, namely when we have no significant future performance obligations and collectibility of the fees is assured.

#### **4. Commitments and Contingencies**

*Facility and Equipment Leases*

As of September 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.

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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:

| <b>Year ending December 31:</b> | <b>Lease Commitments</b>    | <b>Sub-Lease Commitments</b> |
|---------------------------------|-----------------------------|------------------------------|
|                                 | <b>Amounts In Thousands</b> |                              |
| 2006 (Remainder of Year)        | \$ 116                      | \$ 57                        |
| 2007                            | \$ 474                      | \$ 171                       |
| 2008                            | \$ 494                      | \$                           |
| 2009                            | \$ 253                      | \$                           |
| Thereafter                      | \$ 5                        | \$                           |
|                                 | \$ 1,342                    | \$ 228                       |

### *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 each of the United States, Europe and Japan, and approvals from each of 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. 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 twelve months. If the anticipated milestones are achieved, we will likely become obligated to issue approximately 250,000 restricted shares of our common stock and pay up to approximately \$4 million in cash during the twelve-month period. If all of our contingent milestones were achieved, our potential contingent cash development and regulatory milestone obligations, aggregating approximately \$48 million as of September 30, 2006, would be due approximately as follows: \$4 million in less than 1 year; \$3 million between 1 and 3 years; \$2 million between 3 and 5 years; and \$39 million after 5 years.

### *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, 2007 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 shall immediately vest and will be exercisable for one year

from the date of termination; provided, however, if the board determines that 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**

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

We are party to various other 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.

**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 payment of a milestone pursuant to the license agreement for RenaZorb, as well as 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 nine-month period ended September 30, 2006.

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.

**Common Stock Reserved for Future Issuance**

As of September 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   | 4,282,092         |
| Exercise of warrants  | 9,939,363         |
| <b>Total shares of common stock reserved for future issuances</b> | <b>15,340,934</b> |

**Stock-Based Compensation**

At September 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

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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

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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 September 30, 2006, approximately 2.8 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 nine-month period ended September 30, 2006:

Stock Options:

During the nine-month period ended September 30, 2006, we 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 nine-month period ended September 30, 2006, was estimated at approximately \$3.04, using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%; expected volatility of 79.60%; risk free interest rate of 4.61%; and an expected life of five years.

|  | Common<br>Stock<br>Options | Weighted<br>Average<br>Exercise<br>Price | Weighted<br>Average<br>Remaining Term<br><br>(In Years) | Aggregate<br>Intrinsic<br>Value<br><br>(In Thousands) |
|--|----------------------------|--|---|---|
| <b>Outstanding at beginning of period</b>            | 3,661,682                  | \$ 6.98                                  |   |   |
| Granted  | 746,500                    | \$ 4.57                                  |   |   |
| Exercised  |                            | \$                                       |   |   |
| Forfeited  | (51,877 )                  | \$ 3.29                                  |   |   |
| Expired  | (74,213 )                  | \$ 8.22                                  |   |   |
| <b>Outstanding, at the end of period</b>             | 4,282,092                  | \$ 6.59                                  | <b>7.10</b>   | <b>\$ 3,223</b>                                       |
| <b>Vested and expected to vest, at end of period</b> | 4,212,301                  | \$ 6.60                                  | <b>7.08</b>   | <b>\$ 3,189</b>                                       |
| <b>Exercisable, at the end of period</b>             | 2,886,267                  | \$ 7.03                                  | <b>6.54</b>   | <b>\$ 2,545</b>                                       |

The aggregate intrinsic value in the table above represents the total difference between the Company's closing common stock price on September 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 September 30, 2006. This amount changes based on the fair market value of the Company's common stock.

During the nine-month period ended September 30, 2006, the stock-based charge in connection with the expensing of stock options was \$2.7 million. As of September 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 2.44 years.

Restricted Stock:

|   | Restricted<br>Stock<br>Awards | Weighted<br>Average<br>Grant date<br>Fair Value |
|---|-------------------------------|---|
| <b>Nonvested at beginning of period</b> | 115,000                       | \$ 4.26   |
| Granted                                 | 80,000                        | \$ 4.23   |
| Vested                                  | (48,750 )                     | \$ 4.25   |
| Forfeited                               |                               | \$  |
| <b>Nonvested, at the end of period</b>  | 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 nine-month period ended September 30, 2006, the stock-based charge in connection with the expensing of restricted stock awards was \$245,000. As of September 30, 2006, there was \$461,000 of unrecognized stock-based compensation cost related to nonvested restricted stock awards, which is expected to be recognized over a weighted average period of 2.26 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. As of September 30, 2006, we accrued approximately \$101,000 in connection with the Company's match for 2006 through that date; and in October 2006, we issued 22,197 shares of common stock as the Company's match.

