

SPECTRUM PHARMACEUTICALS INC

Form 10-K/A

May 13, 2003

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

**Washington, D. C. 20549**

**FORM 10-K/A**

**Amendment Number Two**

**[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)**  
**OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2002

**[ ] 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**

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT: None

SECURITIES REGISTERED PURSUANT TO SECTION 12 (g) OF THE ACT:

Common Stock, \$.001 par value

Common Stock Purchase Warrants  
Rights to Purchase Series B Junior Participating Preferred Stock

## Edgar Filing: SPECTRUM PHARMACEUTICALS INC - Form 10-K/A

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the act).

Yes  No

The aggregate market value of the voting common equity held by non-affiliates of the registrant as of June 28, 2002 was \$6,147,364.

As of May 7, 2003, there were 3,108,100 shares of the registrant's common stock outstanding.

### **DOCUMENTS INCORPORATED BY REFERENCE**

None

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The primary purpose of this Amendment is to update the Company's financial statements to report the subsequent event of the issuance of a 444 shares of Series D 8% Cumulative Convertible Voting Preferred Stock for gross cash proceeds of \$4.4 million and the re-issuance of the independent auditors opinion to remove their explanatory paragraph regarding a doubt about our ability to continue as a going concern. The Annual Report on Form 10-K for the year ended December 31, 2002, as filed with the Securities and Exchange Commission on March 28, 2003, and the Amendment Number One to the Annual Report on Form 10-K for the year ended December 31, 2002, as filed with the Securities and Exchange Commission on April 30, 2003, are hereby amended and restated in their entirety as follows.

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*Spectrum Pharmaceuticals, Inc.'s Annual Report on Form 10-K contains certain words, not limited to, believes, may, will, expects, intends, estimates, anticipates, plans, seeks, or continues, that are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. 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. Spectrum Pharmaceuticals, Inc.'s actual results may differ materially from the results projected in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this Report including the Risk Factors, and in ITEM 7 Management's Discussion and Analysis of Financial Condition and Results of Operations included in this ITEM 1.*

## **PART I**

### **ITEM 1. BUSINESS**

#### **General**

Spectrum Pharmaceuticals, Inc., was incorporated in Colorado as Americus Funding Corporation (AFC) in December 1987. In August 1996, AFC changed its name to NeoTherapeutics, Inc. and in June 1997, the Company was reincorporated in the State of Delaware. In December 2002, NeoTherapeutics changed its name to Spectrum Pharmaceuticals, Inc. Spectrum Pharmaceuticals had four subsidiaries at December 31, 2002: NeoOncoRx, Inc., 90.48% owned by Spectrum Pharmaceuticals and incorporated in California in November 2000; NeoTherapeutics GmbH, wholly owned by Spectrum Pharmaceuticals and incorporated in Switzerland in April 1997; NeoGene Technologies, Inc., 88.4% owned by Spectrum Pharmaceuticals and incorporated in California in October 1999; and NeoJB LLC, organized in California in April 2002 and 80% owned by Spectrum Pharmaceuticals. NeoTravel, Inc., a previously wholly owned subsidiary of Spectrum Pharmaceuticals was liquidated on December 31, 2002. Advanced ImmunoTherapeutics, Inc., a previously wholly owned subsidiary of Spectrum Pharmaceuticals, was merged into Spectrum Pharmaceuticals in 2001. In addition, NeoOncoRx, Inc. was liquidated during the first quarter of 2003. Unless the context otherwise requires, all references to the Company, we, our, us, Spectrum and Spectrum Pharmaceuticals refer to Spectrum Pharmaceuticals, Inc., NeoTherapeutics GmbH, Advanced ImmunoTherapeutics, NeoTravel, NeoGene, NeoOncoRx and NeoJB LLC as a consolidated entity. We conduct all of our activities as Spectrum Pharmaceuticals.

We were a development stage pharmaceutical company through the second quarter ended June 30, 2002. Beginning in the third quarter ended September 30, 2002, we are no longer a development stage enterprise in that we have commenced our planned principal operations of (1) in-licensing of oncology drug candidates and the further development of and strategic alliances for these drug candidates, (2) the out-licensing of our neurology drug candidates to strategic partners and (3) the development and marketing of generic drugs in the United States and have generated revenue from these operations.

Also during the year, our functional genomics business was engaged in discovering gene functions and validating novel molecular targets for innovative drug development. On July 19, 2002, we adopted a formal plan to discontinue the operations of our functional genomics business. However, as part of a change in management and reassessment of the Company's strategy in August 2002, we altered our plans to discontinue the operations and changed the focus of the business to out-licensing the genomics technology and the administration of two Pfizer collaboration agreements. During the first quarter of 2003, we transferred our rights to the two Pfizer collaboration agreements to The Regents of the University of California, Irvine (UCI) in exchange for the termination of certain obligations due to UCI (For more information see Note 7 to the Consolidated Financial Statements). We have eliminated all further functional genomics research operations and the associated research funding commitments to UCI.

For financial information regarding our business activities, please see Item 8. Financial Statements.

#### **Pharmaceutical Business**

Our pharmaceutical business engages in the development of novel drugs to treat significant medical diseases or indications associated with cancer. We currently have three drug candidates in clinical trial development satraplatin, Eoquin (formerly Neoquin) and elsamitucin. We also plan to continue to pursue in-license additional clinical stage cancer drugs from other pharmaceutical companies. We believe that this method of drug development is a cost effective and expedient business strategy. Some of our drug candidates may prove to be beneficial in additional disease indications

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as our research progresses. Our pharmaceutical business has never produced products or rendered services that generate revenues from sales.

**Products in Development**

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

ONCOLOGY		
Drug Candidate	Target Indication	Phase of Development
satraplatin *	Prostate cancer	Phase 3: Study expected to begin in 2003
Eoquin	Bladder cancer	Phase 1/2: Study in progress
elsamitrucin	Radiation sensitization non-Hodgkin's lymphoma	Phase 2: Study expected to begin in 2004

\* On September 30, 2002, we entered into a Co-Development and License Agreement with GPC Biotech AG for the development of satraplatin.

**Oncology, Oncology Drug Candidates and Development Strategy, and Cancer and Therapeutic Targets****Oncology**

Cancer is the second leading cause of death in the United States, accounting for approximately 25% of all deaths. In the United States, approximately 1.3 million new cancer cases are expected to be diagnosed in 2003 and over 550,000 persons are expected to die from the disease in 2003, which is an average of approximately 1,500 deaths per day. More than three quarters of all cancers are diagnosed after age 50. Statistics show that in the United States men have a 50% probability and women have a 33% probability of developing cancer in their lifetime. Accordingly, social demand for improved and novel cancer treatments is very high. In addition, the National Institute of Health estimates that \$60 billion was spent in 2000 for all direct cancer-related health expenditures. Cancers with anticipated cases over 100,000 per year include prostate, colon, breast and lung. Cancers with anticipated cases over 50,000 per year include non-Hodgkin's lymphoma, bladder and skin.

Cancer is usually a malignant tumor or growth caused when cells multiply uncontrollably, destroying healthy tissue. The different forms are:

*Sarcomas*: a malignant tumor that begins growing in connective tissue such as muscle, bone, fat, or cartilage;

*Carcinomas*: a malignant tumor that starts in the epithelium (a thin layer of tightly packed cells lining internal cavities, ducts, and organs and covering exposed bodily surfaces) of an organ or body part and may spread to other parts of the body;

*Leukemias*: a type of cancer in which abnormal white blood cells displace normal blood cells leading to infection, anemia (a blood condition in which there are too few red blood cells or the red blood cells are deficient in hemoglobin, resulting in poor health), bleeding, and other disorders, and often proves fatal; and

*Lymphomas*: a malignant tumor originating in a lymph node, for example, Hodgkin's lymphoma or any of the range of cancers known as non-Hodgkin's lymphomas.

All cancers involve the malfunction of genes that control cell growth and division. Extensive unrestrained growth of cancerous cells may result in the person's death. Cancer causing agents include both internal and external factors such as chemicals, radiation, viruses, hormones, immune deficiency conditions, and inherited changes in the genes. The production of cancerous cells most likely results from a combination of factors the body experiences over time. At times it is difficult to diagnose cancer in early stages, therefore, many cancers are far advanced when diagnosed. The typical treatment for cancer include surgery, radiation, chemotherapy, hormones, and immunotherapy.





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Novel cancer drugs are very exciting; however, we believe that traditional chemotherapeutic agents will remain the primary treatment for cancer for the foreseeable future. Currently, we in-license oncology drug candidates that are in clinical trials from pharmaceutical companies. These drug candidates have the potential to be effective therapeutic agents with less side-effects than drugs currently on the market. We intend to develop and commercialize them in the United States and in world markets. We do not currently have in-house capabilities to perform drug discovery for cancer-related therapies. The drug candidates that we in-license typically have smaller market potential than larger pharmaceutical companies target. Large pharmaceutical companies typically require a minimum annual sales potential of \$250 to \$300 million; therefore, these companies are typically motivated to out-license drug candidates with expected sales potential below this market level. Late stage drug candidates generally have a higher success rate with respect to obtaining necessary FDA approval and ultimately being distributed commercially. We believe that our in-licensing of late-stage oncology drug candidates will position us to generate product revenues earlier than if we had attempted to develop oncology drug candidates through in-house drug discovery efforts. Although we are required to make milestone payments and royalty payments under the in-licensing agreements, we expect that our anticipated earlier realization of revenues and contribution to overhead and profit should bring a quicker return on investment.

*Satraplatin:* Currently used in treating a wide range of cancers, platinum derivatives have been available for some time and are one of the most widely used anti-cancer agents. Satraplatin is an oral chemotherapy drug belonging to the class of platinum derivatives such as currently available, cisplatin and carboplatin. Like cisplatin and carboplatin, satraplatin interrupts DNA replication, thus killing the tumor cells. Satraplatin offers the following potential advantages over the currently used platinum-based therapies; 1) patient convenience and acceptance, 2) improved compliance, 3) reduced hospitalization, and 4) cost savings to patient and health care system. In previous clinical studies, satraplatin has demonstrated benefits in the treatment of several cancers particularly prostate cancer. Johnson Matthey PLC developed satraplatin and we in-licensed satraplatin in 2001. On September 30, 2002, we entered into a Co-Development and License agreement with GPC Biotech for the development and commercialization of satraplatin. Under this agreement, GPC Biotech has agreed to fully fund development and commercialization expenses for satraplatin. Spectrum may receive up to \$22 million in license fees and milestone payments. GPC Biotech expects to initiate a Phase 3 clinical study in the third quarter of 2003.

*Eoquin :* Eoquin (EO9, apaziquone) has the potential to improve treatment of bladder cancer and a wide variety of other cancers. The New Drug Development Office (NDDO) Research Foundation in the Netherlands developed Eoquin and 80 related derivatives and we in-licensed these compounds from them in 2001. Eoquin is a prodrug (an inactive drug compound), which is activated by special enzymes present in high amounts in cancer cells. The activated form of Eoquin kills tumor cells, with less risk of harming normal body cells. We are currently conducting a Phase 1/2 clinical trial in Europe of Eoquin for superficial bladder cancer. Results from the first patient in our Phase 1/2 clinical trial showed a complete response (complete disappearance of the tumor as confirmed by biopsy) after receiving six treatments with Eoquin over a period of six weeks. During the fourth quarter of 2002, we agreed to expand this study to four additional sites.

*Elsamitrucin:* Elsamitrucin is an antitumor antibiotic with dual inhibition of the enzymes topoisomerase I and II, two key enzymes involved in the process of DNA replication and cell multiplication. This inhibiting activity results in DNA breaks which prevent the correct replications of DNA, resulting in cell death. Elsamitrucin has demonstrated a marked and broad antitumor activity in experimental models and was well tolerated showing minimal toxicity to bone marrow. Bristol-Myers Squibb developed elsamitrucin and we in-licensed it from them in 2001. We may initiate a Phase 2 clinical study in early 2004.

**Cancer and Therapeutic Targets**

*Prostate Cancer.* Prostate cancer is the most commonly diagnosed malignancy and the second leading cause of cancer death among men in the United States. The American Cancer Society estimates that approximately 221,000 new cases of prostate cancer will be diagnosed in the United States in 2003. Furthermore, an estimated 29,000 men die annually from prostate cancer in the United States out of an estimated 165,000 prostate cancer-related deaths worldwide. Currently, the initial treatment of prostate cancer includes surgery along with radiation and hormone-based therapies. Approximately 30% of all newly diagnosed prostate cancer patients will progress to hormone-refractory prostate cancer. Currently approved therapies are only effective in treating the symptoms of advanced prostate cancer. We plan to initiate a Phase 3 clinical study of satraplatin in hormone-refractory prostate cancer in the third quarter of 2003.

*Non-Hodgkin's Lymphoma.* Non-Hodgkin's lymphoma is the fourth most commonly diagnosed malignancy and the fifth leading cause of cancer death among persons in the United States. The American Cancer Society estimates that approximately 53,000 new cases of non-Hodgkin's lymphoma will be diagnosed and an estimated 23,000 persons will die from non-Hodgkin's lymphoma in the United States during 2003. Although chemotherapy and radiation therapy can induce a very high initial response rate, about half of the patients will eventually relapse and die from the disease. There is a large

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unmet medical need for new treatments to help increase survival in these patients. Elsamitrucin may prove to be an important addition in treating this disease. We may initiate a Phase 2 clinical study of elsamitrucin for the treatment of non-Hodgkin's lymphoma in 2004.

*Bladder Cancer.* Bladder cancer is the sixth most commonly diagnosed malignancy and the tenth leading cause of cancer death among persons in the United States. The American Cancer Society estimates that approximately 57,000 new cases of bladder cancer will be diagnosed and an estimated 13,000 persons will die from bladder cancer in the United States during 2003. Treatment for bladder cancer consists of removal of the tumor by local surgery or electric cauterization. Chemotherapy is used with the aim of delaying and reducing frequency of recurrences in these patients. New therapies for all stages of bladder cancer are in very high demand. We currently have an ongoing Phase 1/2 clinical study of Eoquin for the treatment of superficial bladder cancer.

*Radiation Sensitization.* Radiotherapy therapy along with chemotherapy have been the primary treatment for a number of cancers. Sometimes the cancer cells can be primed to respond better to radiation therapy by pre-treatment with a radiation sensitization drug. We believe Eoquin may have the potential to act as a radiosensitizer.

## **Generic Business**

Our plan is to generate revenue from our generic business to fund the development of our oncology drug candidates. We plan on partnering with low cost providers and focus on drug products which we believe will generate meaningful revenues and generate profits quickly. In 2002, we formed a joint venture, NeoJB LLC, with J.B. Chemicals & Pharmaceuticals Ltd. (JBCPL). JBCPL has high technology manufacturing facilities that produce first class products at competitive prices. JBCPL has the advantage of scale because they produce large volumes for Asian and European markets. We also intend to expand our generic business with other partners who can provide us low cost, high quality drug products.

Our plan calls for our first Abbreviated New Drug Application (ANDA) for a generic drug candidate to be approved in late 2003 or early 2004, and for Spectrum to begin generating revenues from generic drug sales in 2004. We plan on filing three ANDAs during 2003 and another five during 2004, so that we have multiple avenues for achieving revenues and for growing revenues from the generic business. Success in the execution of our plan would lead to profits from the generic business before the end of 2005.

The climate of today's healthcare industry and the advancement of managed care make it important to bring more economically priced products to the market. The generics industry is facing a period of unprecedented growth, with \$100 billion worth of global blockbusters set to face U.S. patent expiration by 2005. Spectrum, with strategic partnerships with several state-of-the-art Indian generic drug-manufacturing companies, hopes to take advantage of the changing dynamics of the generics market.

