Spectrum Pharmaceuticals, Inc.

Committed to Building a Strong and Sustainable Business

2004 Annual Report

mission statement

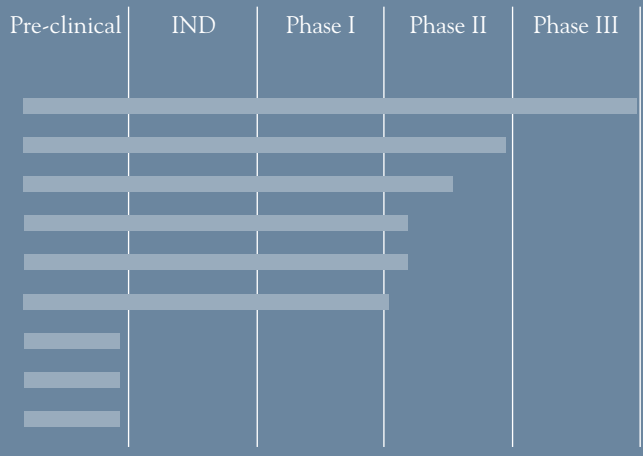
At Spectrum Pharmaceuticals, Inc., we bring the expertise and passion for excellence of our team to acquire, develop and commercialize pharmaceuticals for unmet medical needs while building value for our shareholders.

key achievements since january '04:

- Advanced clinical development of our three lead anti-cancer drugs
- Acquired a new Phase II drug and initiated two multi-center trials with both oncology and non-oncology applications
- Acquired two late-stage pre-clinical drugs
- Filed seven abbreviated new drug applications (ANDAs) with the FDA
- Received acceptance of Paragraph IV certification (first to file) for one of those ANDAs
- Received FDA approval of ciprofloxacin, our first ANDA
- Strengthened management team and enhanced development capabilities
- Regained NASDAQ National Market listing
- Strengthened the balance sheet

who we are

Spectrum Pharmaceuticals, Inc. is a specialty pharmaceutical company with an oncology focus **committed** to acquiring, developing and commercializing drug products for the treatment of cancer and other unmet medical needs. What sets us apart is our risk-reduced business model of maintaining a diversified portfolio of drugs and our strategy of sharing development and marketing risk for some of our drugs with our partners. We also build shareholder value through alliances with manufacturing and distribution partners, taking advantage of opportunities such as in the field of generic drugs. Our commitment is to build a successful pharmaceutical company with sustainable future growth.



PROPRIETARY DRUGS/INDICATIONS

Satraplatin	Hormone Refractory Prostate Cancer
EOquin™	Refractory Superficial Bladder Cancer
Elsamitrucin	Refractory Non-Hodgkin's Lymphoma
SPI-153	Hormone Dependent Prostate Cancer
SPI-153	Benign Prostatic Hypertrophy
Satraplatin	Non-Small Cell Lung Cancer
EO-9	Radiation Sensitizer
RenaZorb™	End Stage Renal Disease
SPI-1620	Adjunct to Chemotherapy

GENERIC PRODUCTS

10 ANDAs Filed

- Ciprofloxacin—Approved September 10, 2004
- Carboplatin
- Fluconazole
- Sumatriptan—Filed under Paragraph IV
- Four Ophthalmics
- Two Specialty Products

STRATEGIC ALLIANCES

Europe:
- GPC Biotech AG
- Johnson-Matthey PLC
- NDDO Research Foundation
- Zentaris GmbH

India:
- JB Chemicals & Pharmaceuticals Ltd.
- FDC Ltd.
- Shantha Biotechnics Pvt. Ltd.

U.S.:
- Altair Nanotechnologies, Inc.
- Chicago Labs, Inc.
- Cura Pharmaceuticals Co., Inc.
- Bristol-Myers Squibb Company
- Lannett Company, Inc.


Lot: 052404BN4
Exp.date: 05-06
EOquin
Store at +2°
Spectrum


Elsamitrucin

proprietary drugs

Strategies

- Focus on oncology
- Expand our diversified product portfolio
- Reduce development risk by in-licensing relatively late-stage drugs
- Leverage management expertise for acquisition, development, and commercialization activities

A major strength of Spectrum Pharmaceuticals is the ability to select and acquire promising drugs, and develop them for indications where they have the best chance of approval. We have been successful in acquiring several such drugs—one in Phase III, three in Phase II and two in pre-clinical development. Our goal for the two pre-clinical drugs is to file investigational new drug applications (INDs) with the Food and Drug Administration (FDA) within the next 12 to 15 months.

We credit our ability to acquire compounds to three key strengths. The first is the vast network of our key development team led by Luigi Lenaz, M.D., our Chief Scientific Officer. Dr. Lenaz has worked his whole career developing oncology drugs, both in academic centers and in the pharmaceutical industry, including 20 years at Bristol-Myers Squibb. He has been involved in the development of the most widely used oncology drugs including doxorubicin, epirubicin, cisplatin, etoposide, carboplatin and paclitaxel.

Our second key strength is our ability to continue to find the "diamonds in the rough" by recognizing the potential in drugs already under development. Our development team on average has over 20 years of relevant industry experience per person. We try and select only those compounds that we believe can be commercialized in a shorter timeframe than normal drug development. We also undertake the acquisition of promising pre-clinical candidates when we believe that the therapy is novel and that the drug candidates have a higher probability of regulatory approval than that for a typical compound at a similar stage of development.

The third strength is our experience in developing drugs for the treatment of cancer and other unmet medical needs. While there have been rapid and significant advances in the field of cancer therapy over the past 20 years, the treatment of cancer remains a challenge, even today. Many cancer patients have few, if any, treatment options once they become refractory (resistant) to existing cancer therapies. Our goal is to acquire and develop the next-generation of novel drugs with better efficacy and safety than existing ones. Almost all of our current drugs aim to fulfill the unmet medical needs of patients with refractory cancer.

Our strategy is to move our proprietary drugs as rapidly as possible through clinical testing and regulatory approval. To do that most efficiently and cost-effectively, we have assembled a team of highly qualified clinical and other development experts while also building a select network of partners and alliances to supplement our in-house capabilities.

Our approach of acquiring relatively late-stage drugs further helps to reduce our risks in drug development. By targeting challenging niche oncology markets, we may have an increased likelihood of obtaining expedited regulatory review through the FDA's fast-track designation. That is the case with our lead drug candidate, satraplatin, for second-line chemotherapy for hormone-refractory prostate cancer.

The acquisition of commercially viable compounds is only the first step in the drug commercialization process. Our strategy is to move our proprietary drugs as rapidly as possible through clinical testing and regulatory approval. To do that most efficiently and cost-effectively, we have assembled a team of highly qualified clinical and other development experts while also building a select network of partners and alliances to supplement our in-house capabilities. Where appropriate, we also consider partnering with other pharmaceutical or biotechnology companies with different resources to further the development of a specific drug. This strategy was pursued with SPI-153, which we are developing with the assistance of Zentaris GmbH, a German biotechnology company.

Again, one of our differentiating factors is that we are moving multiple proprietary drug products toward the market, relying on our experienced in-house team and working closely with capable strategic partners. This strategy enables us to keep tight control over our development costs and timelines, and helps advance Spectrum Pharmaceuticals toward our overall objective of building a strong and sustainable business.

Proprietary Drugs

- Satraplatin— Phase III
- Elsamitrucin—Phase II
- EOquin™— Phase II
- SPI-153— Phase II
- SPI-1620— Pre-clinical
- RenaZorb™— Pre-clinical

This strategy enables us to keep tight control over our development costs and timelines, and helps advance Spectrum Pharmaceuticals toward our overall objective of building a strong and sustainable business.

generic drugs

Strategies

- Take advantage of lower entry cost
- Establish relationships and Spectrum as a brand name
- Generate near term revenue
- Create synergies with proprietary oncology products

To generate near-term revenues, we decided in 2002 to develop a portfolio of generic drugs through manufacturing and marketing relationships. Since then, without requiring any investment in manufacturing facilities, we have built a broad generic platform that includes anti-infective, ophthalmic, anti-cancer and other specialty product targets. Keeping development costs low is one of our key priorities: Every dollar of profit we generate from generic sales will help our proprietary drug development and, thus, is a dollar we do not have to raise by selling equity.

We believe that as a small company, we can move quickly to take advantage of new opportunities such as in the field of generic drugs. In the next five years many blockbuster drugs will lose patent protection. Our generics development team led by Dr. Ashok Gore, Senior VP of Pharmaceutical Operations and Regulatory Compliance, has exceptional knowledge and expertise in pharmaceutical drug development. With several partnerships that we have already established in India, Europe and the United States, we believe we are in a position to take advantage of this opportunity.