**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 nine-month period ended September 30, 2006. The weighted average grant date fair value of warrants granted during the nine-month period ended September 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<br>Warrants | Weighted Average<br>Exercise Price |
|---|--------------------------|------------------------------------|
| <b>Outstanding at beginning of period</b> | 9,920,703                | \$ 7.20                            |
| Granted                                   | 50,000                   | \$ 5.25                            |
| Repurchased                               |                          | \$                                 |
| Exercised                                 | (5,750 )                 | 3.00                               |
| Forfeited                                 |                          |                                    |
| Expired                                   | (25,590 )                | \$ (150.50 )                       |
| <b>Outstanding, at the end of period</b>  | <b>9,939,363</b>         | <b>\$ 6.83</b>                     |
| <b>Exercisable, at the end of period</b>  | <b>9,839,363</b>         | <b>\$ 6.84</b>                     |



## 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, plans, 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 as well as those discussed in our periodic reports filed with the Securities and Exchange Commission including our Annual Report on Form 10-K. 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 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 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 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 a few generic products approved by the FDA for marketing in the United States. In addition, we have a few neurology compounds that we may out-license to third parties for further development.

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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.

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## 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. Key developments anticipated in the next 12 to 18 months are:

- ***Satraplatin:*** In September 2006, we announced positive results from the phase 3 trial conducted by our development partner, GPC Biotech AG, or GPC Biotech. A rolling submission of a New Drug Application, or NDA, with the FDA had commenced in December 2005, and is expected to complete in the fourth quarter of 2006. A European marketing application is expected to be filed in the first half of 2007.
- ***Levofolinic acid (LFA):*** We expect to respond in early 2007 to certain chemistry and manufacturing questions raised by the FDA during the review of the NDA for LFA.
- ***EOquin*** : We intend to initiate phase 3 trials in the United States in the next few months to evaluate EOquin in superficial (non-invasive) bladder cancer after completion of a 20-patient pilot study which recently commenced and after approval of a special protocol assessment by the FDA.
- ***Ozarelix:*** 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 (BPH). Evaluation of the data from the Phase 2 clinical trials in each of those indications is proceeding. We recently announced preliminary data from these trials, and anticipate commencing a phase 3 clinical trial in BPH in 2007. Also, we plan to initiate a study in healthy female volunteers for endometriosis in Europe over the next several months after approval is received from the appropriate regulatory authorities.
- ***Sumatriptan succinate injection:*** In connection with this ANDA, we are challenging GlaxoSmithKline's patent. Trial is set for November 13, 2006. Pursuant to our agreement with Par, Par shall provide financial and legal support, including payment of legal expenses for the sumatriptan litigation.

## 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 September 30, 2006, have exceeded \$200 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 \$50 million in cash, cash equivalents and marketable securities that we had on hand as of September 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 proprietary 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 including our share of the profits from sales of the generic drugs, we 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 2007 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

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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

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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 ingredients, clinical trials, patent related legal costs, and product liability insurance, among others, for each significant proprietary drug product, and other proprietary and generic drug products 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.

- Satraplatin: The costs of conducting clinical trials worldwide are being borne entirely by our co-development partner GPC Biotech and its sublicensee. 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. In connection with the milestone obligations related to satraplatin, each of our contingent future payment obligations is generally matched by a corresponding, greater milestone payment obligation of GPC Biotech to us.
- Levofolinic acid (LFA): In April 2006, we acquired the rights to the NDA filing pending at the FDA. During the nine-month period ended September 30, 2006, excluding indirect costs, we spent approximately \$1.1 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 \$1.5 million.
- EOquin : During the nine-month period ended September 30, 2006, excluding indirect costs, we spent approximately \$1.8 million on the development of EOquin . 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.
- Ozarelix: During the nine-month period ended September 30, 2006, excluding indirect costs, we spent approximately \$2.2 million on the development of ozarelix, including an accrual for an anticipated milestone payment. Estimated expenditures for the next twelve months are subject to considerable uncertainty, and are largely dependent on the final results from the analysis of the complete phase 2 study data, and on the outcome of 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.
- SPI-1620: During the nine-month period ended September 30, 2006, excluding indirect costs, we incurred approximately \$1.1 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.
- Other: During the nine-month period ended September 30, 2006, excluding indirect costs, we incurred approximately \$2.0 million on the development of other proprietary and generic drug products, including costs for products for which we anticipate filing ANDAs in the future. Estimated expenditures for the next twelve months are subject to considerable uncertainty, and are largely dependent on continued positive results from our preclinical studies, and the initiation of any clinical trials.

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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 twelve months. Upon successful achievement of these milestones, we will likely become obligated to pay up to approximately \$4 million in cash and issue approximately 250,000 shares of our common stock during the twelve-month period.

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*Net Cash used in Operating Activities*

During the nine-month period ended September 30, 2006, the net cash used in operations was approximately \$13.3 million, net of interest income of approximately \$2.0 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 exceed the approximately \$5 million average during recent quarters. As discussed above under *Liquidity and Capital Resources*, estimated expenditures for the next twelve months are subject to considerable uncertainty, and are largely dependent on continued positive results from our preclinical studies, and the initiation of any clinical trials, the final results from current phase 2 study data, and on the outcome of discussions with the FDA regarding our planned phase 3 clinical trials.