Our first ANDA was submitted in January 2003 for Ciprofloxacin and plans are well underway for the next series of compounds that will be prepared during 2003.

## ***Joint Venture with J.B. Chemicals & Pharmaceuticals Ltd.***

J.B. Chemicals & Pharmaceuticals Ltd operates 12 manufacturing facilities, which produce high quality bulk pharmaceuticals and drug products, intermediates, specialty pharmaceuticals and herbal remedies. JBCPL's products are marketed and well accepted in over 50 countries.

JBCPL has been an innovative and profitable participant in the pharmaceutical industry for more than 25 years, and has maintained its competitive manufacturing position by investing heavily in technology and automation in its plants. Manufacturing scale has also been critical to JBCPL's success. With sales of its products throughout Asia, Europe, Africa and South America, JBCPL is well positioned to be a competitive source of generic drugs in the United States.

Last year, Spectrum and JBCPL formed NeoJB LLC to enable Spectrum to utilize JBCPL's high quality, cost competitive drug manufacturing capabilities through the sale of JBCPL's generic drugs in the United States. NeoJB LLC is an 80% and 20% joint venture of Spectrum and a subsidiary of J. B. Chemicals & Pharmaceuticals Ltd., respectively.

## **Neurology Products**

We also have a portfolio of neurology drug candidates that we are interested in out-licensing for further development. Our drug candidates include; AIT-034 for dementia, SPPI-339 for attention deficit disorders, SPPI-356 for psychosis, schizophrenia and other mood disorders and Neotrofin for neurodegenerative diseases. A summary of each of our drug candidates are as follows:



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*AIT-034:* AIT-034 has been demonstrated in animal studies to enhance memory and to reverse memory deficits in severely impaired animals. AIT-034 has structural similarities to piracetam, a compound suggested to be both memory enhancing and neuroprotective. However, AIT-034 has been shown to have advantages over piracetam in animal models for learning and memory, with AIT-034 demonstrating a different efficacy profile and higher potency. AIT-034 has been shown to have positive memory enhancing effects in animal models of memory recall and reverse amnesia induced by specific treatments in young, adult and aged mice. The memory enhancing effects of AIT-034 are most pronounced in aged animals (24 month old mice) in which the drug restored learning and memory recall in animals that had no apparent recall capacity, a model in which other memory-enhancing agents were ineffective. Toxicity studies conducted to date indicate that AIT-034 does not induce any systemic toxicity in animals. An IND application for AIT-034 was filed in September 2001. The FDA issued new toxicology and safety testing guidelines just prior to our filing the IND and has requested that these additional studies be completed prior to the start of the first clinical trial.

*Neotrofin :* The FDA allowed an IND for Neotrofin in June 1997. The first clinical trial of Neotrofin in the United States began in July 1997. Additional Phase 1 clinical trials evaluating safety and pharmacokinetic parameters have been conducted with Neotrofin. The results from the Phase 1 clinical trials indicate that Neotrofin is rapidly absorbed after oral administration and produces no serious side effects, even at high doses.

Five Phase 2 clinical trials of Neotrofin have been completed with a range of doses of Neotrofin for a treatment period of one to three months. The Phase 2 studies completed to date demonstrate non-statistically significant improvements in memory and behavior in patients with mild to moderate Alzheimer's disease. One of these studies was initiated in the United States in the third quarter of 1999 to study the effects of oral Neotrofin in the brain using PET (Positron Emission Tomography) imaging technology. The results of this study indicated that certain doses of Neotrofin (500 and 1000 mg/day) demonstrated positive effects on cognition in psychometric tests and positive effects on PET and EEG (electroencephalogram) parameters. In 2002, we completed a Phase 2 clinical trials of Neotrofin in patients with Alzheimer's disease and Parkinson's disease. The results of these studies indicated there was no statistically significant improvements noted for the primary endpoints under investigation. Studies in spinal cord injury and chemotherapy-induced peripheral neuropathy have been completed. Preliminary results were not positive and therefore we have stopped all further analysis of the data.

*SPPI-339:* SPPI-339 was designed and selected for the treatment of attention deficit disorders. SPPI-339 appears to produce positive effects on the acquisition of memory in certain models of memory in aged rodents, reverses the memory loss effects of certain pharmacological treatments, and improves attention in models of information processing. Based on research, we believe that SPPI-339 may have greater efficacy and fewer side effects than therapies currently under evaluation for the treatment of mild cognitive impairment and attention deficits associated with aging and dementia.

*SPPI-356:* SPPI-356 was designed and selected for schizophrenia with minimal side effects by combining structural components that are known to have anti-psychotic activity with structural components that may enhance treatment of the negative symptoms of schizophrenia.

## **Business Strategy**

### *Marketing and Sales*

We do not currently sell any products or services on a recurring basis and therefore have no marketing, sales, or distribution organization. We intend to enter into strategic alliances with other pharmaceutical companies to assist us in the development, marketing and sale of our drug candidates. However, we may retain rights to co-market our products in the United States.

We have developed and we in-licensed several drug candidates and drug technology platforms. As of December 31, 2002 our drug candidate pipeline consisted of seven drugs in various stages of development. We believe that we will continue to in-license additional drug candidates that we will be able to develop in-house, co-develop with other pharmaceutical companies, or out-license in exchange for milestone payments and royalties.

### *Strategic Alliances*

We believe that our patented technology platforms provide a commercial opportunity for developing strategic alliances with other pharmaceutical companies. We believe that any such alliance would enable us to expand and diversify our drug candidate portfolio.

We periodically engage in preliminary licensing discussions with one or more pharmaceutical companies with respect to our drug candidates. We anticipate that the terms of any strategic alliance that we enter into for our drug candidates will include an up-front payment, milestone payments and royalties on product sales.



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We have entered into three strategic alliances to in-license niche market oncology drugs. In June 2001, we entered into a licensing agreement with the New Drug Development Office (or NDDO) Research Foundation whereby we acquired exclusive worldwide rights to Eoquin (EO9) and 80 related derivatives for which we paid NDDO an up-front payment. This agreement is subject to certain additional payments based upon achievement of defined milestones.

In August 2001, we entered into a licensing agreement with Johnson Matthey PLC whereby we acquired exclusive worldwide rights to satraplatin (JM216) for which we paid Johnson Matthey PLC an up-front payment and an additional payment in February 2002. This agreement is subject to certain additional payments based upon achievement of defined milestones.

In October 2001, we entered into a licensing agreement with Bristol-Myers Squibb whereby we acquired exclusive worldwide rights to elsamitrucin for which we paid Bristol-Myers Squibb an up-front payment. This agreement is subject to certain additional payments based upon achievement of defined milestones.

In March 2001, we entered into an agreement whereby Pfizer Inc. acquired rights to one of our G-protein-coupled receptor/ligand systems for evaluation in their DrugFinder program. This agreement provides for up-front payments and milestone payments based upon reaching certain milestones in the discovery and development of drug candidates in this system. During 2002, Pfizer reached the first milestone under the terms of the agreement for which we received a milestone payment. In December 2001, we entered into a second DrugFinder agreement with Pfizer Inc. for an additional G-protein-coupled receptor/ligand system under similar conditions as the previous agreement. As a result of the discontinuation of our research activities at our functional genomics subsidiary, NeoGene Technologies, we agreed to assign our rights under these two agreements to the Regents of the University of California, Irvine (UCI), in exchange for the forgiveness of certain current and future payables due to UCI.

On September 30, 2002, we entered into a co-development and license agreement with GPC Biotech AG for the development and commercialization of our lead drug candidate, satraplatin. Under the co-development and licensing agreement, we may receive up to \$22 million in license fees and milestone payments. The license fee consists of a total of \$4 million; \$2 million upon signing (which was received in October of 2002) and \$1 million in cash and a \$1 million equity investment within 30 days after the first dosing of a patient in a registrational study. The remaining payments totaling up to \$18 million upon achieving agreed upon milestones. However, there can be no assurance that any milestone will be achieved. Furthermore, GPC Biotech has agreed to fully fund development and commercialization expenses for satraplatin. Upon commercial sale of satraplatin, if any, we will be entitled to receive royalty payments based upon net sales.

### *Research Collaborations*

We currently have several proprietary compounds in various stages of pre-clinical development. From time to time, we evaluate these compounds for efficacy in specialized assays or test models. We locate expert academic researchers and/or contract research organizations to perform the desired tests and provide them, through their respective academic institutions, with grants and/or contracts to perform the designated tests while we maintain proprietary rights to the compounds. We monitor these studies to ensure that these studies are performed to the highest research standards. As of December 31, 2002, we were not committed to any such research collaborations.

### *Production*

We currently have our compounds manufactured in large scale by third party vendors and have not established plans to build our own manufacturing facilities. In connection with any licensing arrangements we may enter into regarding our drug candidates, we may retain the rights to control the manufacturing and sale of our compounds to our licensees. Preliminary manufacturing proposals have been received for our cancer drug candidates and certain of our neurology compounds and there are no foreseen problems with manufacturing these compounds.

### **Drug Approval Process and Other Government Regulation**

The production and marketing of our products and our research and development activities are subject to regulation for safety, efficacy and quality by numerous governmental authorities in the United States and other countries. In the United States, drugs are subject to rigorous regulation. The Federal Food, Drug and Cosmetics Act, as amended from time to time, and the regulations promulgated thereunder, as well as other federal and state statutes and regulations, govern, among other things, the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of our proposed products. Product development and approval within this regulatory framework take a number of years and involve the expenditure of substantial resources. In addition to obtaining FDA approval for each product, each drug manufacturing establishment must be registered with, and approved by, the FDA. Domestic manufacturing establishments are subject to regular inspections by the FDA and must comply with Good Manufacturing Practices. To supply products for use in the United States, foreign manufacturing establishments must also comply with Good Manufacturing Practices and are subject to periodic inspection by the FDA or by regulatory authorities in certain of such



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countries under reciprocal agreements with the FDA. Drug product and drug substance manufacturing establishments located in the State of California also must be licensed by the State of California in compliance with local regulatory requirements.

### *Estimated Cost of New Drug Development and Approval*

The United States system of new drug approval is one of the most rigorous in the world. According to a December 2001 report by the Tufts Center for the Study of Drug Development, it costs an average of \$802 million and takes between 10 and 15 years to develop a new prescription medicine and bring it to the U.S. market. Approximately one in 1,000 compounds that enter the pre-clinical testing stage eventually makes it to human testing and only one-fifth of those are ultimately approved for commercialization. In recent years, societal and governmental pressures have created the expectation that drug discovery and development costs can be reduced without sacrificing safety, efficacy and innovation. The need to significantly improve or provide alternative strategies for successful pharmaceutical discovery, research and development remains a major health care industry challenge.

### *Drug Discovery*

In the initial stages of drug discovery, before a compound reaches the laboratory, typically thousands of potential compounds are randomly screened for activity in an assay assumed to be predictive of a particular disease process. This drug discovery process can take several years. Once a screening lead or starting point for drug development is found, isolation and structural determination is initiated. Numerous chemical modifications are made to the screening lead in an attempt to improve the drug properties of the lead. After a compound emerges from this process, it is subjected to further studies on the mechanism of action, further in vitro screening against particular disease targets and finally, in vivo animal screening. If the compound passes these evaluation points, animal toxicology studies are performed to begin to analyze the potential toxic effects of the compound, and if the results indicate acceptable toxicity findings, the compound emerges from the basic research mode and moves into the pre-clinical phase.

### *Pre-clinical Testing*

During the pre-clinical testing stage, laboratory and animal studies are conducted to show biological activity of the compound against the targeted disease and the compound is evaluated for safety. These tests can take up to three years or more to complete.

### *Investigational New Drug Application*

After pre-clinical testing, an IND is submitted to the FDA to begin human testing of the drug. The IND becomes effective if the FDA does not reject it within 30 days. The IND must indicate the results of previous experiments, how, where and by whom the studies were conducted, how the chemical compound is manufactured, the method by which it is believed to work in the human body and any toxic effects of the compound found in the animal studies. In addition, the IND clinical protocol must be reviewed and approved by an Institutional Review Board comprised of physicians and lay people at the hospital or clinic where the proposed studies will be conducted. Progress reports detailing the results of both animal studies and human clinical trials must be submitted at least annually to the FDA.

### *Phase 1 Clinical Trials*

After an IND becomes effective, Phase 1 human clinical trials can begin. These studies, involving small numbers of healthy volunteers or patients, can take up to one year or more to complete. The studies determine a drug's safety profile, including the safe dosage range. The Phase 1 clinical studies also determine how a drug is absorbed, distributed, metabolized and excreted by the body. Additional Phase 1 clinical trials, which may be conducted at any time during the clinical development of a new drug, evaluate interactions between the test drug and drugs commonly used in the target population and safety in patients with compromised organ systems.

### *Phase 2 Clinical Trials*

In Phase 2 clinical trials, controlled studies of volunteer human patients with the targeted disease assess the drug's effectiveness. These studies are designed primarily to determine the appropriate dose levels and to evaluate the effectiveness of the drug on humans as well as to determine if there are any side effects on humans. These studies can take up to two years or more.



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### *Phase 3 Clinical Trials*

This phase can last up to three years or more and usually involves large numbers of human patients with the targeted disease. During the Phase 3 clinical trials, physicians monitor the human patients to determine drug candidate efficacy and to observe and report any adverse reactions that may result from long-term use of the drug on a large, more widespread, human patient population.

### *New Drug Application (NDA)*

After completion of all three clinical trial phases, if the data indicates that the drug is safe and effective, an NDA is filed with the FDA. The NDA must contain all of the information on the drug that has been gathered to date, including data from the clinical trials. NDAs are often over 100,000 pages in length. After passage of the Prescription Drug User Fee Act, average review times for new medicine applications dropped from nearly 30 months in 1992 to less than 12 months.

### *Fast Track Review*

In September 1998, the FDA clarified procedures for accelerating the approval of drugs to be marketed for serious diseases for which the manufacturer can demonstrate the potential to address unmet medical needs. We do not know whether any of our drug candidates will fulfill this requirement because there are drugs currently approved and available for related therapies. However, our drug candidates might qualify for fast track classification if the disease indication for which we are seeking approval has no other current therapies available in the market. At this time, we have not requested fast track designation for any of our drug candidates.

The FDA also made provisions for priority review of drugs. A drug will qualify for priority review if it provides a significant improvement compared to marketed products in the treatment, diagnosis or prevention of a disease regardless of whether the indication is serious or life-threatening. We believe that some of our drug candidates may qualify for priority review.

### *Approval*

If the FDA approves the NDA, the drug becomes available for physicians to prescribe to patients for treatment. We must continue to submit periodic reports to the FDA, including descriptions of any adverse reactions reported by doctors prescribing the drug. For certain drugs which are administered on a long-term basis, the FDA may request additional clinical studies (Phase 4) after the drug has begun to be marketed to evaluate long-term effects. The marketing of a drug after FDA approval is subject to substantial continuing regulation by the FDA, including regulation of manufacturing practices and the advertising and promotion of the drug. Certain drugs are removed from the market after receiving FDA approval for a variety of issues ranging, for example, from reports of side effects to unexplained patient death. Some drugs return to the market only after the FDA agrees that issues identified have been adequately addressed or eliminated.

In addition to regulations enforced by the FDA, we are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and future federal, state or local regulations, all of which are amended from time to time. Our research and development activities involve the controlled use of hazardous materials, chemicals, biological materials and various radioactive compounds. We must comply with safety procedures for handling and disposing of such materials according to the standards prescribed by state and federal regulations, however, no matter how good compliance is with safety procedures, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In addition, under certain circumstances, we may become liable due to violations by our vendors and other partners that are subject to the same standards prescribed by state and federal regulations.