LOT:C350401
EXP:03/06
Marketed by:
Spectrum Pharmaceuticals
Irvine, CA 92618
Manufactured by:

to our shareholders

The remarkable transformation of our Company, which was set in motion in late 2002, continues. I am proud to report that we had another year of excellent accomplishments and incredible productivity.

During 2004 and early this year, we continued to execute our strategy with precise focus and utmost dedication resulting in many significant achievements:

- Acquired three drugs including one anti-cancer drug in Phase II clinical trials
- Expanded and advanced our clinical projects for anti-cancer indications
- Received FDA approval for ciprofloxacin, our first ANDA
- Filed seven ANDAs for a variety of drugs that included anti-cancer injectables, ophthalmics and others with one application filed with a Paragraph IV certification
- Entered into five new strategic alliances
- Strengthened our internal development capabilities by adding key team members

A major focus of our business is developing drugs for cancer patients. In spite of many advances, cancer continues to be a leading cause of death. Many patients are left with few, if any, options once they become refractory to treatment. We are aggressively pursuing acquisition, development and commercialization of therapies for these refractory conditions and other unmet medical needs with these patients in mind. Our shareholders should take pride in knowing that their investment is at work in developing new treatments for cancer patients. At the same time, we hope to generate revenue from our generic drug strategy, which could offset some of the expenses of our proprietary drug development.

We made rapid progress in all areas of our business while keeping a close watch on our expenses, which for the entire year averaged about $1 million per month. We closed the year with over $39 million in operating funds, and we have no debt.

We believe Spectrum Pharmaceuticals is uniquely positioned for increasing shareholder value, as our diversified, expanding portfolio is expeditiously developed for market.

We believe that fundamental to our current and future business success is a diversified portfolio of drugs that are chemically unrelated, have different mechanisms of action and may be beneficial in treating a variety of tumors and other diseases for which there is a need for better treatments.

Expanding Our Diversified Product Portfolio

Our portfolio of clinical stage anti-cancer drugs consists of one drug in Phase III for hormone-refractory prostate cancer (satraplatin) and three drugs in Phase II for refractory superficial bladder cancer, refractory non-Hodgkin's lymphoma and hormone dependant prostate cancer.

We believe that fundamental to our current and future business success is a diversified portfolio of drugs that are chemically unrelated, have different mechanisms of action and may be beneficial in treating a variety of tumors and other diseases for which there is a need for better treatments. Our aggressive pursuit of this strategy has led to the acquisition of SPI-153, RenaZorb™ and SPI-1620 since August 2004. SPI-153 is currently being investigated in a Phase II study for a non-cancer indication, benign prostate hypertrophy (BPH).

In parallel, we continued to advance the development of our existing proprietary products, and expand and build a solid base in generic drugs. Our first ANDA was only filed in 2003. As of today we have filed nine additional ANDAs which are currently under review at the FDA.

People, Partnerships and Risk Reduced Strategy

We are proud of our in-house team of 26 dedicated employees, who thrive on meeting challenges daily and continue to excel in everything they do. This year we added 10 key members to the team. We are firm believers in reducing development and marketing risk by working with other successful companies to create new opportunities for accelerated growth. We announced alliances with Shantha Biotechnics Pvt. Ltd., an Indian biotechnology company dedicated to developing and marketing biologics, vaccines and other products using novel, recombinant technology; Zentaris GmbH, a drug discovery company based in Germany; Altair Nanotechnologies, Inc. with expertise in nanoparticle technology based in Nevada; Chicago Labs, Inc., a drug discovery company based in Illinois; and Cura Pharmaceuticals Co., Inc., a marketing company based in New Jersey. As of this writing we have alliances with 12 different companies, and all alliances are unique and designed to take advantage of our partners' strengths and expertise.

Corporate Governance

We strive to conduct business to the highest of ethical standards, integrity, transparency and discipline. This year again, as in 2003, a good part of our resources, both financial and human were spent on ensuring compliance with various new regulations including the Sarbanes-Oxley Act. We hired consultants and other experts in the field and have been working diligently with our outside counsel, external auditors, SEC and NASDAQ in this regard.

The Future

Spectrum is no longer dependant on the success of any one drug or one technology. By relentlessly focusing on our risk reduced strategy of building a diversified portfolio of drugs, both proprietary and generic, by joining hands with various companies that create new opportunities, by expanding our management team with talent, and by managing our expenses, the progress we have made in a short time is impressive. We are proud to be building a company with such a diversified portfolio. The NDA filing of our lead drug satraplatin, with data expected on over 900 patients, is anticipated in the second half of 2006. Our next lead drug, EOquin™, is rapidly advancing as we completed enrollment in the Phase II trial. We also expect that our recently acquired pre-clinical drugs, RenaZorb™ and SPI-1620 will advance to human testing within the next 12–15 months. We also expect approval of carboplatin in the near term.

In Conclusion

2004 was an excellent year! We became less dependant on any one drug, expanded our portfolio of drugs, made new alliances and added several key employees to position our Company well for the future. We did all this while keeping a tight control on expenses.

We very much appreciate the continued support and confidence of our stockholders, employees, board members and strategic partners. We realize that your investment in Spectrum is an investment in our future. We will continue to focus on the fundamentals to build a strong and sustainable business, which we believe will ultimately lead to enhanced shareholder value.

May 10th, 2005

Rajesh C. Shrotriya, M.D.
Chairman, CEO and President
Spectrum Pharmaceuticals, Inc.

our committed team

We Invest in People

We have recruited a team of high-caliber professionals to drive our vision, strategy and unique business model forward. All members of our executive management team have shown accomplishments in their fields, and most came to Spectrum from within the pharmaceutical industry. Our project leaders are mostly M.D.s or Ph.D.s.

Yet to Spectrum Pharmaceuticals, "high-caliber" goes beyond education, training and experience. We seek out employees who have passion for what they do, a commitment to excellence and a devotion to bringing our vision of Spectrum Pharmaceuticals to fruition. They take personal responsibility for making a difference in our operations, in our accomplishments, in our efforts to build value for shareholders and, ultimately, in the lives of patients.

We Team Up With Partners

One of Spectrum Pharmaceuticals' competitive advantages is that we work very hard to reduce the risks inherent in our complex and competitive markets. We hope to succeed through our close, strategic alliances.

These alliances consist of key development, manufacturing and distribution agreements in the United States, India and Europe.

At Spectrum Pharmaceuticals, Inc., we credit our committed team of employees and partners for our accomplishments to date and for realizing our future possibilities.

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

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

For the fiscal year ended December 31, 2004

or

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

For the transition period from to

Commission File Number: 000-28782

Spectrum Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**93-0979187**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
157 Technology Drive Irvine, California	**92618**
(Address of principal executive offices)	*(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

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 Exchange Act Rule 12b-2). Yes ☑ No ☐

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2004 was $86,466,288 based on the closing sale price of such common equity on such date.

As of March 1, 2005 there were 15,326,484 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the Registrant's 2005 Annual Meeting of Stockholders, to be filed on or before April 29, 2005, are incorporated by reference into Part III of this Form 10-K.

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FORWARD-LOOKING STATEMENTS

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," and also contains predictions, estimates and other forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and in reliance upon the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are based on the beliefs of the Company's management as well as assumptions made by and information currently available to the Company's management. Readers should not put undue reliance on these forward-looking statements. Reference is made in particular to forward looking statements regarding the success of our drug candidates, product approvals, product sales, development timelines, product acquisitions, liquidity and capital resources and trends. 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" in "ITEM 1 — Business", and in "ITEM 7 — Management's Discussion and Analysis of Financial Condition and Results of Operations" included in PART II. We do not plan to update any such forward-looking statements and expressly disclaim any duty to update the information contained in this filing except as required by law.

Unless the context otherwise requires, all references to the "Company", "we", "us", "our", "Spectrum" and "Spectrum Pharmaceuticals" refer to Spectrum Pharmaceuticals, Inc. and its subsidiaries, as a consolidated entity. We primarily conduct all our activities as Spectrum Pharmaceuticals.

PART I

Item 1. *Business*

Corporate Background and Business Strategy

Spectrum Pharmaceuticals, Inc. is a Delaware corporation that was originally incorporated in Colorado as Americus Funding Corporation in December 1987, became NeoTherapeutics, Inc. in August 1996, was reincorporated in Delaware in June 1997, and was renamed Spectrum Pharmaceuticals, Inc. in December 2002. Prior to August 2002, when we announced a shift in our strategic focus, we were engaged in the discovery and development of neurology drugs as well as functional genomics research.