*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 nine-month period ended September 30, 2006, we reinvested our funds with Lehman Brothers acting as primary cash manager. This reinvestment resulted in the net conversion of approximately \$11 million of cash and cash equivalents into marketable securities.

*Net Cash provided by and used for Financing Activities*

During the nine-month period ended September 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 September 30, 2006 Compared to the three-month period ended September 30, 2005***

During the three-month period ended September 30, 2006, we incurred a net loss of approximately \$7.4 million compared to a net loss of approximately \$5.2 million in the three-month period ended September 30, 2005. The increase of approximately \$2.2 million in the net loss was primarily due to increases in research and development expense, partially offset by a decrease in legal expense.

During the three-month period ended September 30, 2005, we had \$56,000 of revenues representing amounts received from the GPC Biotech under our license agreement for commissions on drug products used by GPC Biotech in clinical trials. The timing and amount of future commissions is neither predictable nor assured. Generic product sales were \$92,000 and \$128,000 during the three-month periods ended September 30, 2006 and 2005, respectively. Future product sales are dependent on our distributors reordering the product from us.

Research and development expenses increased by approximately \$2.5 million, from approximately \$3.3 million in the three-month period ended September 30, 2005 to approximately \$5.8 million in the three-month period ended September 30, 2006, due to the expanded scope of our research and development activities, including an increase in the number of personnel in preparation for the commencement of a phase 3 trial for EOquin in the next few months. Approximately \$1.3 million of the increase is attributable to an accrual for a milestone payable upon the successful conclusion of a phase 2 trial for ozarelix, such that the data support the commencement of a phase 3 trial.

General and administrative expenses decreased by approximately \$0.7 million, from approximately \$2.2 million in the three-month period ended September 30, 2005 to approximately \$1.5 million in the three-month period ended September 30, 2006, primarily due to a decrease in legal expense in connection with the lawsuit regarding our patent challenge of GlaxoSmithKline's Imitrex® injection. As described elsewhere in this report, the agreement with Par for the distribution of our generic products obligates Par to provide financial and legal support, including the payment of all legal expenses, for the ongoing patent challenge for sumatriptan succinate injection.

Stock-based charges increased by approximately \$0.5 million from \$0.2 million in the three-month period ended September 30, 2005 to approximately \$0.7 million in the three-month period ended September 30, 2006, primarily due to our adoption of SFAS 123(R), effective January 1, 2006.

Other income consisted of net interest income of approximately \$0.7 million for the three-month period ended September 30, 2006 and approximately \$0.3 million for the three-month period ended September 30, 2005. The increase of





approximately \$0.4 million is attributable to significantly higher average interest rates and balances of investable funds in 2006.

***Results of Operations for the nine-month period ended September 30, 2006 Compared to the nine-month period ended September 30, 2005***

During the nine-month period ended September 30, 2006, we incurred a net loss of approximately \$22.3 million compared to a net loss of approximately \$15.0 million in the nine-month period ended September 30, 2005. The increase of approximately \$7.3 million in the net loss was primarily due to increases in research and development expense, partially offset by a decrease in legal expense, and 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 of its oncology assets; and the issuance of common stock to Altair Nanotechnologies, Inc. in connection with a payment to Altair Nanotechnologies, Inc., the licensor of RenaZorb , of a milestone pursuant to our license agreement and additional amounts for transfer of technology related to formulation improvements to RenaZorb .

During the nine-month period ended September 30, 2005, we also recorded \$56,000 of revenues representing amounts received from the GPC Biotech under our license agreement for commissions on drug products used by GPC Biotech in clinical trials. The timing and amount of future commissions is neither predictable nor assured. Generic product sales were \$92,000 and \$368,000 during the nine-month periods ended September 30, 2006 and 2005, respectively. Future product sales are dependent on our distributors reordering the product from us.

Research and development expenses increased by approximately \$3.3 million, from approximately \$10.3 million in the nine-month period ended September 30, 2005 to approximately \$13.6 million in the nine-month period ended September 30, 2006, due to the expanded scope of our research and development activities, including an increase in the number of personnel in preparation for the commencement of a phase 3 for EOquin in the next few months. Approximately \$1.3 million of the increase is attributable to an accrual for a milestone payable upon the successful conclusion of a phase 2 trial for ozarelix, such that the data support the commencement of a phase 3 trial.

General and administrative expenses decreased by approximately \$0.3 million, from approximately \$4.7 million in the nine-month period ended September 30, 2005 to approximately \$4.4 million in the nine-month period ended September 30, 2006, primarily due to a decrease in legal expense in connection with the lawsuit regarding our patent challenge of GlaxoSmithKline 's Imitrex® injection. As described elsewhere in this report, the agreement with Par for the distribution of our generic products obligates Par to provide financial and legal support, including the payment of all legal expenses, for the ongoing patent challenge for sumatriptan succinate injection.