For marketing outside the United States, we and our prospective licensees are subject to foreign regulatory requirements governing human clinical trials and marketing approval for drugs in the respective countries. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country.

### *Abbreviated New Drug Application (ANDA)*

An ANDA is the process created for the accelerated approval of generic drugs. An ANDA must certify that the generic drug does not infringe on existing patent(s) or certify that the patent(s) for the brand-name product is invalid. The ANDA must also demonstrate that the generic drug is bioequivalent to the brand-name product.

## **Research and Development**

## Edgar Filing: SPECTRUM PHARMACEUTICALS INC - Form 10-K/A

Since our inception, we have devoted substantially all of our resources and efforts to research and development. Research and development expenditures are expensed at the time we incur them and were approximately \$38.8 million in 2000, \$20.6 million in 2001 and \$12.7 million in 2002.

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### **Patents and Proprietary Rights**

Patents and other proprietary rights are vital to our business. Our policy is to seek patent protection for our proprietary compounds and technology, and we intend to protect our technology, inventions and improvements to inventions that are commercially important to the development of our businesses. We also intend to rely on trade secrets, know-how, continuing technology innovations and licensing arrangements to develop and maintain our competitive position. In addition, we have applied for registration of several trademarks, including certain of our product candidates.

We currently hold rights to thirteen U.S. patents and currently have seventeen U.S. patent applications pending, however, we have determined that we will not be maintaining eight of the U.S. patents and thirteen of the U.S. patent applications relating to Neotrofin. In addition, we have a number of foreign patents and foreign patent applications pending, which have been granted corresponding to issued U.S. patents. Our U.S. issued patents expire beginning 2003 through 2020. It is possible that the scope of the coverage claimed in our patent applications could be significantly reduced prior to a patent being issued.

All issued, allowed and pending patents were assigned, by the inventors, to us. In connection with these assignments, we granted to one of the inventors, Dr. Alvin Glasky, a royalty of two percent of all revenues derived by us from the use and sale of any products that are covered by any of the aforementioned patents or any subsequent derivative patents, in each case for the life of the patent. However, Dr. Glasky will not receive any royalties with respect to sales of products which utilize patent rights licensed to us by McMaster University as described below. In the event Dr. Glasky dies, his estate or family shall be entitled to continue to receive royalties at the rate of two percent.

With respect to five issued U.S. patents, we entered into a license agreement whereby McMaster University has licensed to us all patent rights belonging to McMaster University contained in such patents. These patents contain a subset of claims to which McMaster University claims patent rights. This agreement calls for annual minimum royalty payments of \$25,000 per year to McMaster University, until expiration of the related patent rights, and for us to pay to McMaster University a royalty of five percent of the net sales of all products sold by us that incorporate the patent rights licensed to us by McMaster University.

The patent positions related to our drug candidates are generally uncertain and involve complex legal and factual issues. Third parties may assert patent or other intellectual property infringement claims against us with respect to our products or technology or other matters. There may be third-party patents and other intellectual property relevant to our products and technology of which we are not aware.

Patent litigation is becoming more common in the pharmaceutical industry. Litigation is sometimes necessary to defend against or assert claims of infringement, to enforce our patents, to protect trade secrets we own or to determine the scope and validity of proprietary rights of third parties. No third party has asserted that we are infringing upon their patent rights or other intellectual property, nor are we aware that we are infringing upon any third party's patent rights or other intellectual property. We may, however, be infringing upon a third party's patent rights or other intellectual property, and litigation asserting such claims might be initiated in which we would not prevail or we would not be able to obtain the necessary licenses on reasonable terms, if at all. All such litigation, whether meritorious or not, as well as litigation initiated by us against third parties, is time consuming and very expensive to defend or prosecute and to resolve.

If our competitors prepare and file patent applications in the United States that claim technology we also claim, we may have to participate in interference proceedings required by the Patent and Trademark Office to determine priority of invention, which could result in substantial costs, even if we ultimately prevail. Results of interference proceedings are highly unpredictable and may result in us having to try to obtain licenses in order to continue to conduct clinical trials, manufacture or subsequently market certain of our drug candidates.

We rely on unpatented trade secrets and improvements, unpatented know-how, and continuing technological innovation to develop and maintain our competitiveness. We protect such information with employee, consultant, and corporate partner and/or collaborator confidentiality agreements as such relationships are formed. Confidentiality agreements provide that all confidential information developed or made known to an individual during the course of the employment or consulting relationship shall be kept confidential and shall not be disclosed to third parties except in specified circumstances. Agreements with employees provide that all inventions conceived by the individual while employed by us are our exclusive property. Confidentiality agreements are sometimes not honored, and if breached, we might not have adequate remedies and our trade secrets and improvements, unpatented know-how, and continuing technological innovation might become known. Additionally, our competitors may independently discover our trade secrets and improvements, unpatented know-how, and continuing technological innovation.

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### **Competition**

The pharmaceutical industry is characterized by rapidly evolving technology and intense competition. Many companies of all sizes, including a number of large pharmaceutical companies as well as several specialized pharmaceutical companies, engage in drug research and development activities similar to ours.

Our pharmaceutical business competitors that have products on the market or in research and development that are in the same clinical focus as us include Amgen, Inc., Bayer AG, Eli Lilly and Co., Novartis AG, Bristol-Meyers Squibb Company, Glaxo SmithKline, IDEC Pharmaceuticals, Vertex Pharmaceuticals, Inc., Guilford Pharmaceuticals, Inc., Cephalon, Inc., Aventis, Elan Corporation, Pfizer, Inc., Janssen Pharmaceutica, Inc. and Shire Pharmaceuticals Group plc, among others. Competitors that have a strategic and clinical focus similar to ours include AVI Biopharma, Inc., Chiron Corp., Corixa Corp., Dendreon Corp., Genta Inc., Imclone Systems Incorporated, MGI Pharma, Inc. and SuperGen, Inc., among others. Many of our competitors are large-cap companies such as Eli Lilly and Company, Shire Pharmaceuticals, and Bristol-Myers Squibb focusing on a wide range of diseases and drug indications, and many are small to medium-cap, public and private companies, often with niche focuses. Companies that have a similar generic strategy include American Pharmaceuticals, Barr Laboratories, Sicor, Inc., Teva Pharmaceuticals and Watson Pharmaceuticals. Although we have broadened our focus during the past two years, we remain very niched-focused. Companies focused on similar niche-markets are numerous, making the market landscape very diversified and competitive.

Technologies under development by other pharmaceutical companies could result in treatments for diseases and disorders for which we are developing our own treatments. Several other companies are engaged in research and development of compounds that are similar to our research. In the event that one or more of these programs is successful, the market for some of our drug candidates could be reduced or eliminated.

In addition, colleges, universities, governmental agencies and other public and private research institutions conduct research and are becoming more active in seeking patent protection and licensing arrangements to collect license fees, milestone payments and royalties in exchange for license rights to technologies that they have developed, some of which may directly compete with our technologies. These companies and institutions also compete with us in recruiting highly qualified scientific personnel. Many of our competitors have substantially greater financial, research and development, human and other resources than we do. Furthermore, large pharmaceutical companies have significantly more experience than we do in pre-clinical testing, human clinical trials and regulatory approval procedures, among other things.

Although we have conducted clinical trials with respect to Neotrofin and Eoquin and begun preparation for a clinical trial with respect to satraplatin, we have not conducted clinical trials or sought the approval of the FDA with respect to any of our other drug candidates. Furthermore, if we are permitted to commence commercial sales of any of our drug candidates and decide to manufacture and sell such products ourselves, we will also be competing with respect to manufacturing efficiency and marketing capabilities, which are business activities and processes in which we have no prior experience.

Any product for which we obtain FDA approval must also compete for market acceptance and market share. For example, cisplatin and carboplatin are the most prevalent platinum-based derivatives used in chemotherapy and are the primary treatment for many of the cancer types we are pursuing. Our drug candidate, satraplatin, if the FDA ever approves it, would likely compete against these drugs directly. Unless satraplatin is shown to have better efficacy and is as cost effective if not more cost effective than cisplatin and carboplatin, it may not gain acceptance by the medical field and therefore never be successful commercially.

We expect technological developments and improvements in the fields of our business to continue to occur at a rapid rate and, as a result, expect competition to remain intense. Although we think, based on the preliminary pre-clinical and clinical test results involving certain of our drug candidates, that we will be able to continue to compete in the clinical development of drug candidates in our market niche, we may be wrong. Additionally, we do not have sufficient resources to compete with major pharmaceutical companies in the areas of later-stage clinical testing, manufacturing and marketing.

### **Website Access to Current and Periodic Reports**

Additional information, including current and periodic reports filed with the SEC, on the Company can be obtained, free of charge, from our website at [www.spectrumpharm.com](http://www.spectrumpharm.com).

### **Employees**

As of December 31, 2002, we had eighteen (18) full-time employees; of which four hold M.D. degrees and two hold Ph.D. degrees, and two (2) part-time employees. We cannot assure you that we will be able to attract and retain qualified personnel in sufficient numbers to meet our needs. Our employees are not subject to any collective bargaining agreements, and we regard our relations with our employees to be good.



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**RISK FACTORS**

Our business, financial condition, operating results and prospects can be impacted by a number of factors, including but not limited to those set forth below and elsewhere in this report, any one of which could cause our actual results to differ materially from recent results or from our anticipated future results. Factors that may affect our business, financial condition, operating results, include:

**Our losses will continue to increase as we expand our development efforts, and our efforts may never result in profitability.**

Our cumulative losses during the period from our inception in 1987 through December 31, 2002 were approximately \$141.7 million, almost all of which consisted of research and development and general and administrative expenses. We lost approximately \$46.4 million in 2000, \$27.8 million in 2001, and \$17.6 million in 2002. We expect our losses to continue in the future as we expand our clinical trials and increase our research and development activities. We currently do not sell any products or services and we may never achieve significant revenues or become profitable. Even if we eventually generate revenues from sales, we nevertheless expect to incur operating losses over the next several years.

**Our business does not generate the cash needed to finance our current and anticipated operations.**

During the three-month period ended December 31, 2002, our expenses were approximately \$3.8 million. We anticipate that our expenses will be reduced to approximately \$1.5 million, or lower, per quarter starting with the first quarter in 2003.

At the present time, our business does not generate cash from operations needed to finance our short-term operations. We will rely primarily on raising funds through the sale of our securities, and/or out-licensing our drug candidates and technology, to meet all of our short-term cash needs. We have generated operating losses since our inception and our existing cash and investment securities, are not sufficient to fund our current planned pharmaceutical operations beyond June 2004. Therefore, we will need to seek additional funding by June 2004, or sooner, through public or private financings, including equity financings, and through other arrangements to continue operating our businesses and meet our short-term and long-term cash needs. Additionally, our long-term business plans require that we enter into collaborative partnership agreements and strategic alliance agreements with larger pharmaceutical companies to co-develop, manufacture and market our product candidates.

We may not be able to raise additional funds on favorable terms, if at all. Accordingly, we would be forced to significantly change our business plans and restructure our operations to conserve cash, which would likely involve some, combination, or all of the following:

Out-license or sell some or all of our intellectual, technological, and/or tangible property not presently contemplated and at terms that we believe would not be favorable to us;

Further reduce the size of our workforce, including the number of our scientific personnel;

Reduce the scope and nature of our research and drug development activities; and

Terminate operating leases and other contractual arrangements.

We will need substantial additional funds to support the continued research and development of our potential products. Since we currently have no products available for commercial sale and minimal revenues from licensing in our oncology business, we must use capital to fund our operating expenses. Our operating expenses, and consequently our capital requirements, will depend on many factors, including:

continued scientific progress in research and development to identify and develop or obtain additional drug candidates; the costs and progress of preclinical and clinical testing of our anti-cancer drugs and additional drug candidates;

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cost involved in filing, prosecuting and enforcing patent claims;

effect of competing technological developments;

cost of manufacturing scale-up;

cost of commercialization activities;

time and cost involved in obtaining regulatory approvals; and

our ability to establish collaborative and other arrangements with third parties, such as licensing and manufacturing agreements.

**Our efforts to in-license and develop new drug development targets may fail.**

In 2002 we shifted our strategic focus from discovery and development of neurology drugs to the in-licensing of oncology drug candidates and the further development of and forming strategic alliances for these drug candidates, and the out-licensing of our neurology drug candidates to strategic partners. In the fourth quarter of 2002 we announced plans to pursue regulatory approval in the United States of generic drugs manufactured by J.B. Chemicals & Pharmaceuticals Ltd. or JBCL, an Indian company, through our existing joint venture, NeoJB LLC. We may not in-license, discover or validate any more new drug development targets based on our efforts.

**Our potential drug candidates are in various stages of clinical and pre-clinical development and may not prove safe or effective enough to obtain regulatory approval to sell any of them.**

We have acquired rights to three anti-cancer drugs and we have commenced a clinical trial of our Eoquin drug candidate for superficial urinary bladder cancer. We expect that we will need to complete additional trials before we will be able to apply for regulatory approval to sell any of our potential drug candidates. Our other proposed drug candidates are in various stages of development. We cannot be certain that any of our proposed drug candidates will prove to be safe or effective in treating cancer, disorders of the nervous system, or any other diseases or indications. Our former lead drug candidate, Neotrofin, failed to demonstrate efficacy in previous trials for Alzheimer's disease and Parkinson's disease. All of our proposed drugs will require additional research and development, testing and regulatory clearance before we can sell them. We cannot be certain that we will receive regulatory approval to sell any of our proposed drugs. We do not expect to have any oncology products commercially available for at least five years, if at all.

On September 30, 2002, we entered into a co-development and license agreement with GPC Biotech AG for the development and commercialization of our lead drug candidate, satraplatin. GPC Biotech has agreed to fully fund development and commercialization expenses for satraplatin. We will not have control over the drug development process and therefore, the success of our lead drug candidate will depend upon the efforts of a third party. There is no assurance that GPC Biotech will be successful in the clinical development of the drug, the achievement of any milestones such as the acceptance of an NDA (New Drug Application) filing by the United States Food and Drug Administration or the eventual commercialization of satraplatin.

**Our efforts to enter the generic drug market may fail.**

We plan to use our management's experience with the regulatory approval process in the United States to seek the introduction of generic drug products into the United States, which may include generic drugs produced by other pharmaceutical companies or developed internally by us. While some members of our management have experience with obtaining regulatory approval of drug candidates in the United States, we have limited experience with generic drug products, and, as a company, we have not successfully obtained regulatory approval of any of our drug candidates.

On January 15, 2003, we announced the filing of our first Abbreviated New Drug Application, or ANDA, with the United States Food and Drug Administration. The filing was made by our NeoJB LLC subsidiary on behalf of JBCPL, and relates to a generic drug product manufactured by JBCPL. We cannot be certain that the FDA will approve this ANDA, or if approved, that we will be able to complete a transfer pricing agreement with JBCPL to allow NeoJB to market the drug product in the United States on terms favorable to us or at all.

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Even if we obtain regulatory approval to market one or more generic drug products in the United States, we may face opposition from the producers of the branded versions of these drugs. Branded pharmaceutical companies have historically been aggressive in seeking to prevent generic competition, including the extensive use of litigation.

In addition, many branded pharmaceutical companies increasingly have used state and federal legislative and regulatory means to delay generic competition. These efforts have included:

pursuing new patents for existing products which may be granted just before the expiration of one patent which could extend patent protection for a number of more years or otherwise delay the launch of generics;

using the Citizen Petition process to request amendments to FDA standards;

seeking changes to the United States Pharmacopeia, an organization which publishes industry recognized compendia of drug standards; and

attaching patent extension amendments to non-related federal legislation.