We are a specialty pharmaceutical company engaged in the business of acquiring, developing and commercializing prescription drug products for various indications. Our business model is to acquire and develop a diversified portfolio of proprietary and generic drug products, with a mix of near-term and long-term revenue potential. While our primary strategic focus is on proprietary drug products addressing cancer and other unmet medical needs, we are also leveraging our developmental and regulatory capabilities, and those of our strategic alliance partners, to enhance the potential for realizing near-term revenues by taking advantage of opportunities for developing and commercializing select generic drug products with a focus on specific niche categories. We plan to execute our business strategy by attracting and retaining talented people, entering into strategic business alliances, and maintaining a strong cash position.

As of the date of filing this report, we have six proprietary drug product candidates under development: satraplatin, EOquin™, elsamitrucin, SPI-153; RenaZorb™; and SPI-1620, one Abbreviated New Drug Application, or ANDA, for ciprofloxacin tablets, approved by the United States Food and Drug Administration (FDA) and eight ANDAs pending at the FDA.

Since August 2002, when we shifted our strategic focus, through the date of this report, we have accomplished the following major milestones:

- Recapitalized the Company by securing over $55 million in equity financing.
- Enhanced our research and development capabilities and strengthened our management team.
- Entered into several strategic business alliances to position the Company for growth.

- Advanced clinical development of our drug product candidates:
  - Entered into a co-development and license agreement for the development of satraplatin, an orally administered platinum-derived chemotherapy agent which has demonstrated an initial indication of efficacy in treating hormone refractory prostate cancer. Satraplatin is currently in a Phase 3 trial for hormone refractory prostate cancer. The costs of conducting clinical trials are being borne entirely by our co-development partner GPC Biotech AG.
  - Initiated the development of and advanced into a Phase 2 trial, EOquin™, a synthetic prodrug (an inactive drug compound) which is activated by certain enzymes present in higher amounts in cancer cells than in normal cells, for its intended initial indication, refractory superficial bladder cancer.
  - Initiated the development of and advanced into a Phase 2 trial, elsamitrucin, an anti-tumor antibiotic that acts as a dual inhibitor of two key enzymes involved in DNA replication, topoisomerase I and II, for its intended initial indication, refractory non-Hodgkin's lymphoma.
- Acquired three new proprietary drug product candidates:
  - In-licensed SPI-153, a LHRH (Luteinizing Hormone Releasing Hormone, also known as GnRH or Gonadotropin Releasing Hormone) antagonist and are preparing to commence clinical trials to evaluate it for safety and efficacy in its intended initial indications, hormone-dependent prostate cancer and benign prostatic hypertrophy. We also plan to evaluate the compound for the treatment of endometriosis.
  - In-licensed RenaZorb™, two second-generation lanthanum-based phosphate binding agents, and plan to complete preclinical studies and conduct clinical trials to evaluate it for safety and efficacy in its intended initial indication, hyperphosphatemia, i.e., high phosphate levels in blood, in patients with end-stage renal (kidney) disease and/or chronic kidney disease.
  - In-licensed SPI-1620, an endothelinB agonist which stimulates receptors on endothelial cells to selectively dilate tumor blood vessels and thereby selectively increase the delivery of anti-cancer drugs to cancer tissue. We plan to complete preclinical studies and conduct clinical trials to evaluate SPI-1620 for safety and efficacy as an adjunct to chemotherapy for the treatment of cancer.
- Filed nine ANDAs with the FDA seeking approval for marketing generic versions of branded prescription drugs whose patent protection and/or marketing exclusivity is scheduled to expire in the near-term, or has already expired:
  - One of the ANDAs, for ciprofloxacin tablets, a synthetic, broad-spectrum anti-bacterial agent, was approved by the FDA in September 2004.
  - One of the ANDAs filed in October 2004, for sumatriptan succinate injection, the generic form of GlaxoSmithKline's Imitrex® injection, which is used for the acute treatment of migraine attacks and of cluster headache episodes in adults, included a Paragraph IV certification. GlaxoSmithKline has commenced suit against us alleging that the filing of our ANDA infringes their patent. We believe that the patent that we have challenged covering GlaxoSmithKline's Imitrex® injection, which with pediatric exclusivity is set to expire on February 6, 2009, is invalid, unenforceable and/or or will not be infringed by our generic product candidate. Imitrex® injection is also covered by a patent which together with pediatric exclusivity does not expire until June 28, 2007. This patent is not currently being challenged by any third party.
  - The other seven ANDAs are still pending at the FDA.

We plan to continue to evaluate acquisitions, or in-licensing, of additional promising clinical-stage as well as near-clinical-stage drugs from other companies and institutions; and expect to file several ANDAs in 2005 and beyond and to have several generic drugs FDA approved and marketed in the U.S. over the next 5 years. In addition, we plan to seek additional strategic alliances to manufacture, develop and market our current and future drug products.

Drug Product Candidates

Proprietary drugs

New drug development, whereby drug product candidates are tested with a view to filing a New Drug Application (NDA) (or similar filing in other countries) and eventually obtaining marketing approval is an inherently uncertain, lengthy and expensive process, requiring several clinical trials to demonstrate to the satisfaction of the U.S. Food and Drug Administration (FDA) and other regulatory authorities in the United States and other countries, that the products are both safe and effective in their respective indications. Our proprietary drug strategy is designed to address the significant risks of drug development by focusing our acquisition and development efforts on clinical stage drug candidates (those in human trials). We do, however, also undertake the acquisition and development of promising pre-clinical drug candidates when we believe that the therapy is novel and/or when we believe the drug candidates have a higher probability of regulatory approval than that of a typical compound at a similar stage of development.

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

Drug Candidate	Target Indication	Development Status
Satraplatin	Hormone Refractory Prostate Cancer	Late Phase 3
EOquin™ (EO9) ..	Refractory Superficial Bladder Cancer	Late Phase 2
Elsamitrucin	Refractory non-Hodgkin's Lymphoma	Phase 2
SPI-153	Hormone Dependent Prostate Cancer	Phase 2 expected to begin in 2005
SPI-153	Benign Prostatic Hypertrophy	Phase 2 expected to begin in 2005
Satraplatin	Non-small Cell Lung Cancer	Phase 1/2
EO9	Radiation Sensitization	Pre-clinical
RenaZorb™	End-stage Renal Disease, Chronic Kidney Disease	Pre-clinical
SPI-1620	Adjunct to Chemotherapy	Pre-clinical

While other indications have not yet been identified, some of our drug candidates may prove to be beneficial in additional disease indications as we continue to study and develop these drug candidates. In addition, we have a few neurology compounds that we may out-license to third parties for further development.

We believe our proprietary drug candidates have the potential to be effective therapeutic agents with some advantages over existing therapies. Our goal is to develop and, if successful, commercialize these drugs in the United States and worldwide (to the extent of the territorial rights in our licenses).

Overview of Indications We Are Targeting

Cancer

Cancer is the second leading cause of death in the United States, accounting for approximately 25% of all deaths. In its most recent annual report, the American Cancer Society reported that in the under 85 age group, cancer is the leading cause of death. In the United States, approximately 1.4 million new cancer cases are expected to be diagnosed in 2005 and over 570,000 persons are expected to die from the disease in 2005. Accordingly, there is significant demand for improved and novel cancer treatments.

Cancer occurs when abnormal cells divide without control. These cells can invade nearby tissues or spread through the bloodstream and lymphatic system to other parts of the body. 5 to 10 percent of all cancers are believed to be due to inheriting a faulty gene. The remaining 90 to 95 percent are believed to be caused by damage to the genes during a person's lifetime. These damaging agents can be internal, such as hormones or an altered immune system, or external, such as viruses, and exposure to chemicals or harmful ultraviolet

sunrays. Sometimes ten or more years may pass between exposure and cancer detection. Cancer is currently treated by surgery, chemotherapy, radiation therapy, hormonal therapy and immunotherapy.

We believe that traditional chemotherapeutic agents are likely to remain the mainstay therapy for cancer for the foreseeable future. However, we continue to seek additional novel drugs, drug delivery methods and combination therapies that address cancer or cancer related indications with significant unmet medical need. Accordingly, we are actively seeking novel and proprietary oncology drug candidates that:

- have demonstrated initial safety and efficacy in clinical trials and/or we believe have a higher probability of regulatory approval than that of a typical compound at a similar stage of development;
- target cancer indications with significant unmet medical need, where current treatments either do not exist or are not effective; and
- we believe are acquirable at a fair value based on our judgment of clinical and commercial potential.

Benign Prostatic Hypertrophy

Benign prostatic hypertrophy is a non-cancerous enlargement of the prostate. Enlargement of the prostate is controlled by testosterone. According to the National Institutes of Health, benign prostatic hypertrophy affects more than 50% of men over age 60 and as many as 90% of men over the age of 70. Treatment options for benign prostatic hypertrophy include surgery and medications to reduce the amount of tissue and increase the flow of urine.