Stock-based charges increased by approximately \$5.4 million, from \$0.9 million in the nine-month period ended September 30, 2005 to approximately \$6.3 million in the nine-month period ended September 30, 2006, primarily due to our adoption of SFAS 123(R), effective January 1, 2006. Also in the nine-month period ended September 30, 2006, we recorded a stock-based charge of approximately \$2.7 million in connection with the acquisition of the oncology assets of Targent, Inc. and approximately \$0.6 million in connection with a payment to Altair Nanotechnologies, Inc., the licensor of RenaZorb , of a milestone pursuant to our license agreement and additional amounts for transfer of technology related to formulation improvements to RenaZorb .

Other income consisted of net interest income of approximately \$2.0 million for the nine-month period ended September 30, 2006 and approximately \$0.8 million for the nine-month period ended September 30, 2005. The increase of approximately \$1.2 million is attributable to significantly higher average interest rates and balances of investable funds in 2006.

**Off-Balance Sheet Arrangements**

None.

**Contractual and Commercial Obligations**

The following table summarizes our contractual and other commitments, including obligations under facility and equipment leases, as of September 30, 2006:

|                                      | Total     | Less than<br>1 Year | 1-3 Years | 3-5 Years | After<br>5 Years |
|--------------------------------------|-----------|---------------------|-----------|-----------|------------------|
| <b>Contractual Obligations (1)</b>   |           |                     |           |           |                  |
| Capital Lease Obligations (2)        | \$        | \$                  | \$        | \$        | \$               |
| Operating Lease Obligations (3)      | \$ 1,342  | \$ 469              | \$ 864    | \$ 9      | \$               |
| Purchase Obligations (4)             | \$ 3,501  | \$ 3,277            | \$ 224    | \$        | \$               |
| Contingent Milestone Obligations (5) | \$ 47,826 | \$ 3,772            | \$ 3,079  | \$ 1,875  | \$ 39,100        |
| Total                                | \$ 52,669 | \$ 7,518            | \$ 4,167  | \$ 1,884  | \$ 39,100        |

(1) The table of contractual and commercial obligations excludes contingent payments that we may become obligated to pay upon the occurrence of future events whose outcome is not readily predictable. Such significant contingent obligations are described below under *Employment Agreements*.

(2) As of September 30, 2006, we had no capital lease obligations.

(3) The operating lease obligations are primarily the facility lease for our corporate office, which extends through June 2009.

(4) Purchase obligations represent the amount of open purchase orders and contractual commitments to vendors, for products and services that have not been delivered, or rendered, as of September 30, 2006.

(5) Contingent milestone obligations are payable contingent upon successfully reaching certain development and regulatory milestones as further described below under *Licensing Agreements*. While the amounts included in the table above represent all of our potential cash development and regulatory milestone obligations as of September 30, 2006, given the unpredictability of the drug development process, and the impossibility of predicting the success of current and future clinical trials, the timelines estimated above do not represent a forecast of when payment milestones will actually be reached, if at all. Rather, they assume that all development and regulatory milestones under all of our license agreements are successfully met, and represent our best estimates of the timelines. In the event that the milestones are met, we believe it is likely that the increase in the potential value of the related drug product will exceed the amount of the milestone obligation.

#### *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 drug product candidates. With regard to one of our drug product candidates, satraplatin, we have out licensed our rights to GPC Biotech. We are required to use commercially reasonable efforts to develop the drug product candidates, 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 the 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 each of the United States, Europe and Japan, and approvals from each of those regulatory agencies.

Given the uncertainty of the drug development process, we are unable to predict with any certainty when, if at all, 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 twelve months. If the anticipated milestones are achieved, we will likely become obligated to issue approximately 250,000 restricted shares of our common stock and pay up to approximately \$4 million in cash during the twelve-month period. If all of our contingent milestones were

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achieved, our potential contingent cash development and regulatory milestone obligations, aggregating approximately \$48 million as of September 30, 2006, would be due approximately as follows: \$4 million in less than 1 year; \$3 million between 1 and 3 years; \$2 million between 3 and 5 years; and \$39 million after 5 years.

### *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 clinical trial centers, clinical research organizations, data monitoring centers, and with

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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, 2007 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 any approved bonus. The officer is also entitled to medical, dental and other benefits for two years following termination. In addition, all options held by the officer shall immediately vest and will be exercisable for one year from the date of such termination. However, if the board determines that 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.

### ***Critical Accounting Policies and Estimates***

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. 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. On an on-going basis, we evaluate our estimates, including cash requirements, by assessing: planned research and development activities and general and administrative requirements, required clinical trial activity, market need for our drug candidates and other major business assumptions.