In addition, some branded pharmaceutical companies have engaged in state-by-state initiatives to enact legislation that restricts the substitution of some generic drugs. Some of these initiatives could have an impact on products that we will seek to introduce to the United States. We have limited resources, and may not be able to effectively respond to these or other measures that may be taken by pharmaceutical companies that produce the branded version of our generic products.

**We must comply with the listing requirements of the Nasdaq SmallCap Market or we could be delisted and the liquidity of our common stock would decline.**

Our common stock was transferred from the Nasdaq National Market to the Nasdaq SmallCap Market where it began trading on October 16, 2002. On December 11, 2002, we changed our name to Spectrum Pharmaceuticals, Inc., and began trading under the ticker symbol SPPI. To remain listed on this market, we must meet Nasdaq's continued listing requirements. Among other requirements, Nasdaq rules require that a SmallCap Market company maintain a minimum stockholders' equity of \$2.5 million or a minimum market value of listed securities of \$35 million or a net income from continuing operations (in latest fiscal year or 2 of the last 3 fiscal years) of at least \$500,000. As of December 31, 2002, we were not in compliance with this standard and we have received a notice indicating that our securities are subject to delisting. The Company has requested and been granted a hearing before a Nasdaq Listing Qualifications Panel to review the delisting notice. As a result of the issuance of the shares of our convertible preferred stock, we believe we have regained compliance with this standard. However, there is no assurance that the Panel will grant the Company's request for continued listing or that we will be able to maintain compliance with any of the continued listing requirements. If we fail to do so, our common stock could be delisted from the Nasdaq SmallCap Market.

If our common stock is delisted from the Nasdaq SmallCap Market, we would likely seek quotation on the American Stock Exchange or a regional stock exchange, if available. However, quotation on such a market or exchange could reduce the market liquidity for our common stock. If our common stock is not quoted on another market or exchange, trading of our common stock could be conducted in the over-the-counter market on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. As a result, an investor would find it more difficult to dispose of, or obtain accurate quotations for the price of, our common stock.

If our common stock is delisted from the Nasdaq SmallCap Market, we fail to obtain quotation on another market or exchange, and the trading price remains below \$5.00 per share, trading in our common stock might also become subject to the requirements of certain rules promulgated under the Securities Exchange Act of 1934, which require additional disclosure by broker-dealers in connection with any trades involving a stock defined as a penny stock (generally, any equity security not listed on a national securities exchange or quoted on Nasdaq that has a market price of less than \$5.00 per share, subject to certain exceptions). Many brokerage firms are reluctant to recommend low-priced stocks to their clients. Moreover, various regulations and policies restrict the ability of stockholders to borrow against or margin low-priced stocks and declines in the stock price below certain levels may trigger unexpected margin calls. Additionally, because brokers' commissions on low-priced stocks generally represent a higher percentage of the stock price than commissions on higher priced stocks, the current price of the common stock can result in an individual stockholder paying transaction costs that represent a higher percentage of total share value than would be the case if our share price were higher. This factor may also limit the willingness of institutions to purchase our common stock. Finally, the additional burdens imposed upon broker-dealers by these requirements could discourage broker-dealers from facilitating trades in our common stock, which could severely limit the market liquidity of the stock and the ability of investors to trade our common stock.



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Nasdaq corporate governance rules prohibit an issuer of listed securities from issuing 20% or more of its outstanding voting stock in one transaction or a series of related transactions other than a public offering at less than the greater of book value or the then current market value, without obtaining prior stockholder consent. While we have obtained stockholder approval of this type of financing in the past, we do not currently have stockholder approval to do similar financings in the future. We do not generate sufficient revenues to fund operations, and we do not currently have sufficient cash on hand to fund our operations beyond June 2004. While we are exploring all financing and strategic alternatives, we will need to raise additional funds through the sale of securities by June 2004, or sooner, to continue operating our business. Based on our recent experience and our current financial position, we believe that we might need to offer our securities at a discount to market price in order to attract investors to provide these funds. Therefore Nasdaq's 20% share limitation rule may hinder or prevent financing transactions from occurring.

Nasdaq corporate governance standards also require us to notify Nasdaq no later than fifteen (15) days prior to entering into a transaction that may result in the potential issuance of common stock greater than ten percent (10%) of the total shares of common stock outstanding. Several of our recent financings have been very sensitive to market conditions, and consequently have only had a short time period in which they could be completed. Therefore this 15 day notification rule may hinder or prevent similar financing transactions from occurring.

### **Competition for patients in conducting clinical trials may prevent or delay approval of a drug candidate and strain our limited financial resources.**

Many pharmaceutical companies are conducting clinical trials in patients with the cancer types that Spectrum's drug candidates target. As a result, we must compete with them for clinical sites, physicians and the limited number of patients who fulfill the stringent requirements for participation in clinical trials. Also, due to the confidential nature of clinical trials, we cannot be certain how many of the eligible cancer patients may be enrolled in competing studies and consequently not available to us. This competition may increase costs of our clinical trials and delay the introduction of our potential products.

### **Any failure to comply with extensive governmental regulation could prevent or delay product approval or cause governmental authorities to disallow our products after approval and subject us to criminal or civil liabilities.**

The FDA and comparable agencies in foreign countries impose many requirements on the introduction of new drugs through lengthy and detailed clinical testing and data collection procedures, and other costly and time consuming compliance procedures. These requirements apply to every stage of the clinical trial process and make it difficult to estimate when any of our drug candidates will be available commercially, if at all. Our proprietary compounds will require substantial clinical trials and FDA review as new drugs. Even if we successfully enroll patients in our clinical trials, patients may not respond to our potential drug candidates. We think it is prudent to expect setbacks. While we believe that we are currently in compliance with applicable FDA regulations, if we fail to comply with the regulations applicable to our clinical testing, the FDA may delay, suspend or cancel our clinical trials, or the FDA might not accept the test results. The FDA, or any comparable regulatory agency in another country, may suspend clinical trials at any time if it concludes that the trials expose subjects participating in such trials to unacceptable health risks. Further, human clinical testing may not show any current or future product candidate to be safe and effective to the satisfaction of the FDA or comparable regulatory agencies or the data derived from the clinical tests may be unsuitable for submission to the FDA or other regulatory agencies.

We cannot predict with certainty when we might submit any of our drug candidates currently under development for the regulatory approval required in order to commercially sell the products. Once we submit a drug candidate for commercial sale approval, the FDA or other regulatory agencies may not issue their approvals on a timely basis, if at all. If we are delayed or fail to obtain these approvals, our business and prospects may be significantly damaged. If we fail to comply with regulatory requirements, either prior to seeking approval or in marketing our products after approval, we could be subject to regulatory or judicial enforcement actions. These actions could result in:

product recalls or seizures;

injunctions;

civil penalties;

criminal prosecution;

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refusals to approve new products and withdrawal of existing approvals; and

enhanced exposure to product liabilities.

**The loss of key researchers or managers could significantly hinder our drug development process and might cause our business to fail.**

Our success depends upon the contributions of our key management and scientific personnel. The loss of Dr. Luigi Lenaz, our President Oncology Division, would damage the development of our anti-cancer business substantially. Dr. Lenaz has an employment agreement with us that will expire on July 1, 2003, with automatic one year renewals thereafter unless Dr. Lenaz or we gives notice of intent not to renew at least 90 days in advance of the renewal date. We also may need substantial additional expertise in marketing and other areas in order to achieve our business objectives. Competition for qualified personnel among pharmaceutical companies is intense, and the loss of key personnel, or the inability to attract and retain the additional skilled personnel required for the expansion of our business, could significantly damage our business.

**If we cannot protect or enforce our intellectual property rights adequately, the value of our research could decline as our competitors appropriate portions of our research.**

We actively pursue patent protection for our proprietary products and technologies. We hold rights to thirteen U.S. patents and currently have seventeen U.S. patent applications pending. The Company has determined it will not be maintaining eight of the U.S. patents and thirteen of the U.S. patent applications relating to Neotrofin. Our issued patents expire between 2003 and 2020. In addition, we have numerous foreign patents issued and patent applications pending corresponding to our U.S. patents. However, our patents may not protect us against our competitors. We may have to file suit to protect our patents or to defend our use of our patents against infringement claims brought by others. Because we have limited cash resources, we may not be able to afford to pursue or defend against litigation in order to protect our patent rights.

We also rely on trade secret protection for our unpatented proprietary technology. Trade secrets are difficult to protect. While we enter into proprietary information agreements with our employees, consultants and others, these agreements may not successfully protect our trade secrets or other proprietary information.

**We are a small company relative to our principal competitors and our limited financial and research resources may limit our ability to develop and market new products.**

Many companies, both public and private, including well-known pharmaceutical companies such as Amgen, Inc., Bayer AG, Eli Lilly and Company, Novartis AG, Bristol-Meyers Squibb Company, Glaxo SmithKline, IDEC Pharmaceuticals, Vertex Pharmaceuticals, Inc., Guilford Pharmaceuticals, Inc., Cephalon, Inc., Aventis, Elan Corporation, Pfizer, Inc., Janssen Pharmaceutica, Inc. and Shire Pharmaceuticals Group plc, are developing products to treat certain of the diseases we are pursuing. Competitors that have a strategic and clinical focus similar to ours include AVI Biopharma, Inc., Chiron Corp., Corixa Corp., Dendreon Corp., Genta Inc., Imclone Systems Incorporated, MGI Pharma, Inc. and SuperGen, Inc. among others. Companies that have a similar generic strategy include American Pharmaceuticals, Barr Laboratories, Sicor, Inc., Teva Pharmaceuticals and Watson Pharmaceuticals. Many of these companies have substantially greater financial, research and development, manufacturing, marketing and sales experience and resources than us. As a result, our competitors may be more successful than us in developing their products, obtaining regulatory approvals and marketing their products to consumers.

Numerous oncology drugs are on the market for each cancer type we are pursuing. For example, cisplatin and carboplatin are the most prevalent platinum-based derivatives used in chemotherapy. Our product candidate, satraplatin, if the FDA ever approves it, would likely compete against these drugs directly. Unless satraplatin is shown to have better efficacy and is as cost effective if not more cost effective than cisplatin and carboplatin, it may not gain acceptance by the medical field and therefore never be successful commercially.

**Our limited experience at managing and conducting clinical trials ourselves may delay the trials and increase our costs.**

We may manage and conduct some future clinical trials ourselves rather than hiring outside clinical trial contractors. We believe managing and conducting clinical trials ourselves has reduced and could continue to reduce the

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costs associated with our clinical trials and gives us more control over the clinical trial process. However, while some of our management has had experience at conducting clinical trials, we have limited experience in doing so as a company. While we have not experienced significant delays or increased costs to date by conducting clinical trials ourselves, as we move forward with our self-conducted clinical trials, our limited experience may delay the completion of our clinical trials and increase our costs.

### **We may be dependant on third parties for clinical testing, manufacturing and/or marketing.**

We may not conduct some clinical trials ourselves, and we will not manufacture any of our proposed products for commercial sale nor do we have the resources necessary to do so. Our current management does not have any experience marketing pharmaceutical products. We intend to contract with larger pharmaceutical companies or contract research organizations to conduct such activities. In connection with our efforts to secure corporate partners, we may seek to retain certain co-marketing rights to certain of our drug candidates, so that we may promote our products to selected medical specialists while our corporate partner promotes these products to the medical market generally. We cannot be certain that we will be able to enter into any partnering arrangements on this or any other basis. If we are not able to secure adequate partnering arrangements, we will have to hire additional employees or consultants with expertise in marketing, since our current employees have no experience in these areas. We cannot be certain that sufficient employees with relevant skills will be available to us. Any increase in the number of our employees would increase our expense level, and could make it harder for us to make a profit.

In addition, we cannot be certain that we or our potential corporate partners can successfully introduce our proposed products or that such proposed products will achieve acceptance by patients, health care providers and insurance companies. Further, it is possible that we may not be able to secure arrangements to manufacture and market our proposed products at prices that would permit us to make a profit. To the extent that clinical trials are conducted by corporate partners, we may not be able to control the design and conduct of these clinical trials.

### **We may be subject to product liability claims, and may not have sufficient product liability insurance to cover any claims, which may expose us to substantial liabilities.**

We may be exposed to product liability claims from patients who participate in our clinical trials, or, if we are able to obtain FDA approval for one or more of our potential products, from consumers of our products. Although we currently carry product liability insurance in the amount of \$5 million per occurrence, it is possible that the amounts of this coverage will be insufficient to protect us from future claims. Further, we cannot be certain that we will be able to maintain our existing insurance or obtain or maintain additional insurance on acceptable terms for our clinical and commercial activities or that such additional insurance would be sufficient to cover any potential product liability claim or recall. Failure to maintain sufficient insurance coverage could have a material adverse effect on our business, prospects and results of operations if claims are made that exceed our coverage.

### **The use of hazardous materials in our research and development efforts imposes certain compliance costs on us and may subject us to liability for claims arising from the use or misuse of these materials.**

Our research and development efforts involve the use of hazardous materials, including biological materials, chemicals and radioactive materials. We are subject to federal, state and local laws and regulations governing the storage, use and disposal of these materials and some waste products. We believe that our safety procedures for the storage, use and disposal of these materials comply with the standards prescribed by federal, state and local regulations. However, we cannot completely eliminate the risk of accidental contamination or injury from these materials. If there were to be an accident, we could be held liable for any damages that result, which could exceed our financial resources. We currently maintain insurance coverage of up to \$1,000,000 per occurrence for injuries resulting from the hazardous materials we use, and up to \$25,000 per occurrence for pollution clean up and removal, however, future claims may exceed these amounts. Currently the costs of complying with federal, state and local regulations are not significant, and consist primarily of waste disposal expenses.

### **There are a substantial number of shares of our common stock eligible for future sale in the public market. The sale of these shares could cause the market price of our common stock to fall. Any future equity issuances by us may have dilutive and other effects on our existing stockholders.**

There were 2,726,019 shares of our common stock outstanding as of December 31, 2002. In addition, security holders held options, warrants and other rights as of December 31, 2002 which, if exercised, would obligate us to issue up to an additional 1,091,859 shares of common stock at a weighted average exercise price of \$50.09 per share, of which

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671,233 shares are subject to options or warrants which are currently exercisable at a weighted average exercise price of \$71.58 per share. In addition, on May 7, 2003, we completed a financing resulting in the issuance of 444 shares of our Series D 8% Cumulative Convertible Voting Preferred Stock, which are convertible into a total of 1,889,361 shares of our common stock at a conversion price of \$2.35 per share. In addition, the investors received 944,681 warrants to purchase our common stock at an exercise price of \$3.00 per share and 944,681 warrants to purchase our common stock at an exercise price of \$3.50 per share. A substantial number of those shares, when we issue them upon exercise, will be available for immediate resale in the public market. The market price of our common stock could fall as a result of such resales due to the increased number of shares available for sale in the market.

We have financed our operations, and we expect to continue to finance our operations, primarily by issuing and selling our common stock or securities convertible into or exercisable for shares of our common stock. Any issuances by us of equity securities may be at or below the prevailing market price of our common stock and may have a dilutive impact on our other stockholders. These issuances would also cause our net income, if any, or loss per share to decrease in future periods. As a result, the market price of our common stock could drop.

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

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 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 fail to meet the expectations of stock market analysts and investors. 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 2002, the price of our common stock ranged between \$101.25 and \$0.80, as adjusted to reflect a 25-for-1 reverse split of our outstanding common stock that we effected on September 6, 2002, and the daily trading volume, adjusted to reflect the reverse split has been as high as 777,764 shares and as low as 940 shares, with a recent average from January 2, 2003 up to and including May 7, 2003 of approximately 53,000 shares.