End-Stage Renal Disease and Chronic Kidney Disease: Hyperphosphatemia

Hyperphosphatemia, or high phosphate levels in blood, affects patients with chronic kidney disease, especially end-stage kidney disease patients on dialysis. It can lead to significant bone disease (including pain and fractures) and cardiovascular disease, and is independently associated with increased mortality. Treatment of hyperphosphatemia is aimed at lowering blood phosphate levels by: (1) restricting dietary phosphorus intake; and (2) using, on a daily basis, and with each meal, oral phosphate binding drugs that facilitate fecal elimination of dietary phosphate rather than its absorption from the gastrointestinal tract into the bloodstream. Restricting dietary phosphorus intake has historically not been a successful means of serum phosphate control, and phosphate binders are the mainstay of hyperphosphatemia management.

According to the United States Renal Data System's 2004 Annual Report and the National Kidney Foundation, there are an estimated 340,000 patients with end-stage renal disease in the United States. The end-stage renal disease population is estimated to grow by approximately 8% annually and is expected to reach 500,000 patients by 2010. We anticipate growth in the use of phosphate binders due to (1) recommendations for expanded use of phosphate binders in Stage 3 and Stage 4 chronic kidney disease (8 million patients in the United States) under the revised National Kidney Foundation Kidney Disease Outcomes Quality Initiative, or K/DOQI, clinical guidelines; (2) trends in treatment toward separating control of phosphate levels from control of calcium levels, based on K/DOQI guidelines, creating more demand for non-calcium, non-aluminum phosphate binders, including lanthanum-based agents; (3) reimbursement for oral medications for dialysis patients under a new Medicare plan, beginning in 2006; and (4) significant room to improve patient compliance, currently as low as 40% for some phosphate binders.

Currently marketed therapies for treating hyperphosphatemia include aluminum-based phosphate binders, calcium-based phosphate binders and non-calcium, non-aluminum phosphate binders. Under the new National Kidney Foundation K/DOQI guidelines, non-calcium, non-aluminum phosphate binders are recommended as first line or long-term therapy for the management of hyperphosphatemia.

Our proprietary drug candidates

Satraplatin: Satraplatin, an orally administered platinum-derived chemotherapy agent, is being developed by our co-development partner GPC Biotech AG (Nasdaq: GPCB) as a second-line chemotherapy

treatment for its intended initial indication, hormone-refractory prostate cancer. Cancer is referred to as refractory when it has not responded or is no longer responding to previous treatment.

Prostate cancer is the second leading cause of cancer deaths in men. According to figures released by the American Cancer Society, approximately 232,090 new cases and 30,350 deaths will occur in the U.S. during 2005. The initial treatment of prostate cancer includes surgery along with radiation therapy and hormonal therapy. Although hormonal therapy is generally very effective, and produces a response in most patients, it is usually non-curative. The average duration of response to initial hormonal treatment is eighteen months. Once the disease progresses after the initial hormonal treatment, it is considered hormone refractory. For those patients failing hormone therapy, treatment currently involves chemotherapy, which is also non-curative and is limited to improvement of symptoms of cancer with only limited prolongation of survival.

Platinum compounds continue to represent one of the most widely used classes of chemotherapeutic agents in modern cancer therapy and are typically used in combination with other chemotherapeutic agents for the treatment of various types of cancer. While the platinum compounds currently on the market are intravenously administered, satraplatin is an orally administered compound. We believe an orally administered platinum-derived chemotherapeutic agent may offer important clinical and commercial advantages over platinum drugs that need to be intravenously administered in a hospital setting, including ease of administration and patient convenience. These advantages, in turn, could potentially lead to improved patient compliance as well as potential cost savings to patients and the healthcare system.

A pivotal Phase 3 trial, the SPARC (Satraplatin and Prednisone Against Refractory Cancer) trial for satraplatin in hormone-refractory prostate cancer, was initiated by GPC Biotech in September 2003, following completion of a Special Protocol Assessment (an assessment by a special committee of the FDA). Also in September 2003, the FDA granted fast track designation to satraplatin as a second-line chemotherapy for patients with hormone-refractory prostate cancer. In February 2004, GPC Biotech announced the receipt of a Scientific Advice Letter from the European Agency for the Evaluation of Medicinal Products enabling the Phase 3 pivotal trial on satraplatin to proceed in Europe using the SPARC protocol. Enrollment for the Phase 3 pivotal SPARC trial is proceeding as planned. GPC Biotech anticipates to begin a rolling NDA submission, where GPC can submit different sections of the NDA when the sections are ready instead of waiting for the NDA to be complete before submission, in 2005, and, assuming positive data, to complete the NDA filing in the second half of 2006. A phase 1/2 trial of satraplatin in combination with simultaneous, standard doses of radiotherapy was opened for accrual in patients with locally advanced non-small cell lung cancer. Additional clinical trials designed to evaluate the potential of satraplatin for the treatment of other cancers, including in combination with a taxane-based therapy, are expected to begin in 2005.

The decision to pursue hormone-refractory prostate cancer as the initial indication for satraplatin was based, among other things, on results from a randomized, 50-patient study initiated in June 1998 in first-line chemotherapy for hormone-refractory prostate cancer sponsored by Bristol-Myers Squibb that were presented at the American Society of Clinical Oncology Annual Meeting in June 2003. The data from this study have also been published in the peer-reviewed journal "Oncology". The data demonstrated statistically significant improvement in time to disease progression and doubling of progression-free survival in the satraplatin-treated group compared to the control group.

In addition to hormone-refractory prostate cancer, satraplatin has shown initial indication of anti-tumor activity in ovarian and small cell lung cancers in Phase 2 trials conducted to date.

See "Business Alliances — Johnson Matthey PLC and GPC Biotech AG" for commercial terms relating to satraplatin licensing and development.

EOquin™: EOquin, a synthetic prodrug (an inactive drug compound) which is activated by certain enzymes present in higher amounts in cancer cells than in normal cells, is currently being developed for its intended initial indication, refractory superficial bladder cancer, or cancer which has not invaded the muscle of the bladder wall. EOquin™ is the trademarked name for our drug product candidate EO9 (apaziquone).

The American Cancer Society estimates that there will be 63,210 new cases and 13,180 deaths from bladder cancer in 2005 in the United States. Superficial bladder cancer accounts for 75 to 80 percent of all cases of bladder cancer at first diagnosis. The initial treatment of this cancer is surgical removal of the tumor. Because of the high frequency of early recurrences of the tumor, patients are usually prescribed additional therapy to prevent or delay such recurrences. This additional therapy generally consists of immunotherapy or chemotherapy drugs instilled directly into the bladder.

Since EOquin™ is activated to a greater degree within tumor cells, we believe it carries a lesser risk of killing or harming normal body cells. During the fourth quarter of 2003, we initiated a multi-national, multi-center, open-label, non-randomized Phase 2 clinical trial. The decision to initiate Phase 2 trials in this indication was based, among other things, on results from Phase 1 trials that demonstrated that EOquin™ had no systemic toxicity, and was well tolerated at the dose level chosen for the Phase 2 trials. More importantly, EOquin™ demonstrated an initial indication of anti-tumor activity against refractory superficial bladder cancer, as evidenced by eight of twelve patients showing a complete response, defined as the complete disappearance of the tumor as confirmed by biopsy, after receiving six treatments with EOquin™ over a period of six weeks. Of these eight patients, only one has experienced a recurrence after eighteen months, with the seven other patients disease free for at least six months after treatment and three of the patients disease free for over a year, with the longest follow-up over two years. The primary objective of the Phase 2 trial is to evaluate tumor response (the level of anti-tumor activity of EOquin™), with time to recurrence and overall safety as the secondary objectives. We hope to determine the level of anti-tumor activity in a larger number of patients. The current status of the Phase 2 trial:

- We completed enrollment of the phase 2 trial.
- To date, the phase 2 data has confirmed anti-tumor activity against refractory superficial bladder cancer, as evidenced by nineteen of thirty-one patients (~61%) showing a complete response after receiving six weekly treatments with EOquin™ instilled into the urinary bladder.
- Results also demonstrated that EOquin™ was well-tolerated, with no systemic toxicity, and local toxicity limited to chemical cystitis (inflammation of the urinary bladder), dysuria (difficulty of urination) and hematuria (blood in the urine). While follow-up was short, no responding patient has relapsed, confirming the response duration observed in a previous phase 1 trial.

In January 2005, we received from the U.S. Patent and Trademark Office a Notice of Allowance for our patent application for EOquin™ entitled "Medical Compositions for Intravesical Treatment of Bladder Cancer." This patent, when issued, will cover EOquin™ for use in the treatment of superficial bladder cancer in the United States and will not expire until November 2022. We may seek European and Japanese development and marketing partners for EOquin™.