The SEC defines critical accounting policies as those that are, in management's view, most important to the portrayal of our financial condition and results of operations and most demanding of our judgment. We consider the following policies to be critical to an understanding of our consolidated financial statements and the uncertainties associated with the complex judgments made by us that could impact our results of operations, financial position and cash flows.

### ***Stock-Based Charges***

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 the marketability restrictions 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.

### ***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

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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.

#### ***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, license 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.

### **ITEM 3. Quantitative and Qualitative Disclosures About Market Risk**

We are exposed to certain market risks associated with interest rate fluctuations and credit risk on our cash equivalents and marketable securities, which investments are entered into for purposes other than trading. The primary objective of our investment activities is to preserve principal, while at the same time maximizing yields without significantly increasing risk. We do not utilize hedging contracts or similar instruments.

Our primary exposures relate to (1) interest rate risk on our investment portfolio, and (2) credit risk of the companies' bonds in which we invest. We manage interest rate risk on our investment portfolio by matching scheduled investment maturities with our cash requirements.

Our investments as of September 30, 2006 are primarily in floating rate securities, short-term government securities and money market accounts. Because of our ability to redeem these investments at par with short notice, changes in interest rates would have an immaterial effect on the fair value of these investments. If a 10% change in interest rates were to have occurred on September 30, 2006, any decline in the fair value of our investments would not be material. 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 selecting securities that generally have third party insurance coverage in the event of default by the issuer.

In addition, we are exposed to foreign currency exchange rate fluctuations relating to payments we make to vendors and suppliers using foreign currencies. In particular, we have foreign expenses associated with our ongoing clinical studies in Europe, where some of our obligations are incurred in Euros. We mitigate such risk by maintaining a limited portion of our cash in Euros. Although fluctuations in exchange rates have an effect on our payment obligations, such fluctuations have not had a material impact on our financial condition or results of operations as of or for the nine-month period ended September 30, 2006.



#### **ITEM 4. Controls and Procedures**

We have established disclosure controls and procedures (as such terms are defined in Rules 13(a)-15(e) and 15(d)-15(e)) under the Securities Exchange Act of 1934, as amended, or the Exchange Act), that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer (our principal executive officer) and Vice President Finance (our principal financial officer), as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide a reasonable level of assurance of reaching our desired disclosure control objectives.

As required by SEC 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 Vice President Finance, of the effectiveness of the design and operation of our disclosure controls and procedures as of September 30, 2006, the end of the period covered by this report, or the Evaluation Date. Based on the foregoing, our Chief Executive Officer and Vice President Finance concluded that our disclosure controls and procedures were effective and were operating at the reasonable assurance level.

There has been no change in our internal controls over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

### **PART II OTHER INFORMATION**

#### **ITEM 1. Legal Proceedings**

##### ***Sumatriptan succinate injection Paragraph IV Litigation***

In October 2004, we filed with the FDA an abbreviated new drug application for sumatriptan succinate injection 6mg/0.5mL seeking approval to engage in the commercial manufacture, sale and use of the sumatriptan succinate injection product in the United States. Sumatriptan succinate injection is marketed by GlaxoSmithKline under the brand name Imitrex® injection and is used for the acute treatment of migraine attacks with or without aura and the acute treatment of cluster headache episodes in adults. On February 18, 2005, GlaxoSmithKline filed a lawsuit against us in the United States District Court for the District of Delaware, alleging infringement of the patent on Imitrex® injection.

While it is not possible to determine with any degree of certainty the ultimate outcome of the foregoing legal proceeding, we believe that we have a meritorious basis for our challenge of the patent. Pre-trial briefs have been filed and a pre-trial hearing has been held. Trial is set to begin on November 13, 2006. Pursuant to our agreement with Par, Par shall provide financial and legal support, including payment of legal expenses, for the sumatriptan litigation. In addition, we have made other regulatory filings with the FDA related to sumatriptan succinate injection, which may result in additional legal proceedings related to this litigation that may impact this litigation.

On October 10, 2006, Dr. Reddy's Laboratories announced that it settled its patent litigation with GlaxoSmithKline relating to sumatriptan succinate tablets, subject to government review. This case was a separate proceeding from our case, held in the U.S. District Court for the Southern District of New York.

Additional information regarding this litigation can be found in our annual report on Form 10-K filed with the Securities and Exchange Commission on March 15, 2006, and our quarterly reports on Form 10-Q filed on May 8, 2006 and August 8, 2006.

##### ***Other***

We are party to various other 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.

#### **ITEM IA. Risk Factors**



**RISK FACTORS**

An investment in our common stock involves a high degree of risk. Our business, financial condition, operating results and prospects can be impacted by a number of factors, any one of which could cause our actual results to differ materially from recent results or from our anticipated future results. As a result, the trading price of our common stock could decline,

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and you could lose a part or all of your investment. You should carefully consider the risks described below with all of the other information included in this Quarterly Report. For discussion of some of our potential risks or uncertainties, refer to Part I, Item 1A., Risk Factors, included in our Form 10-K for the fiscal year ended December 31, 2005 as filed with the SEC. The following risk factors are the only material changes to the risk factors described in the Form 10-K.