### **Certain provisions of our preferred stock may prevent or make it more difficult for us to raise funds or take certain other actions.**

Certain provisions of the Preferred Stock and Warrant Purchase Agreement and Certificate of Designation, Rights and Preferences of the Series D 8% Cumulative Convertible Voting Preferred Stock ( Preferred Stock ) may require us to obtain the approval of the preferred stockholders to (i) amend, alter or repeal any provision of the Charter or Bylaws which may be deemed to adversely affect the terms of the Preferred Stock (ii) offer, sell or designate a security senior to or equal with the Preferred Stock, (iii) sell or issue common stock or securities convertible into or exercisable for shares of our common stock below \$2.35 per share, (iv) incur any bank or non-trade indebtedness, (v) grant or make any mortgage or pledge of our property, (vi) merge or consolidate with another entity or sell or dispose of substantially all of our assets or businesses or (vii) take certain other actions which may be deemed to adversely affect the terms of the Preferred Stock. These provisions may make it more difficult for management, the board of directors or stockholders of the Company to take certain corporate actions and could delay, discourage or prevent future financings. These provisions could also limit the price that certain investors might be willing to pay for shares of our common stock.

### **Certain charter and bylaws provisions and our stockholder rights plan may make it more difficult for someone to acquire control of us or replace current management.**

Certain 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 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.

On December 13, 2000, we adopted a Stockholder Rights Plan pursuant to which we have distributed rights to purchase units of our capital 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 20% 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 20% 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.

**Our business is sometimes involved, or perceived by the public to be involved, in activities that may be seen as morally unacceptable and therefore may be legislated against, preventing us from engaging in certain research and development activities and eventually**

**marketing certain drug candidates.**

Our business involves the use of animals for certain research and development activities. Some groups perceive this as inhumane or otherwise morally unacceptable. If pressure by these groups and others results in legislation that limits or prevents any of our research and development activities, our business may be significantly harmed.

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**ITEM 2. PROPERTIES**

Our primary research and development and corporate administrative offices are located in a 34,320 square foot facility containing office and laboratory space, constructed for us in Irvine, California. We also sub-lease from the Regents of the University of California, Irvine (UCI), a 10,000 square foot laboratory and administrative facility in Irvine, California, adjacent to the University in which we conducted our functional genomics business activities. Each of our facilities is suitable and adequate to undertake our current research efforts, however, at this time, we are currently utilizing only half of the Irvine facility.

The primary Irvine facility is occupied under a non-cancelable lease for seven years through May 2004 and contains two five-year options to renew. The base monthly rent for the primary Irvine facility is currently \$42,862 which amount is subject to certain cost of living increases, plus taxes, insurance and common area maintenance. Under our sub-lease with UCI, sub-lease payments are at the rate of 50% of the basic rent charge, subject to certain conditions and commenced during June 2001. Under those conditions, if UCI is not able to pay all or part of their 50% portion of the sublease payment, we are obligated to pay, in addition to our 50% of the sub-lease payment, the amount that UCI is not able to pay. During 2001 and 2002, we paid approximately 85% and 82% of the sublease obligations, respectively. The base monthly rent is \$13,864, plus taxes, insurance, common area maintenance and scheduled rent increases for succeeding years over the five-year term of the sublease.

We are currently in negotiations with UCI regarding potential over billing of lease costs during 2001 and 2002 and future obligations under the lease given our decision to eliminate our functional genomics research and return the technology back to the University. All amounts in the financial statements that follow reflect what has been billed, including amounts disputed by Spectrum. No adjustments to these amounts will be made until a formal settlement agreement is signed.

We lease a small administrative office in Zurich, Switzerland on an expense-sharing basis. The financial and other terms of this lease are ordinary and are not material to our business.

**ITEM 3. LEGAL PROCEEDINGS**

We are not aware of any litigation matters pending that will materially affect our condensed consolidated financial statements. We are sometimes involved in matters of litigation that we consider ordinary routine litigation incidental to our business.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

No matters were submitted to a vote of security holders during the fourth quarter ended December 31, 2002.

**Table of Contents****PART II****ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS****Common Stock**

As of May 7, 2003, there were 3,108,100 shares of common stock outstanding and 377 shareholders of record. On May 7, 2003, the closing bid price of our common stock was \$2.66 per share.

**Market for Securities**

Our common stock is traded on the Nasdaq SmallCap Market under the symbol SPPI. The high and low trades of our common stock reported by Nasdaq during each quarter ended in 2001 and 2002 were as follows:

	<b>High</b>	<b>Low</b>
<b>Year 2002</b>		
Quarter Ended		
March 31	\$ 101.25	\$ 40.25
June 30	\$ 67.25	\$ 3.50
September 30	\$ 6.50	\$ 0.80
December 31	\$ 2.75	\$ 0.91
<b>Year 2001</b>		
Quarter Ended		
March 31	\$ 147.00	\$ 139.50
June 30	\$ 104.50	\$ 98.50
September 30	\$ 80.50	\$ 75.00
December 31	\$ 91.75	\$ 88.75

The high and low trades of our common stock reported by Nasdaq reflect inter-dealer prices, without retail mark-ups, mark-downs or commissions, and may not represent actual transactions. Common stock prices have been restated to reflect for the 25-for-1 reverse split of our outstanding common stock approved by our stockholders on September 5, 2002 and completed on September 6, 2002.

**Dividends**

We have never paid cash dividends on our common stock and we do not intend to pay dividends in the foreseeable future.

**Recent Sales of Unregistered Securities**

The following is a summary of transactions involving sales of our securities that were not registered under the Securities Act of 1933, as amended (the Securities Act), and have not been previously included in a quarterly report on Form 10-Q. Exemption from registration was relied upon under Section 4(2) of the Securities Act for all transactions listed.

On November 21, 2002, NDDO Research Foundation ( NDDO ) acquired 55,618 shares of our common stock pursuant to a license agreement with us at a value of \$1.76 per share. We made no solicitation in connection with the agreement, other than communications with NDDO; we obtained representations from the organization regarding its investment intent, experience and sophistication; and the shares were not acquired as part of a plan of financing.

On November 21, 2002, NDDO Oncology B.V. ( NDDO Oncology ) acquired 45,944 shares of our common stock at a purchase price of \$1.76 per share for settlement of certain accounts payable due to NDDO Oncology in connection with services performed. We made no solicitation in connection with NDDO Oncology's acquisition, other than communications with NDDO Oncology; we obtained representations from NDDO Oncology regarding its investment intent, experience and sophistication; and the shares were not acquired as part of a plan of financing.

## Edgar Filing: SPECTRUM PHARMACEUTICALS INC - Form 10-K/A

On November 21, 2002, Clinical Pharmaceuticals Trials ( Clinical Pharmaceuticals ) acquired 8,500 shares of our common stock at a purchase price of \$1.76 per share for settlement of certain accounts payable due to Clinical Pharmaceuticals in connection with services performed. We made no solicitation in connection with Clinical Pharmaceuticals acquisition, other than communications with Clinical Pharmaceuticals; we obtained representations from Clinical Pharmaceuticals regarding its investment intent, experience and sophistication; and the shares were not acquired as part of a plan of financing.



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On November 21, 2002, GRAM Laboratories ( GRAM ) acquired 198,864 shares of our common stock at a purchase price of \$1.76 per share for settlement of certain accounts payable due to GRAM in connection with services performed. We made no solicitation in connection with GRAM's acquisition, other than communications with GRAM; we obtained representations from GRAM regarding its investment intent, experience and sophistication; and the shares were not acquired as part of a plan of financing.

On November 21, 2002, Symbion Research ( Symbion ) acquired 48,000 shares of our common stock at a purchase price of \$1.76 per share for settlement of certain accounts payable due to Symbion in connection with services performed. We made no solicitation in connection with Symbion's acquisition, other than communications with Symbion; we obtained representations from Symbion regarding its investment intent, experience and sophistication; and the shares were not acquired as part of a plan of financing.

On November 21, 2002, Oppenheimer Wolff & Donnelly LLP ( Oppenheimer ) acquired a five-year warrant to purchase up to 161,460 shares of our common stock at \$0.25 per share for settlement of certain accounts payable due to Oppenheimer in connection with its services as our intellectual property counsel. We made no solicitation in connection with Oppenheimer's acquisition, other than communications with Oppenheimer; we obtained representations from Oppenheimer regarding its investment intent, experience and sophistication; and the shares were not acquired as part of a plan of financing.

**ITEM 6. SELECTED FINANCIAL DATA**

The following table presents our selected financial data. Financial data for the years ended 2000, 2001 and 2002 and as of December 31, 2001 and 2002 has been derived from our audited financial statements included elsewhere in this Form 10-K and should be read in conjunction with those financial statements and accompanying notes and with Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations. Financial data for the years ended 1998 and 1999 and as of December 31, 1998, 1999 and 2000 has been derived from our audited financial statements not included herein.

**CONSOLIDATED FINANCIAL INFORMATION (in thousands):**

<b>Statement of Operations Data for the Years Ended December 31:</b>	<b>1998</b>	<b>1999</b>	<b>2000</b>	<b>2001</b>	<b>2002</b>
Revenues	\$	\$	\$	\$ 41	\$ 2,371
Operating expenses:					
Research and development	8,542	20,058	38,767	20,611	12,726
General and administrative	3,123	3,465	5,107	7,580	4,102
Restructuring expenses					3,050
Settlement of litigation		2,458			
Loss from operations	(11,665)	(25,981)	(43,874)	(28,150)	(17,507)
Other income (expense)	60	(9)	(2,553)	315	(127)
Net loss	\$(11,605)	\$(25,990)	\$(46,427)	\$(27,835)	\$(17,634)
Basic and diluted loss per share	\$ (51.75)	\$ (92.00)	\$(109.25)	\$ (36.50)	\$ (12.34)
	<b>_____</b>	<b>_____</b>	<b>_____</b>	<b>_____</b>	<b>_____</b>
<b>Balance Sheet Data at December 31:</b>	<b>1998</b>	<b>1999</b>	<b>2000</b>	<b>2001</b>	<b>2002</b>
Cash, cash equivalents and marketable securities	\$2,867	\$ 9,681	\$11,470	\$ 7,157	\$1,578
Property and equipment, net	3,252	3,161	3,416	4,689	802
Total assets	6,826	13,174	15,781	12,825	3,453
Current liabilities	2,364	4,757	5,110	5,212	2,522
Long-term debt, less current portion	1,126	637	474	464	158
Other non-current-liabilities	46	75	87	362	101
Minority interest in consolidated subsidiaries			7,280		
Total stockholders' equity	\$3,290	\$ 7,705	\$ 2,830	\$ 6,787	\$ 672



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**ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

You should read the following discussion of the financial condition and results of our operations in conjunction with the financial statements and the notes to those statements included elsewhere in this report. The discussion in this report contains forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. The cautionary statements made in this report should be read as applying to all related forward-looking statements wherever they appear in this report. Our actual results could differ materially from those discussed here. Factors that could cause or contribute to these differences include those discussed in Risk Factors, as well as those discussed elsewhere.

**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. On an on-going basis, we evaluate our estimates, including cash requirements resulting from estimating: planned research and development activities and general and administrative requirements, the retention of key personnel, certain clinical trial results, maintained market need for our drug candidates and other major business assumptions.

We believe that our most significant accounting policies that affect our more significant judgments and estimates used in the preparation of our consolidated financial statements are:

*Liquidity*

Since our inception, we have incurred cumulative losses of approximately \$141.7 million through December 31, 2002, and expect to incur substantial losses over the next several years.

On August 20, 2002, we announced a shift in our strategic focus from discovery and development of neurology drugs to the in-licensing of oncology drug candidates and the further development of and strategic alliances for these drug candidates and the out-licensing of our neurology drug candidates to strategic partners. As a result of these changes and the completion of a large Alzheimer's disease clinical trial, our expense rate fell from approximately \$7 million per quarter to approximately \$1.7 million during the three-month period ended December 31, 2002 (exclusive of restructuring, drug product and formulation charges), and we expect it to continue to fall to approximately \$1.5 million, or lower, per quarter beginning in the first quarter of 2003 (exclusive of drug product and formulation costs). The recent and the prospective reduction in the expense rate is principally due to reductions in clinical, research and administrative personnel representing an approximate 78% reduction in personnel since December 2001, the termination of a facility lease for office space used to administer the Alzheimer's disease clinical trial, the reduction of expenses for the manufacturing of Neotrofin supplies, a reduction in our research and fellowship grant commitments, and the elimination of the research operations of our functional genomics business. Our expense rate in 2003 will be a function of our drug development program. We have expanded a clinical trial of Eoquin for the treatment of superficial bladder cancer which will result in an increase in our expense rate during 2003. In addition, if we decide to initiate a clinical study of elsamitrucin in refractory non-Hodgkin's lymphoma, our expense rate will increase.

On September 30, 2002, we entered into a co-development and license agreement with GPC Biotech AG for the development and commercialization of our lead drug candidate, satraplatin. Under the co-development and licensing agreement, we may receive up to \$22 million in license fees and milestone payments. The license fee consists of a total of \$4 million; \$2 million upon signing (which was received in October of 2002) and \$1 million in cash and a \$1 million equity investment within 30 days after the first dosing of a patient in a registrational study. GPC Biotech has agreed to make additional payments totaling up to \$18 million upon achieving agreed upon milestones. However, there can be no assurance that any milestone will be achieved. Furthermore, GPC Biotech has agreed to fully fund development and commercialization expenses for satraplatin. Upon commercial sale of satraplatin, if any, we will be entitled to receive royalty payments based upon net sales.

At the present time, our business does not generate sufficient cash from operations to finance our short-term operations. We will rely primarily on (a) raising funds through the sale of our common stock and/or (b) out-licensing our technology, to meet all of our short-term cash needs. We have generated operating losses since our inception, however, we believe that our existing cash and investment securities, including cash proceeds from the issuance of securities in January and May 2003 will be sufficient to fund our current planned operations for the next 12 months. As a result, on May 9, 2003, our independent accountant reissued its report for the year ended and as of December 31, 2002. The reissued report eliminated the explanatory paragraph related to going concern that was initially contained in their report dated March 25, 2003.



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*Principles of Consolidation*

Our consolidated financial statements include our accounts including those of our wholly owned and majority owned subsidiaries. We eliminated all significant intercompany accounts and transactions.

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

*Cash and Cash Equivalents*

Cash and cash equivalents consist of cash and highly liquid investments of commercial paper and demand notes with original maturities of 90 days or less.

*Marketable Securities and Short-Term Investments*

We classify investments in debt securities among three categories: held-to-maturity, trading, and available-for-sale. As of December 31, 2002, all of our debt securities holdings were categorized as available-for-sale. We carry available-for-sale securities at fair value, with unrealized gains and losses included as a component of accumulated other comprehensive income (loss) in stockholders' equity. We use quoted market prices to determine the fair value of these investments. If we believe that it is probable that we will be unable to collect all amounts due to us according to the contractual terms of an investment, we consider the impairment as other than temporary and would record an impairment loss.

*Prepaid Expenses and Refundable Deposits*

Prepaid expenses are deferred and later recorded as an expense during the period benefited. Deposits are expected to become refundable at a later date.

*Property and Equipment Purchased or Leased*

We carry property and equipment at historical cost, less accumulated depreciation and amortization. When property and equipment are disposed of, the related cost and accumulated depreciation are removed from the accounts and any resulting gain or loss is reflected in income. Depreciation and amortization are computed using the straight-line method over the following estimated useful lives:

Equipment	5 to 7 years
Leasehold Improvements	The shorter of the estimated useful life or lease term

We review long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicated that the carrying amount of the assets may not be fully recoverable. We assess the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, we reduce the carrying value of the asset to fair value.

*Research and Development*

We expense all research and development activity costs in the period incurred.