We have also initiated an investigation of whether EO9 may have potential utility as a radiation sensitizer in the treatment of certain cancers. Radiotherapy along with chemotherapy has been the primary treatment for a number of cancers. Certain types of cancer cells can be primed through pre-treatment by a radiation sensitizer to respond better to radiation therapy.

See "Business Alliances — NDDO Research Foundation" for commercial terms relating to EOquin licensing and development.

Elsamitrucin: Elsamitrucin, an anti-tumor antibiotic that acts as a dual inhibitor of two key enzymes involved in DNA replication, topoisomerase I and II, is currently being developed for its intended initial indication, refractory non-Hodgkin's lymphoma.

Non-Hodgkin's lymphoma is a tumor arising from the lymph nodes. According to the American Cancer Society, an estimated 56,390 new cases and 19,200 deaths will occur from non-Hodgkin's lymphoma in 2005 in the U.S. In early stages, localized diseased lymph nodes can be treated with radiation therapy. Later stages of this disease are treated with chemotherapy or with chemotherapy plus radiation and highly specific monoclonal antibodies depending on the type of non-Hodgkin's lymphoma. We believe elsamitrucin may

prove to be an important addition in treating refractory non-Hodgkin's lymphoma patients because it has shown some activity when used alone and it has exhibited a relatively low level of associated toxicity.

By inhibiting the activity of the two key enzymes involved in DNA replication, elsamitrucin is thought to lead to DNA breaks that prevent the correct replication of DNA and ultimately result in cancer cell death. In April 2004, we initiated a multi-center, Phase 2 trial in patients with refractory non-Hodgkin's lymphoma. In clinical trials conducted by us and previously by Bristol-Myers Squibb to date, elsamitrucin has also demonstrated a favorable side effect profile. The current status of the Phase 2 trial:

- In November 2004, an abstract on initial positive results from the ongoing phase 2 trial of elsamitrucin in refractory non-Hodgkin's lymphoma was published in the proceedings of the American Society of Hematology Annual Meeting. Elsamitrucin continued to demonstrate early evidence of anti-tumor activity against refractory NHL and a favorable side effect profile.

- We are continuing to enroll patients in the ongoing Phase 2 trial of elsamitrucin in refractory non-Hodgkin's lymphoma and we expect completion by the end of 2005.

We plan to initiate additional studies in head and neck cancer and possibly other tumor types.

See "Business Alliances — Bristol-Myers Squibb" for commercial terms relating to elsamitrucin licensing and development.

SPI-153: SPI-153, a LHRH (Luteinizing Hormone Releasing Hormone, also known as GnRH or Gonadotropin Releasing Hormone) antagonist (a substance that blocks the effects of a natural hormone found in the body) is currently being evaluated for its intended initial indications, hormone-dependent prostate cancer and benign prostatic hypertrophy. We also plan to evaluate the compound for the treatment of endometriosis.

As described earlier, under satraplatin, prostate cancer is the second leading cause of cancer deaths in men. The initial treatment of prostate cancer includes surgery along with radiation therapy and hormonal therapy. We believe SPI-153 may prove to be an important addition in treating hormone-dependent prostate cancer patients because of its ability to induce prolonged testosterone suppression in healthy volunteers as shown in early trials. There are other LHRH antagonist and agonists (a substance that mimics the effects of a natural hormone found in the body) that are currently marketed or are being tested for the treatment of the indications we are pursuing. However, we believe that SPI-153 has certain advantages over other LHRH antagonists which include improved solubility, less tendency for aggregation resulting in greater bioavailability (absorption by the body) and minimal histamine release tendency which should reduce allergic reactions. We also believe that SPI-153 has advantages over LHRH agonists which include immediate and dose dependent suppression of sex hormones and no risk of testosterone surge or clinical flare up.

As described earlier, benign prostatic hypertrophy is a non-cancerous enlargement of the prostate which is caused by testosterone. Unlike GnRH-like drugs, SPI-153, which is an antagonist of GnRH, has the potential to reduce testosterone just enough to reduce both prostate size and symptoms. A GnRH antagonist similar to SPI-153 is in the late stages of clinical development for benign prostatic hypertrophy.

Endometriosis is the displacement of endometrial tissue (the mucous lining of the uterus) to other organs outside the womb. Endometriosis is one of the most common causes of pelvic pain and infertility in women. At least 5.5 million women in North America alone have endometriosis. Based on the stage of the disease the treatment can include hormone therapy or surgery or a combination of both. Current hormonal treatment aims to stop ovulation for as long as possible. SPI-153 is an antagonist (blocker) of GnRH (gonadotropin releasing hormone), a hormone that provokes ovulation. A GnRH antagonist similar to SPI-153 is in the late stages of clinical development for endometriosis.

During the first half of 2005, we plan to initiate clinical trials in hormone-dependent prostate cancer and benign prostatic hypertrophy in Europe and to file an investigational new drug application with the FDA to begin U.S. clinical trials.

See "Business Alliances — Zentaris GmbH" for commercial terms relating to SPI-153 licensing and development.

RenaZorb™: In January 2005, we acquired rights to RenaZorb™, two pre-clinical, second-generation lanthanum-based phosphate binding agents which utilize nanoparticle technology, that have the potential to address hyperphosphatemia, or high phosphate levels in blood, in patients with end-stage renal disease and chronic kidney disease. Please see the discussion of hyperphosphatemia above.

We believe that RenaZorb™ has the opportunity, because of its possible higher capacity for binding phosphate, to significantly improve patient compliance by offering the lowest-in-class dosage (potentially one tablet per meal) and smaller sized tablets to achieve the same therapeutic benefit as other phosphate binders, while also potentially offering a more favorable safety/side effect profile.

See "Business Alliances — Altair Nanotechnologies" for commercial terms relating to licensing and development.

SPI-1620: SPI-1620 is an endothelinB agonist, which can stimulate receptors on endothelial cells, the innermost, simple layer of cells lining the blood vessels to selectively dilate tumor blood vessels and thereby selectively increase the delivery of anti-cancer drugs to cancer tissue.

This technology takes advantage of the fact that there is differential blood supply to the tumors. Tumors get their blood supply from blood vessels that are different from normal blood vessels and mostly have only a layer of endothelium, which contains the endothelial cells. Tumor blood vessels lack smooth muscle and associated innervations found in other blood vessels. When an endothelinB agonist is administered it stimulates receptors on the endothelial cells and leads to enhanced blood supply selectively to the tumors; because of this enhanced blood supply to the tumor the concentration of injected chemotherapeutics such as paclitaxel injection administered after an endothelinB agonist reaches several fold higher in the tumor. In other words, this increased blood supply to the tumor leads to increased concentration of drugs in the tumor and enhanced tumor kill, possibly without any significant increase in untoward effects to normal tissues. This result has only been shown in animal studies to date.

We acquired rights for the above mentioned use of this compound in February 2005 and plan to evaluate its effectiveness as an adjunct to chemotherapy for the treatment of cancer.

See "Business Alliances — Chicago Labs" for commercial terms relating to licensing and development.

Generic drugs

The Drug Price Competition and Patent Term Restoration Act of 1984 signed into law in part to accelerate the approval of generic drugs, created an Abbreviated New Drug Application, or ANDA, approval process to foster generic competition. While an ANDA application is subject to significant regulatory review and scrutiny before approval by the FDA, the costs and timelines associated with the development of a generic drug, the overall timelines associated with the completion of regulatory review and subsequent commercialization of the generic drug product can be significantly shorter as compared to the New Drug Application, or NDA, approval process, and relatively less uncertain and less expensive.

Our generic drugs, their target indications, and status are summarized in the following table, and discussed below in further detail:

Drug Product	Target Indication	Status
Ciprofloxacin tablets	Anti-bacterial	ANDA approved September 2004
Carboplatin injection	Anti-cancer	ANDA pending at the FDA
Fluconazole tablets	Anti-fungal	ANDA pending at the FDA
Sumatriptan succinate injection	Anti-migraine	ANDA pending at the FDA
Other (5 products)	Various	ANDAs Pending at the FDA

As a result of the number of branded pharmaceutical products coming off patent over the next decade, combined with the aging U.S. population and cost-containment efforts by the U.S. Federal Government and private insurance payers, we believe the U.S. market for generic drugs will continue to grow. We plan to capitalize on this growth by focusing our effort in niche categories such as injectable products and oncology drugs where the competition is not as intense and where we can leverage our resources and those of our strategic partners to create synergies with the proprietary drugs we develop.