### Risks Related to Our Business

*Clinical trials may fail to demonstrate the safety and efficacy of our proprietary drug candidates, which could prevent or significantly delay obtaining regulatory approval.*

Prior to receiving approval to commercialize any of our proprietary drug candidates, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA and other regulatory authorities in the United States and other countries, that each of the products is both safe and effective. For each product candidate, we will need to demonstrate its efficacy and monitor its safety throughout the process. If such development is unsuccessful, our business and reputation would be harmed and our stock price would be adversely affected.

All of our product candidates are prone to the risks of failure inherent in drug development. The results of pre-clinical studies and early-stage clinical trials of our product candidates do not necessarily predict the results of later-stage clinical trials. Later-stage clinical trials may fail to demonstrate that a product candidate is safe and effective despite having progressed through initial clinical testing. Even if we believe the data collected from clinical trials of our drug candidates are promising, such data may not be sufficient to support approval by the FDA or any other United States or foreign regulatory approval. Pre-clinical and clinical data can be interpreted in different ways.

Accordingly, FDA officials could interpret such data in different ways than we or our partners do, which could delay, limit or prevent regulatory approval. The FDA, other regulatory authorities, our institutional review boards, our contract research organizations, or we may suspend or terminate our clinical trials for our drug candidates. Any failure or significant delay in completing clinical trials for our product candidates, or in receiving regulatory approval for the sale of any drugs resulting from our drug candidates, may severely harm our business and reputation. Even if we receive FDA and other regulatory approvals, our product candidates may later exhibit adverse effects that may limit or prevent their widespread use, may cause the FDA to revoke, suspend or limit their approval, or may force us to withdraw products derived from those candidates from the market.

Our proprietary drug candidates, their target indications, and status of development are summarized in the following table:

| Drug Candidate | Target Indication   | Development Status                             |
|----------------|---|--|
| Satraplatin    | Hormone Refractory Prostate Cancer                              | Late phase 3; rolling NDA submission has begun |
|                | Metastatic breast cancer  | Phase 2  |
|                | With Taxol® in advanced Non-small Cell Lung Cancer              | Phase 2  |
|                | With Tarceva® in inoperable advanced Non-small Cell Lung Cancer | Phase 2  |
|                | With radiation therapy in Non-small Cell Lung Cancer            | Phase 1/2                                      |
|                | With radiation therapy and Xeloda® in rectal cancer             | Phase 1/2                                      |
|                | With Taxotere® in advanced solid tumors                         | Phase 1  |
|                | With Xeloda® in advanced solid tumors                           | Phase 1  |
|                | With Gemzar® in advanced solid tumors                           | Phase 1  |

| Drug Candidate              | Target Indication  | Development Status   |
|-----------------------------|--|--|
| Levofolinic acid (LFA),     | Osteogenic Sarcoma<br>Colorectal Cancer                    | NDA on file with FDA; CMC responses pending  |
| EOquin                      | Superficial (non-invasive) Bladder Cancer                  | Phase 2 completed; end of phase 2 meeting held with the FDA; IND filed; Pilot Safety Study initiated |
| Elsamitrucin                | Refractory non-Hodgkin's Lymphoma                          | Phase 2  |
| Ozarelix (formerly SPI-153) | Hormone Dependent Prostate Cancer                          | Phase 2  |
|                             | Benign Prostatic Hypertrophy                               | Phase 2  |
| Lucanthone                  | Radiation Sensitizer for Brain Tumors and Brain Metastases | Phase 2  |
| RenaZorb                    | Hyperphosphatemia in End-stage Renal Disease               | Pre-clinical   |
| SPI-1620                    | Adjunct to Chemotherapy                                    | Pre-clinical   |
| SPI-205                     | Chemotherapy Induced Neuropathy                            | Pre-clinical   |

*The development of our drug candidate, satraplatin, depends on the efforts of a third party and, therefore, its eventual success or commercial viability is largely beyond our control.*

In 2002, we entered into a co-development and license agreement with GPC Biotech AG for the worldwide development and commercialization of our lead drug candidate, satraplatin. GPC Biotech has agreed to fully fund development and commercialization expenses for satraplatin. We do not have control over the drug development process and therefore the success of our lead drug candidate depends upon the efforts of GPC Biotech and its new sublicensee. GPC Biotech and its sublicensee may not be successful in the clinical development of the drug, the achievement of any additional milestones such as the acceptance of a New Drug Application, or NDA, filing by the FDA, or the eventual commercialization of satraplatin.

*The eventual FDA approval and subsequent marketing and sale of our drug candidate levofolinic acid, or LFA, may be adversely affected by the marketing and sale efforts of third parties who sell LFA outside North America.*

We have only licensed the rights to develop, market and sell LFA in North America. Other companies, such as Wyeth and Sanofi-Aventis Inc., market and sell LFA in other parts of the world. If, as a result of their actions, negative publicity is associated with LFA, our own efforts to successfully receive FDA approval for, and subsequently, market and sell LFA, may be adversely impacted.