*Stock-Based Compensation*

We account for all of our stock based compensation in accordance with SFAS No. 123, Accounting for Stock-Based Compensation (or SFAS 123) that encourages companies to recognize stock based compensation using a fair market value methodology. Under SFAS 123, the fair value of a stock option (or its equivalent) granted by a public entity shall be estimated using an option-pricing model (for example, the Black-Scholes or binomial model) that takes into account certain assumptions. However, SFAS 123 permits continued use of accounting for employee stock based compensation using the intrinsic value methodology of accounting promulgated by Accounting Principles Board (or APB) Opinion No. 25, Accounting for Stock Issued to Employees (or APB 25). Under the intrinsic method, stock based compensation is measured as the excess, if any, of the quoted market price of our



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common stock at the measurement date over the exercise price.

We recognize non-employee stock based compensation or payments using a fair market value methodology promulgated by SFAS 123.

We recognize employee stock based compensation using the intrinsic value methodology promulgated by APB 25.

### *Basic and Diluted Net Loss Per Share*

We calculate basic and diluted net loss per share using the weighted average number of common shares outstanding and the net loss, less preferred stock dividends, during each year, respectively. We exclude all antidilutive common stock equivalents from the basic and diluted net loss per share calculation.

All share and per share information has been restated to reflect for the 25-for-1 reverse split of our outstanding common stock approved by our stockholders on September 5, 2002 and completed on September 6, 2002.

### *Use of Estimates*

We make certain estimates to prepare our financial statements that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and revenues and expenses reported during the reporting period. Actual results could differ from our estimates.

We have estimated that our current working capital plus funds raised or to be raised subsequent to year end will be sufficient for us to continue as a going concern and therefore have prepared the financial statements on that basis. That basis includes estimating future cash requirements of planned research and development activities and general and administrative requirements, the retention of key personnel, certain clinical trial results, maintained market need for our product candidates, and other major business assumptions. If these estimates prove to be wrong, we may not be able to continue as a going concern.

### *Revenue Recognition*

We have adopted a strategy of co-developing or licensing our drug candidates. Accordingly, we have entered into collaborative research and development agreements and have received funding for pre-clinical research and clinical trials. Payments under these agreements, which are non-refundable, are recorded as revenue as the related research expenditures are incurred pursuant to the terms of the agreement and provided collectibility is reasonably assured. If no further commitments are required of us, the revenue is recognized when the license fee is payable or when all future commitments are satisfied.

License fees comprise initial fees and milestone payments derived from collaborative licensing arrangements. Non-refundable milestone payments continue to be recognized upon (i) the achievement of specified milestones when we have earned the milestone payment, (ii) the milestone payment is substantive in nature and the achievement of the milestone was not reasonably assured at the inception of the agreement. We defer payments for milestone events which are reasonably assured and recognizes them ratably over the minimum remaining period of our performance obligations. Payments for milestones which are not reasonably assured are treated as the culmination of a separate earnings process and are recognized as revenue when the milestones are achieved.

### *Income Taxes*

We recognize deferred tax assets and liabilities for the future tax consequences attributable to differences between the financial statement bases and tax bases of existing assets and liabilities. We recorded a valuation allowance equal to our net deferred tax asset.

## **Results of Operations**

For fiscal years 2000, 2001 and 2002, we devoted our resources primarily to fund research and development that resulted in significant losses. We expect that our operating expenses will decrease in the immediate future as compared to the same period last year due to the shift in our strategic focus and the reduction of the operations during 2002. If we are able to raise sufficient additional funds, further development of our in-licensed anti-cancer drug candidates will likely cause our operational expenses to increase over the next several years. We expect to incur significant additional operating losses for at least the next several years unless such operating losses are offset, if at all, by licensing revenues under our agreement with GPC Biotech AG, strategic alliances with pharmaceutical companies that we are currently seeking and revenue from our generic products. During 2002, our functional genomics operations was reduced, restructured and merged with the pharmaceutical business, and we currently operate as one segment. The following is financial information for the three years ended December 31, 2002:





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<b>Statement of Operations Data for the Years Ended December 31 (in Thousands):</b>	<b>2000</b>	<b>2001</b>	<b>2002</b>
Revenues		41	2,371
Research and development	38,767	20,611	12,726
General and administrative	5,107	7,580	4,102
Restructuring expenses			3,050
Other Income (Expense), net	(1,090)	364	(126)

*Results of Operations for Fiscal 2002 Compared to Fiscal 2001*

Revenue for 2002 resulted from the recognition of the first licensing fee of \$2 million from the co-development and licensing agreement with GPC Biotech AG and the technology out-licensing agreements with Pfizer Inc. entered into during the second and fourth quarters of 2001. We received initial payments of \$300,000 aggregate cash proceeds from entering into these agreements. Additionally, during the three-month period ended June 30, 2002, we received the first milestone payment of \$250,000 from Pfizer Inc. under our March 15, 2001 technology out-license agreement with them. This milestone payment became due at the time Pfizer Inc. formally approved the funding and implementation of a research program with respect to a pharmaceutical lead based on our technology that we licensed to Pfizer Inc. Under these agreements, we entered into strategic alliances with Pfizer Inc. for investigating potential drug targets. We are obligated to pay the Regents of the University of California, Irvine (UCI) 25% of all payments received under these agreements. In accordance with our revenue recognition policy, the initial payments, less amounts owed to UCI, were being recognized as revenue over a three-year period from the date of inception of the respective agreement, whereas substantive milestone payments were recognized as revenue upon receipt, less amounts owed to UCI. Upon termination of all research activities at NeoGene Technologies and the completion of all further commitments under these license agreements, the remainder of the initial payments was recognized as revenue.

Research and development expenses for 2002 compared to 2001 decreased primarily due to the reduction of costs related to our clinical trial for Neotrofin in the treatment of patients with Alzheimer's disease that ended in April 2002, causing a decrease in outside clinical research site costs, a decrease in product manufacturing costs, a decrease in salary and related benefit costs due to a decrease in research and development personnel following the completion of the trial. In addition, as a result of a restructuring, all research activities related to Neotrofin, functional genomics and neurology were eliminated. The decrease was also a result of lower compensation charges during 2002 associated with stock and stock options granted to employees and officers below fair market value as a result of the reduction in force and the cancellation of certain options by several executives. The decrease was partially offset by an increase in salaries and related benefit costs due to additions of research and development personnel in the first half of 2002 compared to the same period in 2001, an increase in depreciation related to acquisitions of equipment and leasehold improvements, an increase in lab supplies and outside contract research due to increased business activities in the first half of 2002 compared to 2001, an increase in general business expenses related to the development of our oncology related drug candidates, increases in occupancy and facility costs due to the building sub-lease entered into in November 2001, a charge of \$102,997 for personnel severance related expenses in the six month period ended June 30, 2002, and a license fee paid for the in-license of one of our oncology drug candidates in 2001. The decrease was also offset by costs related to our clinical trials for Neotrofin in the treatment of patients with Parkinson's disease, spinal cord injuries and neuropathy, which were completed in June, August and October of 2002, respectively.

General and administrative expenses for 2002 compared to 2001 decreased primarily to a general decrease in personnel during 2002, an early termination fee paid in 2001, decreases in consulting, travel and lodging expenses, officer relocation expenses, and a decrease in deferred compensation related to NeoGene stock options granted to employees and officers below fair market value at an exercise price of \$1.00 per share. These decreases were partially offset by an increase in depreciation expense due to the acquisition of equipment during the fourth quarter of 2001 and the first six months of 2002, a charge of \$76,763 related to personnel severance related expenses and an increase in corporate business expenses related to the development of our oncology related drug candidates.

Restructuring expenses were incurred during the six-month period ended December 31, 2002 as a result of a shift in our strategic focus from discovery and development of neurology drugs to the in-licensing of oncology drug candidates and the further development of and strategic alliances for these drug candidates and out-licensing of our neurology drug candidates to strategic partners. As a result of these changes, we laid off 21 employees, two senior executives retired and we incurred significant administrative and legal expenses. The restructuring charge includes legal fees in the amount of \$231,000, a loss on the exchange of assets for certain payables to UCI in the amount of \$312,000, retirement benefits offset against a loan to Dr. Alvin Glasky, the Company's former Chief Executive Officer and a former board member, in the

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amount of \$390,000, \$114,000 in severance benefits to Dr. Glasky, \$200,000 in severance benefits to Samuel Gulko, the Company's former Senior Vice President Finance and Chief Financial Officer, board of directors fees of \$71,000 for special meetings related to the restructuring and personnel severance related expenses of \$59,000. In addition, during the fourth quarter of 2002, we completed a review of our property and equipment and based upon current accounting guidance determined that the equipment was impaired and recorded an impairment in the amount of \$1,669,000.

Other income for 2002 compared to the same period in 2001 decreased due primarily to a decrease in the fair market value of a marketable security investment that we determined to be other than temporary of approximately \$51,000 and a decrease in interest income resulting from lower average marketable securities balances and lower interest rates. These decreases were offset by a receipt of a \$250,000 exclusivity payment from a party negotiating a potential corporate transaction with the Company. During the third quarter of 2002, the exclusivity period expired and we are no longer in discussions with the party.

### *Results of Operations for Fiscal 2001 Compared to Fiscal 2000*

Revenue was approximately \$41,000 during 2001 primarily from recognizing deferred licensing fees earned during 2001 from Pfizer, Inc. and from a single product sale. We did not have any revenue during 2000.

The decrease in research and development expense during 2001 was due primarily to us internally managing the majority of our clinical trials instead of using more expensive outside clinical research organizations. However, for that purpose, additional expenses from an increase in personnel, consultants and office space rent offset a portion of this decrease. The most significant clinical trials we conducted during 2001 were a pivotal Phase 2 clinical trial for Neotrofin for the treatment of Alzheimer's disease, other Neotrofin clinical trials for other neurological indications, and for Eoquin, in the United Kingdom, for the treatment of bladder cancer. We also incurred additional research and development expenses to broaden our pharmaceutical platform base and further development of new drug candidates, including activities to secure drug supplies and to prepare clinical protocols for satraplatin, and the identification of compounds in our psychosis platform. Overall during 2001, research and development expenses increased in the category of salaries due to additional personnel, salary increases and related benefits, increases in pre-clinical expenses related to broadening our pharmaceutical platforms, and increases in consulting expenses primarily due to internally managing the majority of our clinical trials. Offsetting these declines was also a continued ramp up of operations at our functional genomics subsidiary in 2001. These expenses included a significant increase in personnel that increased salary and related benefits and other expenses, offset slightly by a decrease in consulting expense. Additionally, we occupied new facilities under a sub-lease that commenced in June 2001. Under our new sub-lease agreement, we paid for approximately 85% of the expenses of the new facility (see *Properties* for the significant terms of this sub-lease agreement). Prior to 2001, we had no direct occupancy expense related to our functional genomics business.

The increase in general and administrative expense in 2001 when compared to 2000 was due primarily to increases in personnel, salary increases and related benefits, recruiting, relocation, travel and depreciation and amortization. In addition, we paid a break-up penalty fee of approximately \$405,000 in 2001 related to the cancellation of the first debenture tranche of \$10 million under the April 17, 2001 financing and we incurred approximately \$610,000 in investment banking consulting services expense in exchange for warrants to purchase shares of our common stock.

The decrease in interest income during 2001 was due to lower average balances in our investment accounts offset slightly by higher interest rates on our investments. However, the decrease in interest expense during 2001 more than offset the decline in interest income and was due primarily to the non-recurrence of a non-cash charge incurred in 2000 of approximately \$1.6 million of amortization of debt discount and issuance costs associated with convertible debt that was issued and converted into common stock during 2000, partially offset by an increase in interest expense associated with capital lease obligations due to higher interest rates and a higher average lease obligation balance.

### **Subsequent Events Affecting Future Results**

On January 16, 2003, we sold 222,223 shares of our common stock at \$2.25 per share for gross cash proceeds of \$500,000 under our shelf registration statement. The investors also received warrants to purchase up to 55,555 shares of our common stock at an exercise price of \$3.25 per share. Offering costs of this transaction were approximately \$35,000.

On February 3, 2003, we entered into an agreement with a strategic investor who has agreed to invest \$1 million in Spectrum to support the Company's emerging generic drug business. The investment will be subject to the achievement of two milestones, both of which relate to the first Abbreviated New Drug Application (ANDA) filed by Spectrum with the U.S. Food and Drug Administration (FDA) in January 2003. The investor will purchase \$250,000 of unregistered Spectrum common stock upon acceptance by the FDA of the ANDA. The investor will purchase an additional \$750,000 of unregistered Spectrum common stock upon approval of this ANDA by the FDA. The purchase prices in the transactions will be at the closing price of Spectrum stock on the day prior to acceptance and approval, respectively.

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On April 8, 2003, Spectrum announced that Nasdaq has notified the Company that it is not in compliance with Nasdaq's minimum stockholders' equity requirement set forth in Marketplace Rule 4310(c)(2)(B), and that its securities are, therefore, subject to delisting from the Nasdaq SmallCap Market. The Company has requested a hearing before a Nasdaq Listing Qualifications Panel to review the Staff Determination. There can be no assurance the Panel will grant the Company's request for continued listing. However, the hearing request will stay the delisting of the Company's securities pending the Panel's decision.

On April 14, 2003, the Company received notification from the FDA that it had accepted the ANDA for Ciprofloxican. As a result of this notification and in accordance with the agreement entered into on February 3, 2003, a strategic investor has agreed to purchase 125,628 shares of unregistered Spectrum common stock at \$1.99 per share for total proceeds of \$250,000 upon approval of the currency transfer by the Reserve Bank of India.

On May 7, 2003, we sold 444 shares of our Series D 8% Cumulative Convertible Voting Preferred Stock and Series D Warrants to purchase shares of our common stock for gross cash proceeds of \$4,440,000. The preferred stock is convertible into 1,889,361 shares of Spectrum common stock at a price of \$2.35 per share. Dividends on the preferred stock are payable quarterly at an annual rate of 8 percent either in cash or shares of our common stock at the discretion of the Company. In addition, purchasers of the preferred stock received five-year warrants to purchase up to a total of 944,681 shares of our common stock at an exercise price of \$3.00 per share and five-year warrants to purchase up to a total of 944,681 shares of our common stock at an exercise price of \$3.50 per share. Under a preexisting agreement with a placement agent, we issued to a placement agent, in addition to cash fees, a five-year warrant to purchase up to a total of 188,936 shares of our common stock at an exercise price of \$3.00 per share. Offering costs, including cash commissions paid to placement agents of this transaction, are estimated to be \$545,000.

### **Financial Condition**

#### *General*

At the present time, our business does not generate cash from operations needed to finance our short-term operations. We will rely primarily on raising funds through the sale of our securities, and/or out-licensing our technology, to meet all of our short-term cash needs. We have generated operating losses since our inception, however, we believe that our existing cash and investment securities, including cash proceeds from the issuance of securities in January and May 2003 will be sufficient to fund our current planned operations for the next 12 months. As a result, on May 9, 2003, our independent accountant reissued its report for the year ended and as of December 31, 2002. The reissued report eliminated the explanatory paragraph related to going concern that was initially contained in their report dated March 25, 2003.

Over the long-term, we will likely need to continue to raise funds through public or private financings, including equity financings and through other arrangements, to continue operating our business, however, we believe profits from our generic business will help to reduce or possibly eliminate this reliance on the need to raise funds through the sale of our securities.

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*2002 Cash Flow Activities*

At December 31, 2002, we had working capital of approximately \$49,000 that included cash and equivalents of approximately \$1.5 million and short-term investments of approximately \$66,000. In comparison, at December 31, 2001 we had working capital of approximately \$2.8 million that included cash and cash equivalents of approximately \$0.7 million and short-term investments of approximately \$6.4 million. The \$2.8 million decrease in net working capital during the year ended December 31, 2002 is attributable primarily to the loss of \$17.6 million, less non-cash compensation, an impairment charge and other items of approximately \$3.5 million, less changes in operating assets and liabilities of \$2.1 million, plus payments on capital lease obligation of \$0.7 million, partially offset by the sale of approximately \$9.9 million of our common stock.