Our generic drug candidates

Ciprofloxacin. Ciprofloxacin is a synthetic, broad-spectrum anti-bacterial agent that is indicated for the treatment of infections caused by susceptible strains of microorganisms in certain diseases. Ciprofloxacin is available in multiple dosage forms including tablets, oral suspension, otic, intravenous infusion and ophthalmic preparations. In 2003, through our affiliate NeoJB and on behalf of JB Chemical & Pharmaceuticals Limited, our joint venture partner in NeoJB, we filed an ANDA for ciprofloxacin tablets. We received FDA approval of the ANDA for ciprofloxacin tablets in September 2004. Our ciprofloxacin tablets are manufactured by JBCPL utilizing its FDA approved facility in India. In late 4th quarter 2004 we recorded $185,000 revenue from product sales of the first shipment of ciprofloxacin tablets to the Lannett Company, our distributor for ciprofloxacin tablets. In view of the competitive market for sales of ciprofloxacin tablets, we are unable to assess the future revenue potential of this product. Fifteen other companies have received FDA approval to market generic versions of ciprofloxacin tablets, and we have observed a significant reduction in the market price for ciprofloxacin tablets since June 2004, when the pediatric exclusivity for ciprofloxacin expired.

Fluconazole. Fluconazole is a synthetic anti-fungal agent indicated for the treatment of localized and systemic fungal infections. Fluconazole is available in multiple dosage forms including tablets, oral suspension and intravenous infusion. In 2003, through NeoJB, we filed an ANDA for fluconazole tablets on behalf of JBCPL. We have entered into a supply agreement with JBCPL pursuant to which JBCPL will manufacture fluconazole tablets for NeoJB utilizing JBCPL's FDA approved facility in India.

The patent and pediatric exclusivity for Diflucan®, the branded form of fluconazole marketed by Pfizer Inc., had both expired by July 2004. If we receive FDA approval of our ANDA, we may begin marketing and selling fluconazole tablets using one or more third-party distributors with experience selling generic drug products into retail and institutional channels. We may not successfully establish distributor arrangements with a qualified third party distributor for this generic drug product. In addition, the market is very competitive with versions from generic drug manufacturers such as Taro Pharmaceutical Industries, Mylan, Sandoz, Ranbaxy, IVAX, Genpharm, Gedeon Richter, TEVA, Torpharm, Roxane and Pliva approved by the FDA for sale in the U.S. Due to the significant price erosion of the product caused by the number of companies selling the product we may not market our product if it is not economical to do so.

Carboplatin. Carboplatin injection is an anti-cancer drug indicated for the initial treatment of advanced ovarian cancer in combination with other approved chemotherapeutic agents and for the palliative treatment of patients with ovarian cancer recurrent after prior chemotherapy, including patients treated with cisplatin injection, another chemotherapeutic agent. The patent and pediatric exclusivity for Paraplatin®, the branded form of carboplatin injection marketed by Bristol Myers Squibb, had both expired by October 2004,

We filed an ANDA for carboplatin injection and if FDA approval for our ANDA is obtained, we intend to begin marketing and sale of carboplatin injection following such approval. We will initially likely use one or more third party distributors with particular experience distributing injectable oncology drugs to carry out our distribution plan. We may not successfully establish distributor arrangements with third party distributors or be able to acquire the necessary quantities of the drug from our supply sources on commercially feasible terms or terms otherwise acceptable to us. In addition, the FDA has granted ANDA approval to five generic companies, including Pharmachemie, APP, Bedford, Mayne and Pliva. TEVA Pharmaceuticals, through an agreement with Bristol Myers Squibb, is currently selling carboplatin produced by Bristol Myers Squibb as a generic drug.

Sumatriptan succinate injection: Sumatriptan succinate injection is marketed by GlaxoSmithKline under the brand name Imitrex® and is used for the acute treatment of migraine attacks, with or without aura,

and the acute treatment of cluster headache episodes in adults. The total U.S. market size for the branded form of sumatriptan succinate injection 6mg/0.5mL, Imitrex®, is estimated at about $200 million annually. Imitrex® is currently covered by two patents. One patent expires in December 2006, but Imitrex® has been afforded pediatric exclusivity, until June 2007. The second patent expires in August 2008, but pediatric exclusivity protects the product until February 2009.

In October 2004, we filed an ANDA with the FDA for sumatriptan succinate injection 6mg/0.5mL, seeking approval to engage in the commercial manufacture and sale of the sumatriptan succinate injection product in the U.S. Our ANDA includes a paragraph IV certification that the second patent expiring February 6, 2009 (including the pediatric exclusivity period) associated with GlaxoSmithKline's Imitrex® injection, is invalid, unenforceable and/or or will not be infringed by our generic product candidate. On February 18, 2005, GlaxoSmithKline filed a lawsuit against us in the United States District Court for the District of Delaware, alleging infringement of this second patent on Imitrex®. See "Litigation" and "Patents and Proprietary Rights — Paragraph IV Challenge" for additional description of the foregoing legal proceedings. There currently is no legal challenge of the first patent, and therefore, even we were successful in our challenge to the second patent, we will not be able to market our generic product until June 2007.

In 2003, Dr. Reddy's Laboratories Ltd. filed an ANDA with the FDA for sumatriptan succinate *tablets* and GlaxoSmithKline filed a lawsuit against Dr. Reddy's for infringement in the United States District Court for the Southern District of New York. In 2004, Cobalt Pharmaceuticals, Inc. also filed an ANDA with the FDA for sumatriptan succinate tablets and GlaxoSmithKline filed a lawsuit against Cobalt for infringement in the United States District Court for the District of Delaware. The case was transferred to the United States District Court for the Southern District of New York and was consolidated with the case against Dr. Reddy's.

Business Alliances

Strategic business alliances are an important part of the execution of our business strategy. We currently do not have any manufacturing or distribution capabilities. In addition, in general, we direct and pay for all aspects of the drug development process, and consequently incur the risks and rewards of drug development, which is an inherently uncertain process. To mitigate such risks and address our manufacturing and distribution needs we enter into alliances where we believe our partners can provide strategic advantage in the development, manufacturing or distribution of our drugs. In such situations, the alliance partners may share in the risks and rewards of the drug development and commercialization. We have entered into product supply and distribution alliances for the manufacture and sale of some of our drug candidates and intend to enter into additional alliances in the future.

Product Development and Manufacturing

GPC Biotech AG (GPC): In 2002, in exchange for an upfront license fee, and future milestones and royalties, we entered into a Co-Development and License Agreement with GPC for further development and commercialization of satraplatin. Under the terms of this agreement, GPC agreed to fully fund the development expenses for satraplatin. A joint development committee establishes the development plans for satraplatin, with members from both GPC and Spectrum. GPC, however, represents a majority of the committee and the final procedures are effectively decided and implemented by GPC. We have the ability to perform additional studies, if so desired, at our expense. Licensing fees, including upfront fees and milestone payments, received in 2004, 2003, and 2002 amounted to $73,000, $1,000,000 and $2,000,000, respectively. In addition, during 2003, pursuant to the license agreement, GPC made an equity investment of $1,000,000 in 128,370 shares of our common stock at fair value. We are entitled to additional revenues upon achievement of specified milestones, which are generally based on developmental or regulatory events; and royalties, if any, on worldwide sales of the product.

Johnson Matthey PLC: In 2001, we in-licensed exclusive worldwide rights to satraplatin from its developer, Johnson Matthey, in exchange for an upfront fee, additional payments to be made based upon achievement of certain milestones and royalties based on any net sales, if any, if and when a commercial drug is approved and sales are initiated. Each of our contingent future cash payment milestone obligations to

Johnson Matthey is generally matched by a corresponding, greater milestone receivable from GPC Biotech. We did not have to make any cash payments to Johnson Matthey for the upfront fees, milestone payments and equity investments we have received so far from GPC. Johnson Matthey currently supplies GPC with satraplatin for clinical trials, however, we, and therefore, GPC, are under no contractual obligation to purchase satraplatin from Johnson Matthey.

NDDO Research Foundation (NDDO): In 2001, we in-licensed exclusive worldwide rights to EOquin™ and numerous related derivates from the NDDO in the Netherlands, in exchange for an up front fee, additional payments based upon achievement of certain milestones and a royalty based on net sales, if any, if and when a commercial drug is approved and sales are initiated. Currently, we are paying NDDO for clinical research services for our Phase 2 clinical trial with EOquin™.

Bristol-Myers Squibb: We in-licensed exclusive worldwide rights to elsamitrucin from its developer, Bristol-Myers Squibb, in 2001, in exchange for an upfront fee, additional payments based upon achievement of milestones and a royalty based on net sales, if any, if and when a commercial drug is approved and sales are initiated. Currently, we are paying Bristol-Myers Squibb for the active pharmaceutical ingredient for elsamitrucin for our Phase 2 clinical trial.