*Our proprietary drug candidate LFA may not be more effective, safer or more cost efficient than competing drugs and otherwise may not have any competitive advantage, which could hinder our ability to successfully commercialize it.*

LFA is the pure active isomer of calcium leucovorin, a component of standard of care 5-FU containing regimens for the treatment of colorectal cancer and other malignancies. Leucovorin has been sold as a generic product on the market for a number of years. There are a number of generic companies currently selling the product. Even if LFA ultimately receives FDA approval, it may not have better efficacy in treating the target indication or a more favorable side-effect profile than generic leucovorin. If we are not able to demonstrate a competitive advantage over generic leucovorin, we may not be able to obtain a price premium over generic leucovorin. If we are not able to obtain a price premium, we may not be able to manufacture LFA in a cost efficient manner or at a cost below the generic leucovorin cost price. Also, LFA will be offered as part of a treatment regimen, and that regimen may change to exclude LFA. Accordingly, even if FDA approval is obtained for LFA, it may not gain acceptance by the medical field or become commercially successful.

*We may have conflicts with our partners that could delay or prevent the development or commercialization of our product candidates.*

We may have conflicts with our partners, such as conflicts concerning the interpretation of preclinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. If any conflicts arise with any of our partners, such partner may act in a manner that is adverse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating revenues:

- unwillingness on the part of a partner to pay us milestone payments or royalties we believe are due to us under a collaboration;
- uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations;
- unwillingness by the partner to cooperate in the development or manufacture of the product, including providing us with product data or materials;
- unwillingness on the part of a partner to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities;
- initiating of litigation or alternative dispute resolution options by either party to resolve the dispute; or
- attempts by either party to terminate the agreement.

***GlaxoSmithKline filed suit in United States federal court asserting that we have infringed one of their patents for Imitrex® injection by filing our ANDA for sumatriptan injection, the generic form of Imitrex® injection. This challenge may prevent us from commercializing sumatriptan injection until after the patent has expired and may require us to incur the significant effort of technical and management personnel.***

On February 18, 2005, GlaxoSmithKline, or GSK, filed suit in United States federal court to prevent us from proceeding with the commercialization of our generic form of sumatriptan injection. Since patent litigation has been initiated, the FDA will not approve our ANDA until the earlier of 30 months from GSK's receipt of our notice of ANDA acceptance (the 30-month stay) or the issuance of a final non-appealed, or non-appealable court decision finding the Imitrex® patent we are currently challenging invalid, unenforceable or not infringed. If the patent is found to be infringed by the filing of our ANDA, GSK could seek an injunction to block the launch of our generic product until the patent expires.

During 2006, we made additional regulatory filings with the FDA, related to sumatriptan succinate injection, which may result in additional legal proceedings related to this litigation that may delay the litigation and/or delay our ability to launch our generic product.

Our continued defense against the charge of infringement by GSK could require us to divert significant effort of our technical and management personnel away from their regular activities in our business, which could substantially hinder our ability to conduct, advance and grow our business. Recently, GSK settled with Dr. Reddy's Laboratories a similar patent litigation relating to sumatriptan succinate tablets in a separate proceeding. It is not possible to evaluate whether such a settlement will impact our case, favorably or unfavorably. However, through our strategic alliance with Par, Par has agreed to provide us with financial and legal support and therefore, the success of our defense is dependent on their efforts as well.

#### **Risks Related to Our Stock**

***The market price and volume of our common stock fluctuate significantly and could result in substantial losses for individual investors.***

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The stock market from time to time experiences significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These broad market fluctuations may cause the market price and volume of our common stock to decrease. In addition, the market price and volume of our common stock is highly volatile. Factors that may cause the market price and volume of our common stock to decrease include fluctuations in our results of operations, timing and announcements of our bio-technological innovations or new products or those of our competitors, FDA and foreign regulatory actions, developments with respect to patents and proprietary rights, public concern as to the safety of products developed by us or others, changes in health care policy in the United States and in foreign countries, changes in stock market analyst recommendations regarding our common stock, the pharmaceutical industry generally and general market conditions. In addition, the market price and volume of our common stock may decrease if our results of operations

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fail to meet the expectations of stock market analysts and investors. Also, certain dilutive securities such as warrants can be used as hedging tools which may increase volatility in our stock and cause a price decline. While a decrease in market price could result in direct economic loss for an individual investor, low trading volume could limit an individual investor's ability to sell our common stock, which could result in substantial economic loss as well. During 2005, the price of our common stock ranged between \$3.51 and \$7.50, and the daily trading volume was as high as 1,368,400 shares and as low as 16,700 shares. During 2006 through October 31, 2006, the price of our common stock has ranged between \$3.36 and \$6.20, and the daily trading volume has been as high as 6,624,100 shares and as low as 24,300 shares.