We financed our 2002 business operations primarily through sales of securities. During 2002, we raised \$9.9 million and issued 1,407,627 shares of our common stock.

During 2002, we also received a milestone payment of \$187,500, net of amounts paid to UCI, from Pfizer Inc. under one of the technology out-licensing agreements entered into in 2001.

There were 2,726,019 issued and outstanding shares of our common stock as of December 31, 2002. In addition, security holders held options and warrants as of December 31, 2002 which, if exercised, would obligate us to issue up to an additional 1,091,859 shares of common stock, of which 671,233 shares are subject to options or warrants which are currently exercisable at the sole election of the holder. A substantial number of those shares, when issued upon exercise, will be available for immediate resale in the public market.

*2001 Cash Flow Activities*

During 2001, we raised net proceeds of \$28.3 million through the sale of 399,174 shares of our common stock. In addition, we received \$305,000 in licensing fees related to our functional genomics subsidiary.

On January 2, 2001, we filed with the Securities and Exchange Commission a shelf registration statement permitting the sale of our securities with a maximum aggregate public offering price of \$50 million. The registration statement expired in March 2003.

On July 2, 2001, we filed with the Securities and Exchange Commission a registration statement permitting the sale by us, from time to time, of up to \$8.4 million of our common stock directly into the public trading market for our common stock. The common stock sold pursuant to this registration statement will be offered through an underwriter engaged by us on a best efforts basis.

On April 6, 2001, in a special meeting, our stockholders approved an increase in authorized common stock from 25 million to 50 million shares.

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During 2000, we raised net proceeds of \$28.8 million through the sale of 112,224 shares of our common stock. In addition in 2000, we completed the following transactions:

On April 6, 2000, we entered into a financing transaction with two private investor groups. The transaction consisted of (a) \$10 million in 5% subordinated convertible debentures due April 6, 2005, (b) redeemable warrants to purchase up to 160,000 shares of our common stock over a two year period and (c) five-year warrants to purchase from 4,600 shares up to 10,600 shares of our common stock at an exercise price of \$491.75 per share. During 2000, the investor converted the \$10 million of debentures into 62,216 shares of our common stock plus 1,551 shares of our common stock in payment of accrued interest. Also in 2000, we called and the investors exercised 23,456 of our redeemable warrants for 23,456 shares of our common stock in exchange for \$5,120,654 in cash. At both December 31, 2000 and 2001, there were 136,544 redeemable warrants outstanding. The warrants expired in June 2002.

On September 21, 2000, we sold 111,110 shares of Series A convertible preferred stock of our majority owned subsidiary, NeoGene, for \$5 million and a five-year warrant to purchase up to (i) 3,200 shares of our common stock at an exercise price of \$261.75 per share and (ii) 22,676 shares of NeoGene common stock at an exercise price of \$45.00 per share. On August 13, 2001, Spectrum Pharmaceuticals purchased the Series A Preferred Stock of NeoGene for \$5.5 million representing the \$5.0 million face value of the preferred stock plus a \$500,000 redemption fee. The difference of approximately \$0.8 million between the book value of the preferred stock and the amount paid was recorded as a charge to accumulated deficit. We also paid accrued dividends of approximately \$220,000 to the holders of the preferred stock.

On December 18, 2000, we entered into an agreement between our majority owned subsidiary, NeoGene, and an institutional investor for the issuance and sale of NeoGene Series B convertible preferred stock and warrants for aggregate consideration of \$2.0 million. Under the provisions of the agreement, we issued and sold to the investor a total of 44,445 shares of NeoGene Series B Convertible Preferred Stock, at a purchase price of \$45 per share, and issued a five-year warrant to purchase a total of 9,387 shares of NeoGene common stock, at an exercise price of \$45 per share. The investor also received a five-year warrant to purchase an aggregate of 1,200 shares of our common stock, at an exercise price of \$152.50 per share. We also granted an exchange right to the investor that will allow the investor to exchange its shares of NeoGene Series B Preferred for our preferred stock. The exchange right granted the investor the right, at its option, at any time and from time to time after June 18, 2001, to exchange all or a portion of the NeoGene Series B Preferred shares then held by the investor for a number of shares of our designated convertible preferred stock. In June 2001, the investor exercised its right to exchange all of the NeoGene Series B Preferred stock then held by the investor for 200 shares of our 7% Series C convertible Preferred stock. Under the terms of the exchange right, the investor forfeited 4,693 or 50% of the previously granted five-year warrants to purchase shares of NeoGene common stock at an exercise price of \$45 per share. The shares of our 7% Series C Preferred Stock were redeemable, under certain conditions at the option of the holder, and each share is convertible into a number of shares of our common stock equal to \$10,000 divided by the lesser of (i) 100% of the average of the lowest seven closing bid prices of our common stock in the previous 30 trading days, or (ii) \$149.25. In August 2001, the holder of our 7% Series C Preferred Stock converted 170 shares of our 7% Series C Preferred Stock into 19,424 shares of our common stock. In September 2001, we purchased the remaining 30 shares of our 7% Series C Preferred Stock for \$300,000 plus accrued dividends and a settlement fee of approximately \$72,000.

**Related Party Transactions**

During 1987 and 1988, Alvin J. Glasky, Ph.D., a former Chief Executive Officer who was also a major stockholder of ours, loaned a total of \$270,650 to us for working capital purposes, of which \$250,000 plus \$2,000 of accrued interest was canceled in December 1988 in exchange for the issuance of 28 Revenue Participation Units (or RPU s). The RPU s were converted into 4,480 shares of our common stock.

From 1989 through 1993, we borrowed an additional \$757,900 from Dr. Glasky, which, together with accrued interest of \$300,404, aggregated \$1,058,304 on December 31, 1993, at which time we issued 8,000 shares of common stock to Dr. Glasky in exchange for cancellation of \$500,000 of loans made to us. The remaining \$257,900 in principal and \$300,404 of accrued interest were converted to a \$558,304 promissory note. Interest was paid monthly at the annual rate of 9%. The note was partially repaid in 2000 when we advanced cash to Dr. Glasky to pay payroll taxes arising from his exercise of a warrant for 3,527 shares of common stock at \$93.75 per share in August 2000. We made a further partial repayment of the note in 2001. The outstanding balance was repaid on August 16, 2002, in connection with Dr. Glasky's retirement as our Chairman of the Board, Chief Executive Officer and Chief Scientific Officer.

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### *Assignment of Patents by Dr. Alvin Glasky*

Dr. Glasky assigned to us all of his rights in ten patents. In connection with the assignment of these patents to us, we entered into royalty agreements with Dr. Glasky (or the Glasky Agreements), which expire concurrently with the expiration of the underlying patents and any additional patents derived from the underlying patents. Under each of the Glasky Agreements, as amended, we are obligated to pay Dr. Glasky a royalty of two percent (2%) of all revenues derived by us from the use and sale by us of any products or methods included in the patents. In the event of Dr. Glasky's death, the family or estate is entitled to continue to receive, under each Glasky Agreement, royalties at a rate of two percent (2%) for the duration of the respective Glasky Agreement. Under the terms of the Glasky Agreements, Dr. Glasky may terminate the Glasky Agreements and receive a reassignment of the patents if we file a petition under any bankruptcy or insolvency laws or otherwise commence liquidation or winding up of our business.

### *McMaster University Agreement*

On July 10, 1996, we entered into a license agreement with McMaster University (or McMaster) that allows us the use of certain technologies developed by McMaster covered in the patents filed jointly by us and McMaster, all of which are also subject to the Glasky Agreements. Under the agreement, we paid a one time licensing fee of \$15,000 and are obligated to pay to McMaster an annual royalty of five percent (5%) on net sales of products containing compounds developed by McMaster. In July 1997, we began to make, and have continued making, annual minimum royalty payments of \$25,000.

### *Director and Officer Notes for the Exercise of Equity Instruments*

We made loans to certain of our directors and officers for the exercise of stock options or for the purchase of stock. We loaned \$286,560 in 1998, and \$435,649 in 2000. During 2000, one individual paid \$61,560 back to us and during 2001, in connection with the settlement of a litigation matter, we forgave a \$45,000 note to one individual. During the three months ended September 30, 2002, loans made to Dr. Glasky totaling approximately \$390,000 were repaid by the offset of certain liabilities incurred in connection with Dr. Glasky's retirement and Samuel Gulko repaid his loan in connection with his retirement. In June 2002, the original interest rates that were between 7% and 9% were all changed to 4.5% and the maturity dates were extended to June 6, 2004. The notes were secured by a pledge of the common stock purchased with the loan proceeds. In February 2003, we agreed to forgive/terminate all outstanding amounts due under the remaining loan agreements and in return, the board members agreed to return the shares of common stock originally purchased under the loans. For financial statement purposes, the common stock and related notes receivable were eliminated as of December 31, 2002.

### *Outsource Arrangement*

John L. McManus, our Vice President Finance and Strategic Planning, and Michael P. McManus, our Controller, are brothers and co-owners of McManus Financial Consultants, Inc. ( MFC ) and McManus & Company, Inc. ( M&C ). Commencing as of November 1, 2002, we have outsourced the administration, accounting and human resources functions to MFC for a monthly fee of \$7,000. Also commencing as of November 1, 2002, we have outsourced SEC report preparation and other accounting activities to MFC for a monthly fee of \$8,000 per month. From January until June 2002, MFC also performed investor relations activities for us at hourly rates, subject to a minimum annual retainer of \$24,000. M&C now performs all investor relations activities for us for a monthly fee of \$10,000 per month. During the year ended December 31, 2002, MFC received a total of \$82,000 in fees. As a result of these arrangements, Michael P. McManus received no direct compensation from Spectrum for his services as Controller. Both Michael P. McManus and John L. McManus received salaries from MFC that were not related to or determined by revenues from any one particular client of MFC.

## **Contractual and Commercial Obligations**

### *Debt and Capital Leases*

On September 22, 2000, we signed an agreement to lease up to \$2.5 million in equipment from a major equipment leasing and remarketing company (or lessor). Under the terms of the agreement, we could have drawn up to \$2.5 million through September 2001 and are required to make quarterly payments over three years on cumulative advances drawn by us. We drew a total of \$1,029,381 under the lease agreement. The lease is collateralized by the underlying equipment. At the conclusion of the lease term, the equipment may be purchased for fair value at that time, re-marketed by the lessor, or re-leased by us. During 2002, we were not in compliance with one of our debt covenants under this lease agreement because we had not maintained the required minimum balance of cash or equivalents. To cure the event of default, we executed a modification of the lease providing the leaseholder a security interest in our property and equipment and accounts and in return, the leaseholder waived its rights to any remedies or actions due to the default.

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In October 2000, we financed \$151,249 of laboratory equipment through an equipment vendor under a capital lease agreement. Under the terms of the agreement, we are required to make monthly payments of \$4,839 over three years, including effective interest at approximately 9% per annum.

Future installments of debt principal on capital lease obligations are as follows:

<b>Year Ending December 31:</b>	<b>Amount</b>
2003	\$ 306,597
2004	157,581
	<u>\$ 464,178</u>

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## Facility, Property and Equipment Operating Leases

We lease certain facilities for our research and development and administrative functions and our subsidiaries. Certain leases also require scheduled annual fixed rent increases, payments of property taxes, insurance and maintenance. We also sub-lease a facility from a former collaboration partner (see *Joint Venture* below) that requires us to pay 50% of the lease payments plus any shortfall by the collaboration partner. In 2001, we paid approximately 85% of the minimum lease requirements under this lease representing a contingent rental incurred in excess of our 50% commitment of approximately \$102,000 in 2001. In 2002, we paid approximately 82% of the minimum lease requirements under the lease representing a contingent rental incurred in excess of our 50% commitment of approximately \$102,000 in 2002. The minimum lease requirements below include 100% of the minimum lease requirements to be made under this lease. In addition, we lease certain office and telephone equipment under non-cancelable operating leases.

Minimum lease requirements for each of the next five years and thereafter under the property and equipment leases are as follows:

Year ending December 31:	Amount
2003	721,200
2004	424,700
2005	210,700
2006	84,900
2007	
	\$ 1,441,500

Rent expense for the years ended December 31, 2000, 2001 and 2002 aggregated approximately \$637,000, \$808,000 and \$1,382,000, respectively.

*Research and Fellowship Grants*

During 2002, we terminated all research and fellowship grants and at December 31, 2002, we had no further commitments to pay any research or fellowship grants. Grant expense for 2000, 2001 and 2002 was approximately \$1,309,000, \$822,000 and \$332,000, respectively, and is included in research and development on the consolidated statement of operations.

*Licensing Agreements*

We purchased licenses to further develop certain therapeutic compounds. We are contingently liable for certain milestone payments to the licensor if we reach certain development milestones. We have not reached any milestones and cannot determine when or if ever a milestone will be reached. If we reach a milestone, it will likely occur prior to revenues being generated from the related compound.

*Joint Venture*

In September 1999, we entered into a three-year joint venture agreement with the Regents of the University of California, Irvine (UCI) to assist in the marketing and commercialization of discoveries made by certain members of its functional genomics science department. We were obligated under the agreement to fund the joint venture for three years with minimum payments of \$2.0 million over the life of the agreement. During 2002, we cancelled the joint venture and we have no further obligations under this joint venture agreement.

In April 2002, we formed a joint venture with J.B. Chemicals & Pharmaceuticals Ltd. of Mumbai, India ( JBCPL ) and created a new entity, NeoJB LLC, a Delaware limited liability company (NeoJB). We own 80% of NeoJB and a JBCPL subsidiary owns 20% of NeoJB. The business operations of NeoJB is to initially seek U.S. regulatory approval on JBCPL pharmaceutical products and to subsequently market these products in the U.S. and possibly other countries. We will initially fund 100% of NeoJB's operating expenses. In conjunction with the formation of NeoJB, we granted a five-year warrant to JBCPL to purchase up to 4,000 shares of our common stock at an exercise price of \$11.25 per share, equal to the market price of our common stock on the date of grant. The fair value of the warrant was estimated to be \$38,000 using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%; expected volatility of 119.8%; risk free interest rate of 5.0%; and an expected life of five years.



*Employment Agreements*

We entered into employment agreements with certain of our key executive personnel. The agreements provide for, among other things, guaranteed severance payments equal to up to twice the officer's annual base salary upon the termination of employment without cause or upon a change in control under certain circumstances.

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### *Off-Balance Sheet Arrangements*

We have not entered into any off-balance sheet transactions, arrangements and obligations (including contingent obligations) that have or are reasonable likely to have, a material effect on our financial condition, changes in the financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources, other than the previously disclosed contingent rent commitment that is discussed above in this section under *Facility, Property and Equipment Operating Leases*.

### *Other*

On September 30, 2002, we entered into a Co-Development and License Agreement with GPC Biotech AG for the development and commercialization of our lead drug candidate, satraplatin. Under the agreement, we became obligated to maintain certain contractual obligations related to an underlying license agreement for satraplatin.

We have historically conducted research activities involving hazardous materials and are therefore responsible for the decommissioning of our research laboratories. We do not expect costs related to the decommissioning process to be material.