Zentaris GmbH (Zentaris): In 2004, we entered into a license agreement with Zentaris, whereby we acquired an exclusive license to develop and commercialize SPI-153 in North America (including Canada and Mexico) and India. Zentaris received an upfront payment of $1.8 million in cash and equity, and is eligible to receive payments upon achievement of certain development and regulatory milestones, in addition to royalties on potential net sales. Zentaris retains exclusive rights to the rest of world, but will share with Spectrum upfront and milestone payments, royalties or profits from potential sales in Japan. In the event Zentaris, or another licensee, independently develops SPI-153 for territories not licensed to us, we are entitled to receive and utilize the results of those development efforts. With certain exceptions, we are required to purchase all finished drug product from Zentaris for the clinical development of SPI-153 at a set price. The parties will discuss entering into a joint supply agreement for commercial supplies of finished drug product.

Altair Nanotechnologies, Inc.: In January 2005, we entered into a license agreement with Altair Nanotechnologies, Inc., whereby we acquired an exclusive worldwide license to develop and commercialize RenaZorb™ for all human therapeutic and diagnostic uses. We paid Altair an upfront payment of 100,000 shares of restricted Spectrum common stock and made an equity investment of $200,000 for 38,314 shares of Altair common stock, and are obligated to make future payments contingent upon the successful achievement of certain development and regulatory milestones. In addition we will pay royalties and sales milestones on net sales, if any, assuming marketing approval is obtained from regulatory authorities. Under the terms of the agreement, Altair has agreed to work to establish FDA certified cGMP facilities for the manufacture of the active pharmaceutical ingredient contained in this product, in which case it will be the supplier of the active pharmaceutical ingredient to Spectrum.

Chicago Labs: In February 2005, we entered into a license agreement with Chicago Labs, Inc., whereby we acquired an exclusive worldwide license to develop and commercialize SPI-1620 for the prevention and treatment of cancer. We paid Chicago Labs an upfront fee of $100,000, and are obligated to make future payments contingent upon the successful achievement of certain development and regulatory milestones. In addition we will pay royalties and sales milestones on net sales, if any, after marketing approval is obtained from the FDA and other regulatory authorities. Chicago Labs may terminate the agreement if we do not meet certain development deadlines which may be extended by Chicago Labs upon our request if we demonstrate good faith efforts to meet the deadlines.

J.B. Chemicals & Pharmaceuticals Ltd. (JBCPL): In 2002, we formed a joint venture, NeoJB, LLC, with JBCPL, an India based pharmaceutical manufacturer, with a view to utilizing JBCPL's existing manufacturing capabilities to produce selected oral prescription drug products for marketing in the United States. JBCPL operates 11 manufacturing facilities in India, which produce active pharmaceutical ingredients, intermediates ("building blocks" in chemical compounds), finished dosage form pharmaceuticals and herbal remedies. We own an 80% interest in NeoJB, LLC. Through the date of this report, we have filed three ANDAs on behalf of the joint venture. In September 2004, the FDA approved our ANDA for ciprofloxacin

which is manufactured by JBCPL. The joint venture purchases product from JBCPL based on market prices prevailing at the time of purchase, and does not have long-term volume or price commitments.

In 2002, JBCPL granted NeoJB an exclusive license to obtain regulatory approval to market and distribute certain products within the United States, including ciprofloxacin tablets and fluconazole tablets. The agreement provides that we, or NeoJB, will bear all costs of regulatory approvals for the products and that JBCPL will manufacture and supply to NeoJB the products in such quantities as NeoJB may require at prices reasonably acceptable to both parties. The agreement provides that JBCPL shall not enter into any distribution or sale arrangement or grant any license with respect to any product covered by the agreement in the United States unless it first offers to enter into a supply agreement with NeoJB pursuant to certain procedures and conditions. In addition, the agreement provides that NeoJB shall not, for 5 years from the later of the termination of the agreement or expiration of the applicable patents, market in the United States any products which would compete with the distribution, marketing or sale of the products covered by the agreement. The agreement continues so long as JBCPL or any of its affiliates is a member of NeoJB or until jointly terminated by the parties.

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.

Under our alliance agreement with JBCPL, an entity affiliated with JBCPL agreed to invest $1 million in our common stock. The first $250,000 was invested in 2003 following acceptance by the FDA of our ANDA filing for ciprofloxacin, for 125,565 shares of our common stock at a price per share of $1.99, equal to the closing price of our common stock on the date immediately prior to the date of acceptance of the ANDA by the FDA, and the remaining $750,000 which was scheduled for investment in September 2004, upon receipt of the FDA approval of the ciprofloxacin ANDA, was received in February 2005 and we issued 119,617 shares of common stock, at a price per share equal to $6.27, the closing price of our common stock on the date immediately prior to the date of approval of the ANDA by the FDA.

FDC Limited (FDC): In 2003, we entered into an agreement with FDC, an India based pharmaceutical manufacturer, with a view to marketing in the United States certain ophthalmic drugs manufactured by FDC. FDC manufactures, among other products, active pharmaceutical ingredients and certain oral, ophthalmic and otic drugs at their manufacturing facilities in India, and is engaged in selling certain active pharmaceutical ingredients produced at their FDA approved facilities in India into the United States market. Through the date of this report, we have filed four ANDAs for ophthalmic drugs under this alliance. We do not have long-term volume or price commitments, and we anticipate negotiating transfer prices for each product only after FDA approval of the corresponding ANDA is accomplished. Either party may terminate the agreement upon failure to agree to a mutually satisfactory supply price with respect to the products, in which case FDC is prohibited from selling such products within the United States for a price less than that offered to us under the agreement. The agreement continues until jointly terminated by the parties. However, either party may terminate the agreement upon the failure to reach certain milestones within specified time periods.

Shantha Biotechnics Pvt. Ltd. (Shantha): In 2004, we entered into an alliance with Shantha, an Indian biopharmaceutical company engaged in the development, manufacture and commercialization of human healthcare products produced by recombinant technology for the detection and treatment of cancer and infectious diseases. We are responsible for all regulatory, marketing and distribution matters in the United States for certain products currently marketed by Shantha elsewhere in the world and certain other products under development by Shantha. The product candidates under evaluation for development include oncology biologics, cancer diagnostics, as well as vaccines. However, there are no current U.S. regulatory guidelines that allow for generic equivalents to branded biologics to be filed with the FDA using an abbreviated application and review process. The FDA is working with the pharmaceutical industry at-large to better understand the position of the biotech and biopharmaceutical companies regarding the issue of equivalence of biogenerics to the branded products and the equivalence of the processes used to manufacture the active biological ingredient. Until such time that the FDA adopts clear guidelines covering biogenerics and/or Congress creates new laws and regulations that would allow for an abbreviated application, review and approval process for

biogenerics we will not be in a position to move forward in the United States on a number of product candidates covered under this agreement.

Others: In connection with the carboplatin injection and sumatriptan succinate injection ANDAs filed with the FDA, we are negotiating commercial supply and service arrangements with sources for the active pharmaceutical ingredients and developmental laboratories with the capacity to manufacture drug products on a commercial scale, after FDA approval is received. When we file additional ANDAs for other drug products, we expect to enter into similar arrangements, if the products are not covered under one of our business alliances mentioned above.

Sales, Marketing and Distribution

As described below, The Lannett Company markets and distributes our first approved drug product, ciprofloxacin tablets. In 2003 we hired a vice president of marketing and sales and, in light of anticipated FDA approvals, we may hire additional sales and marketing personnel, as needs dictate. We also intend to seek alliances with other third parties to assist us in the marketing and sale of our other drug candidates.

The Lannett Company (Lannett): In 2003, we entered into a sales and distribution agreement with Lannett, a Philadelphia based pharmaceutical company engaged in the marketing and distribution of prescription drugs. Under the agreement Lannett is our exclusive distributor for ciprofloxacin tablets in the United States, and we are obligated to distribute ciprofloxacin tablets only through Lannett. During late 4th quarter of 2004, subsequent to receipt of FDA approval, we sold ciprofloxacin tablets to Lannett. We sell product to Lannett based on market prices prevailing at the time of sale, and do not have any long-term volume or price commitments. The agreement contemplates, and the parties expect, that additional products may be added to the agreement from time to time. Lannett agrees that if it decides to distribute any products other than ciprofloxacin tablets under this agreement, that it will not, without our prior written consent, market, distribute or sell any product that competes with such additional products. The agreement continues for 18 months after the date upon which we were first allowed to sell ciprofloxacin tablets in the United States, unless renewed by mutual agreement.