*Provisions of our charter, bylaws and stockholder rights plan may make it more difficult for someone to acquire control of us or replace current management even if doing so would benefit our stockholders, which may lower the price an acquirer or investor would pay for our stock.*

Provisions of our certificate of incorporation, as amended, and bylaws may make it more difficult for someone to acquire control of us or replace our current management. These provisions include:

the ability of our board of directors to amend our bylaws without stockholder approval;

the inability of stockholders to call special meetings;

the ability of members of the board of directors to fill vacancies on the board of directors;

the inability of stockholders to act by written consent, unless such consent is unanimous;

the establishment of advance notice requirements for nomination for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

These provisions may make it more difficult for stockholders to take certain corporate actions and could delay, discourage or prevent someone from acquiring our business or replacing our current management, even if doing so would benefit our stockholders. These provisions could limit the price that certain investors might be willing to pay for shares of our common stock.

In December 2000, we adopted a stockholder rights plan pursuant to which we distributed rights to purchase units of our series B junior participating preferred stock. The rights become exercisable upon the earlier of ten days after a person or group of affiliated or associated persons has acquired 15% or more of the outstanding shares of our common stock or ten business days after a tender offer has commenced that would result in a person or group beneficially owning 15% or more of our outstanding common stock. These rights could delay or discourage someone from acquiring our business, even if doing so would benefit our stockholders. We currently have no stockholders who own 15% or more of the outstanding shares of our common stock.

## **ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds**

Since our last periodic report, we issued (i) on October 4, 2006, 2,000 shares of our common stock upon the conversion of 1 share of our Series E Convertible Voting Preferred Stock, at a conversion price of \$5.00 per share, (ii) on November 2, 2006, 240,000 shares of our common stock upon the conversion of 120 shares of our Series E Preferred Converting Voting Preferred Stock, at a conversion price of \$5.00, and (iii) on November 2, 2006, 331,914 shares of our common stock upon the conversion of 78 shares of our Series D 8% Cumulative Convertible Voting Preferred Stock, at a conversion price of \$2.35 per share. All of these shares of our common stock were issued without registration under the Securities Act of 1933, as amended, in reliance upon the exemption from registration provided under Section 3(a)(9) of the Securities Act. We received no additional consideration for these conversions.

## **ITEM 3. Defaults Upon Senior Securities**

None

## **ITEM 4. Submission of Matters to a Vote of Security Holders**

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

Information regarding our Annual Meeting of Stockholders on July 6, 2006 was provided in Part II, Item 4, of our quarterly report on Form 10-Q filed with the Securities and Exchange Commission on August 8, 2006.

### **ITEM 5. Other Information (not previously reported in a Form 8-K)**

None

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**ITEM 6. Exhibits**

| Exhibit No. | Description  |
|-------------|--|
| 3.1         | Amended Certificate of Incorporation of the Registrant. (Filed as Exhibit 3.1 to Form 10-Q, as filed with the Securities and Exchange Commission on August 8, 2006, and incorporated herein by reference.)   |
| 3.1.1       | First Amendment to the Certificate of Designation of Series B Junior Participating Preferred Stock of the Registrant. (Filed as Exhibit 3.1 to Form 8-K, as filed with the Securities and Exchange Commission on July 12, 2006, and incorporated herein by reference.) |
| 4.1         | Fourth Amendment to the Rights Agreement. (Filed as Exhibit 4.1 to Form 8-K, as filed with the Securities and Exchange Commission on July 12, 2006, and incorporated herein by reference.)   |
| 4.2+        | Amendment No. 5 to the Rights Agreement dated as of December 13, 2000 by and between the Registrant and U.S. Stock Transfer Corporation.   |
| 10.1+#      | Share Subscription Agreement by and between the Registrant and J B Chemicals & Pharmaceuticals Limited dated as of August 4, 2006.   |
| 10.2+       | Spectrum Pharmaceuticals, Inc. Third Amended and Restated 1997 Stock Incentive Plan.   |
| 31.1+       | Certification of Chief Executive Officer, pursuant to Rule 13a-14 promulgated under the Exchange Act, as created by Section 302 of the Sarbanes-Oxley Act of 2002.   |
| 31.2+       | Certification of Vice President Finance, pursuant to Rule 13a-14 promulgated under the Exchange Act, as created by Section 302 of the Sarbanes-Oxley Act of 2002.  |
| 32.1+       | Certification of Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002.   |
| 32.2+       | Certification of Vice President Finance, pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002.  |

+ Filed herewith.

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



**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

SPECTRUM PHARMACEUTICALS, INC.

Date: November 3, 2006

By: */s/ Shyam K. Kumaria*  
Shyam K. Kumaria, Vice President, Finance  
(Authorized Signatory and Principal Financial  
Officer)

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## EXHIBIT INDEX

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