### **Financial Market Risks**

We are exposed to certain market risks associated with interest rate fluctuations and credit risk on our marketable securities and borrowing arrangements. All investments in marketable securities and borrowing arrangements are entered into for purposes other than trading. Our 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 investments during 2002 and as of December 31, 2002 are fixed rate, short-term corporate and government notes and bonds, which are available for sale. Because the interest rates are fixed, changes in interest rates affect the fair value of these investments but do not affect the interest earnings. Because these financial instruments are considered available for sale, all changes in fair value is recorded in stockholders equity as Unrealized (losses) gains on available-for-sale securities until the investment is either sold or matures, at which time the gain or loss, if any, is recognized as a realized gain or loss in the statement of operations. If a 10% change in interest rates were to have occurred on December 31, 2002, any decline in the fair value of our investments would not be material. In addition, we are exposed to certain market risks associated with corporations credit ratings of which we have purchased corporate bonds (or paper). 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 such corporate bonds, we may lose part or all of our principal. We believe that we effectively manage this market risk by diversifying our corporate bond investments by purchasing a few bonds of many large, well known, companies in a variety of industries.

Our primary exposures relate to (1) interest rate risk on borrowings, (2) our ability to pay or refinance our borrowings at maturity at market rates, (3) interest rate risk on our investment portfolio, and (4) 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. We manage interest rate risk on our outstanding borrowings by using fixed rate debt. While we cannot predict or manage our ability to refinance existing borrowings and investment portfolio, we evaluate our financial position on an ongoing basis.

Our borrowings bear interest at fixed rates. Changes in interest rates affect the fair value of our borrowings, but do not have an impact on interest expense. Because of the relatively short-term nature of our borrowings, fluctuations in fair value are not deemed to be material.

### **Business Outlook**

You should read the following discussion of our business outlook together with the financial statements and the notes to financial statements included elsewhere in this report. This discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those anticipated in these forward-looking statements.

As a result of the failure of a pivotal clinical trial for Neotrofin in Alzheimer s disease to demonstrate statistically significant data showing Neotrofin has efficacy in the treatment of Alzheimer s disease, we changed our strategic direction and installed a new management team. Our new management team has extensive experience in the field of oncology drug development. Our primary business focus in 2003 and beyond will be the development of oncology drugs. Our portfolio currently includes three drugs which are in various stages of clinical development. We plan on launching a Phase 3 clinical trial for satraplatin for the treatment of prostate cancer in the United States during 2003 with our co-development partner, GPC Biotech AG.



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In addition, we expanded a Phase 1/2 clinical study for Eoquin for the treatment of bladder cancer in Europe after the first patient in the trial showed a complete response after receiving six treatments with Eoquin over a period of six weeks, which resulted in the complete disappearance of the tumor as confirmed by biopsy. We have also begun to prepare for a phase 2 study for elsamitrucin for the treatment of non-Hodgkin's lymphoma in 2004. However, our ability to launch or continue with this trial may be limited or prevented if sufficient funds cannot be raised.

The capital markets continue to be poor and access to capital for a drug development company is limited. Therefore, our attempts to raise additional capital may be unsuccessful. If this were to occur, we would likely engage in additional restructuring activities under a board-approved operational restructuring plan, which would include, but would not be limited to (a) layoffs of a substantial number of our personnel, (b) reduction in the scope and nature of our research and development activities, and (c) termination of operating leases and other contractual arrangements. Although these measures would reduce our ongoing burn-rate, there would be certain up-front non-recurring cash costs incurred, including severance and other termination-related costs. However, our hope is that we will be successful in raising the necessary funds for these trials. We intend to continue to expand the number of our drug candidates and indications. If we are able to raise sufficient funds to proceed with our proposed clinical work on all of our drug candidates, we believe that our pipeline of drug candidates will eventually produce outstanding company growth.

Our current pipeline consists of seven drug candidates: satraplatin, elsamitrucin, Eoquin, Neotrofin, AIT-034, SPPI-339 and SPPI-356. We are currently developing these drug candidates for the treatment in prostate cancer, bladder cancer, non-Hodgkin's lymphoma, radiation sensitization as it relates to radiation treatment for cancer, dementia and memory impairment associated with aging, mild cognitive impairment, cognition, stroke, schizophrenia, other neurodegenerative diseases, and attention deficits. Currently, each of our drug candidates relates to life threatening diseases and is novel in its treatment or indication; therefore, we hope for expedited regulatory approval, if appropriate. We believe that all of our proposed drug candidates, with sufficient funding, will eventually be marketed by us or with the assistance and leadership of a co-development partner.

During 2002, we formed a joint venture with an Indian pharmaceutical company for the approval and marketing of generic drugs in the United States. In January 2003, we filed our first Abbreviated New Drug Application (ANDA) for Ciprofloxacin. We plan to file at least four additional ANDAs for a variety of drugs during 2003. We expect to begin marketing our first drug, Ciprofloxacin and other drugs in 2004. We view the potential for generic drug marketing and sales in the United States with the assistance of a low-cost, high quality manufacturer as a tremendous opportunity which we believe will provide us with a source of funding for our research activities, thereby reducing our need to rely on the capital markets to fund our development activities.

We currently lack sufficient funds and strategic alliances to complete our current business plans. We believe that our existing capital resources, will be adequate to fund our capital needs for the next 12 months of operations at our current level, but we will need to secure new funds to complete the development of our drug candidates. We do not know whether or not we will be able to secure sufficient new funds to continue our business plan beyond June 2004 and whether such funds can be obtained in time before we will have to take other actions that we otherwise would not take, like selling certain or all of our intellectual property rights and restructuring our operations or a combination of these activities.

If we are able to secure sufficient new funds and are able to develop strategic alliances with other pharmaceutical businesses for co-development opportunities, we would expect that our operating expenses would increase over the next several years as we expand our research and development and commercialization activities and operations. We expect to incur significant additional operating losses for at least the next several years. We also expect that research and development expenses will increase as we expand our clinical trials on all of our drug candidates. Depending on the results of our ongoing and planned clinical trials for our drug candidates and the outcome of the regulatory approval process, we will expand our marketing and manufacturing abilities as we approach commercializing each of our product candidates.

### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

See ITEM 7 MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS, subheading Financial Market Risks, above.

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**ITEM 8. FINANCIAL STATEMENTS**

**INDEX TO FINANCIAL STATEMENTS**

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**REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS**

To the Board of Directors and Stockholders  
formerly NeoTherapeutics, Inc.:

We have audited the accompanying consolidated balance sheets of NeoTherapeutics, Inc. (a Delaware corporation) and subsidiaries as of December 31, 2001 and 2000, and the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2001. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of NeoTherapeutics, Inc. and subsidiaries as of December 31, 2001 and 2000, and the results of its consolidated operations and its cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments relating to recoverability and classification of asset carrying amounts or the amount and classification of liabilities that might result should the Company be unable to continue as a going concern.

/s/ Arthur Anderson LLP

Orange County, California  
March 27, 2002

**This is a copy of the audit report previously issued by Arthur Anderson LLP in connection with Spectrum Pharmaceuticals, Inc.'s filing on Form 10-K for the year ended December 31, 2001. This audit report has not been reissued by Arthur Anderson LLP in connection with this filing on Form 10-K. See Exhibit 23.2 for further discussion.**

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Independent Auditors' Report

To the Board of Directors and Stockholders of  
Spectrum Pharmaceuticals, Inc. (formerly NeoTherapeutics, Inc.)

We have audited the accompanying consolidated balance sheet of Spectrum Pharmaceuticals, Inc. (formerly NeoTherapeutics, Inc.) (the Company) as of December 31, 2002, and the related consolidated statements of operations, stockholders' equity and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit. The consolidated financial statements of the Company as of December 31, 2001 and for each of the two years in the period then ended were audited by other auditors who have ceased operations, and whose report dated March 27, 2002 on those statements included an explanatory paragraph that described the Company's recurring losses from operations and its net capital deficiency discussed in Note 1 to those financial statements.

We conducted our audit in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the 2002 financial statements referred to above present fairly, in all material respects, the financial position of Spectrum Pharmaceuticals, Inc. (formerly NeoTherapeutics, Inc.) as of December 31, 2002 and the consolidated results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States.

Our report dated March 25, 2003 included an explanatory paragraph related to substantial doubt as to the Company's ability to continue as a going concern. As explained in Notes 1 and 20 to the Company's consolidated financial statements as of and for the year ended December 31, 2002, the Company has secured adequate financings sufficient to fund operations beyond December 31, 2003. Accordingly, this report has eliminated the explanatory paragraph.

/s/ Kelly & Company

Kelly & Company  
Costa Mesa, California  
May 9, 2003

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**SPECTRUM PHARMACEUTICALS, INC. AND SUBSIDIARIES**  
**(formerly NeoTherapeutics, Inc.)**  
**CONSOLIDATED BALANCE SHEETS**

	December 31,	
	2001	2002
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 749,213	\$ 1,511,942
Marketable securities and short-term investments	6,407,388	66,396
Other receivables	474,007	203,558
Property and equipment, held for sale		619,000
Prepaid expenses and refundable deposits	386,229	170,214
	8,016,837	2,571,110
<b>PROPERTY AND EQUIPMENT, at cost:</b>		
Equipment	5,397,052	1,177,828
Leasehold improvements	1,937,912	509,032
Accumulated depreciation and amortization	(2,646,103)	(884,794)
	4,688,861	802,066
OTHER ASSETS - Prepaid expenses and deposits	119,164	79,944
	\$ 12,824,862	\$ 3,453,120
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued expenses	\$ 4,186,085	\$ 2,013,247
Accrued payroll and related taxes	236,223	201,847
Note payable to related party	135,574	
Current portion of capital lease obligations	654,434	306,597
	5,212,316	2,521,691
CAPITAL LEASE OBLIGATIONS, net of current portion	463,705	157,581
OTHER NON-CURRENT LIABILITIES	361,831	101,496
	6,037,852	2,780,768
<b>COMMITMENTS AND CONTINGENCIES (NOTE 12)</b>		
<b>STOCKHOLDERS EQUITY:</b>		
Preferred Stock, par value \$0.001 per share, 5,000,000 shares authorized:		
Issued and outstanding, none at December 31, 2001 and 2002		
Common Stock, par value \$0.001 per share, 50,000,000 shares authorized:		
Issued and outstanding, 951,086 and 2,726,019 shares, respectively	951	2,726
Additional paid in capital	134,682,093	143,831,315
Deferred compensation expense	(1,889,628)	(55,730)
Notes receivable from officers and directors	(615,649)	
Accumulated other comprehensive income	87,065	5,724
Accumulated deficit	(125,477,822)	(143,111,683)
	6,787,010	672,352
Total stockholders equity		



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Total liabilities and stockholders' equity	<u>\$ 12,824,862</u>	<u>\$ 3,453,120</u>
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The accompanying notes are an integral part of these consolidated balance sheets.

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**SPECTRUM PHARMACEUTICALS, INC. AND SUBSIDIARIES**  
**(formerly NeoTherapeutics, Inc.)**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

	Years Ended December 31,		
	2000	2001	2002
<b>REVENUES:</b>			
Licensing	\$	\$ 41,113	\$ 2,371,387
<b>OPERATING EXPENSES:</b>			
Research and development	38,766,884	20,611,119	12,726,499
General and administrative	5,106,812	7,579,866	4,102,435
Restructuring expenses			3,049,815
	43,873,696	28,190,985	19,878,749
<b>LOSS FROM OPERATIONS</b>	(43,873,696)	(28,149,872)	(17,507,362)
<b>OTHER INCOME (EXPENSE):</b>			
Interest income	776,348	693,766	160,717
Interest expense	(1,857,640)	(129,567)	(123,162)
Other expense	(8,702)	(200,694)	(164,054)
<b>Total other income (expense)</b>	(1,089,994)	363,505	(126,499)
<b>NET LOSS BEFORE MINORITY INTEREST IN CONSOLIDATED SUBSIDIARIES</b>	(44,963,690)	(27,786,367)	(17,633,861)
<b>MINORITY INTEREST IN CONSOLIDATED SUBSIDIARIES</b>			
<b>NET LOSS</b>	(1,463,597)	(48,453)	
<b>NET LOSS</b>	\$(46,427,287)	\$(27,834,820)	\$(17,633,861)
<b>BASIC AND DILUTED LOSS PER SHARE</b>	\$ (109.25)	\$ (36.50)	\$ (12.34)
<b>BASIC AND DILUTED WEIGHTED AVERAGE COMMON SHARES OUTSTANDING</b>	424,964	784,949	1,429,380

The accompanying notes are an integral part of these consolidated financial statements.

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**SPECTRUM PHARMACEUTICALS, INC. AND SUBSIDIARIES**  
**(formerly NeoTherapeutics, Inc.)**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY AND COMPREHENSIVE INCOME (LOSS)**

	Preferred Stock		Common Stock		Additional Paid in
	Shares	Par	Shares	Par	Capital
Balance at December 31, 1999			351,134	351	58,425,536
Net loss					
Unrealized gains on available-for-sale securities					
Comprehensive loss					
Sale of common stock, net of issuance costs			112,224	112	28,758,235
Fair value of warrants sold with 5% convertible debentures					10,000,000
Conversion of convertible debentures			63,767	64	1,675,399
Fair value of warrants sold in subsidiary offerings					512,740
Common stock to be issued to vendor for services					105,000
Fair value of warrants to be issued to vendor for services					131,250
Common stock issued to consultants for service			80		23,500
Public warrant exercise			180		51,186
Stock options exercised by employees			3,704	4	539,242
Stock options exercised by non-employees			1,200	1	749
Deferred compensation from employee stock options					959,850
Notes receivable from certain officers and directors to purchase stock or exercise stock options					
Repayment and forgiveness of notes to officers and directors upon exercise of stock options					
Balance at December 31, 2000			532,289	532	101,182,687

[Additional columns below]

[Continued from above table, first column repeated]

	Deferred Compensation	Notes Receivable from Directors and Officers	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
Balance at December 31, 1999		(286,560)	(38,572)	(50,395,931)	7,704,824
Net loss				(46,427,287)	(46,427,287)
			39,335		39,335

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Unrealized gains on available-for-sale securities					
Comprehensive loss			39,335	(46,427,287)	(46,387,952)
Sale of common stock, net of issuance costs					28,758,347
Fair value of warrants sold with 5% convertible debentures					10,000,000
Conversion of convertible debentures					1,675,463
Fair value of warrants sold in subsidiary offerings					512,740
Common stock to be issued to vendor for services					105,000
Fair value of warrants to be issued to vendor for services					131,250
Common stock issued to consultants for service					23,500
Public warrant exercise					51,186
Stock options exercised by employees					539,246
Stock options exercised by non-employees					750
Deferred compensation from employee stock options	(959,850)				
Notes receivable from certain officers and directors to purchase stock or exercise stock options		(435,649)			(435,649)
Repayment and forgiveness of notes to officers and directors upon exercise of stock options		61,560			61,560
Balance at December 31, 2000	(959,850)	(660,649)	763	(96,823,218)	2,740,265

The accompanying notes are an integral part of these consolidated financial statements.

**Table of Contents****SPECTRUM PHARMACEUTICALS, INC. AND SUBSIDIARIES****(formerly NeoTherapeutics, Inc.)****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY AND COMPREHENSIVE INCOME (LOSS)(Continued)**

	Preferred Stock		Common Stock		Additional Paid in Capital
	Shares	Par	Shares	Par	
Balance at December 31, 2000			532,289	532	101,182,687
Net loss					
Unrealized gains on available-for-sale securities					
Comprehensive loss					
Sale of common stock for cash net of issuance costs			399,173	400	28,326,572
Fair value of stock options granted to consultant					10,597
Fair value of warrants issued for consulting services					609,875
Fair value of common stock issued for consulting services			200		22,747
Conversion of Preferred Stock of Subsidiary into Series C Preferred Stock	200	1,973,488			
Conversion of Series C Preferred Stock into common stock	(170)	(1,677,465)	19,424	19	1,677,446