Competition

The pharmaceutical industry is characterized by rapidly evolving technology and intense competition. 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. Several companies are engaged in research and development of compounds that are similar to our research. Technologies under development by these and other pharmaceutical companies could result in treatments for diseases and disorders for which we are developing our own treatments. In the event that one or more of those programs is successful, the market for some of our drug candidates could be reduced or eliminated. Any product for which we obtain FDA approval must also compete for market acceptance and market share.

Competition for Proprietary Products

Competing in the branded product business requires us to identify and quickly bring to market new products embodying technological innovations. Successful marketing of branded products depends primarily on the ability to communicate the effectiveness, safety and value to healthcare professionals in private practice, group practices and managed care organizations. Competition for branded drugs is less driven by price and is more focused on innovation in treatment of disease, advanced drug delivery and specific clinical benefits over competitive drug therapies. Unless our proprietary products are shown to have better efficacy and are as cost effective, if not more cost effective, than other alternatives, they may not gain acceptance by the medical field and therefore never be successful commercially.

Companies that have products on the market or in research and development that are in the same oncology focus as us include Amgen, Inc., Genentech, Inc., Bayer AG, Eli Lilly and Co., Novartis Pharmaceuticals Corporation, Bristol-Myers Squibb Company, GlaxoSmithKline, Biogen-IDEC Pharmaceuticals, Inc., Guilford Pharmaceuticals, Inc., Cephalon, Inc., Sanofi-aventis Inc., Pfizer, Inc., AVI

Biopharma, Inc., Chiron Corp., Corixa Corp., Genta Inc., Imclone Systems Incorporated, MGI Pharma, Inc. and SuperGen, Inc., among others. Many of our competitors are large and well capitalized companies focusing on a wide range of diseases and drug indications, and 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.

In treating hyperphosphatemia, under the new National Kidney Foundation K/DOQI guidelines, non-calcium, non-aluminum binders are the recommended first-line long-term therapy for managing high phosphate levels. To our knowledge, Genzyme Corporation's Renagel® and Shire Pharmaceuticals' Fosrenol® are the only two FDA approved non-calcium, non-aluminum, branded pharmaceuticals specifically for the treatment of hyperphosphatemia in end-stage renal disease. We expect to compete with these products and potentially others based upon phosphate binding capacity, patient compliance, side effects and cost. While we believe RenaZorb™ has the potential to perform better than these competitors, RenaZorb™ is not yet a clinical stage drug and, consequently, if RenaZorb™ is successfully developed and receives FDA approval, it will be a number of years after Renagel® and Fosrenol® have been FDA approved and marketed. In addition, Genzyme and Shire may seek to modify their products or create new therapies that could reduce or eliminate any perceived benefit we believe RenaZorb™ may have over these products.

Competition for Generic Products

The generic drug market is price sensitive and price competitive and revenues and gross profit derived from the sales of generic drug products tend to follow a pattern based on certain regulatory and competitive factors. As patents and regulatory exclusivity for brand name products expire, the first generic manufacturer to receive regulatory approval for the generic equivalents of such products is generally able to achieve significant market penetration and retain market share. As competing generic manufacturers receive regulatory approvals on similar products, market share, revenues and gross profit typically decline, in some cases, dramatically. Accordingly, the level of market share, revenues and gross profit attributable to a particular generic product is normally related to the number of competitors in that product's market and the timing of that product's regulatory approval and launch, in relation to competing approvals and launches. Consequently, we must develop and introduce new generic products in a timely and cost-effective manner to achieve and maintain significant revenues and gross profit. In addition to competition from other generic drug manufacturers, we face competition from brand name companies in the generic market. Many of these companies seek to participate in sales of generic products by, among other things, collaborating with other generic pharmaceutical companies through authorized generic programs or by marketing their own generic equivalent to their branded products.

Companies that have a significant generic presence include American Pharmaceutical Partners, Bedford Laboratories, Barr Laboratories, Sicor, Inc., Teva Pharmaceuticals, Dr. Reddy's Laboratories, Ranbaxy Laboratories, Mylan Laboratories, Inc., Sandoz, and Watson Pharmaceuticals, Inc. Some additional competitors in the generics market include Eon Labs, Inc., Pliva, Inc., Impax Laboratories, Inc. and Akorn, Inc., a competitor particularly in the field of generic ophthalmic drugs.

Please also read our discussion of competition matters in the "RISK FACTORS" section of this report.

Research and Development

From our inception through August 2002, we devoted substantially all of our resources and efforts to early stage drug research and development. Commencing with the launch of our new business strategy in August 2002, we eliminated early stage drug research and development and focused our research and development efforts on development of later stage drug product candidates that are already in or about to enter human clinical trials. Research and development expenditures, including related stock-based charges, are expensed as we incur them and were approximately $8 million in 2004, $5 million in 2003, and $13 million in 2002.

Patents and Proprietary Rights

The Patent Process

The United States Constitution provides Congress with the authority to provide inventors the exclusive right to their discoveries. Congress codified this right in United States Code Title 35 which gave the patent office the right to grant patents to inventors and defined the process for securing a U.S. patent. This process involves the filing of a patent application that teaches a person having ordinary skill in the respective art how to make and use the invention in clear and concise terms. The invention must be novel (not previously known) and non-obvious (not an obvious extension of what is already known). The patent application concludes with a series of claims that specifically describe the subject matter that the patent applicant considers his invention.

The patent office undertakes an examination process that can take from one to five years depending on the complexity of the patent and the problems encountered during examination. Generally, the less novel an invention is, the longer the examination process will last.

In exchange for disclosing the invention to the public, the successful patent applicant is provided a right to exclude others from making, using or selling the claimed invention for a period of 20 years from the filing date of the patent application.

Under certain circumstances a patent term may be extended. Patent extensions are most frequently granted in the pharmaceutical and medical device industries under the Drug Price Competition and Pricing Term Restoration Act of 1984, or commonly known as the Hatch-Waxman Act, to recover some of the time lost during the FDA regulatory process, subject to a number of limitations and exceptions. The patient term may be extended up to a maximum of five years, however, as a general rule, the average extension period granted for a new drug is approximately three years and approximately 18 months for a new medical device. Only one patent can be extended per FDA approved product and a patent can only be extended once.

Generic Drugs and Pediatric Exclusivity

As an incentive for pharmaceutical companies to research the safety and efficacy of their brand name drugs for use in pediatric populations, Congress enacted the Food & Drug Administration Modernization Act of 1997 which included a pediatric exclusivity for brand name drugs. This pediatric exclusivity protects drug products from generic competition for six months after their patents expire in exchange for research on children. For example, if a pharmaceutical company owns a patent covering a brand name drug they can only exclude third parties from selling generic versions of that drug until that patent expires. However, if the FDA grants a brand named drug pediatric exclusivity the FDA will not approve of the sale of any generic drugs for six months beyond the patent term covering the brand name drug. Thus, the pediatric exclusivity effectively extends the brand named company's patent protection for six months. This extension applies to all dosage forms and uses that the original patent(s) covered.

Our Patent, Proprietary Rights and ANDAs

We in-license from third parties certain patent and related intellectual property rights related to our proprietary products. In particular, we have licensed patent rights with respect to satraplatin, EOquin™, elsamitrucin, SPI-153, RenaZorb™ and SPI-1620, in each case for the remaining life of the applicable patents. Except for SPI-153, our agreements generally provide us with exclusive worldwide rights to, among other things, develop, sublicense, and sell the drug candidates. We are generally responsible for all development, patent filing and maintenance costs, sales, marketing and liability insurance costs. In addition, these licenses and agreements may require us to make royalty and other payments, to reasonably exploit the underlying technology of applicable patents. If we fail to comply with these and other terms in these licenses and agreements, we could lose the underlying rights to one or more of our potential products, which would adversely affect our product development and harm our business.

The protection, preservation and infringement-free commercial exploitation of these patents and related intellectual property rights is very important to the successful execution of our proprietary drug strategy. However, the issuance of a patent is not conclusive as to its validity or as to the enforceable scope of the claims

of the patent. Accordingly, our patents and the patents we have in-licensed may not prevent other companies from developing similar or functionally equivalent products or from successfully challenging the validity of our patents. If our patent applications are not approved or, even if approved, if our patents or the patents we have in-licensed, are circumvented or not upheld by the courts, our ability to competitively exploit our patented products and technologies may be significantly reduced. Also, such patents may or may not provide competitive advantages for their respective products or they may be challenged or circumvented by competitors, in which case our ability to commercially exploit these products may be diminished.

From time to time, we may need to obtain licenses to patents and other proprietary rights held by third parties to develop, manufacture and market our products. If we are unable to timely obtain these licenses on commercially reasonable terms, our ability to commercially exploit such products may be inhibited or prevented.

As mentioned above, we have in-licensed from third parties certain patent rights related to our proprietary products. We believe that our patents and licenses are important to our business, but that with the exception of the United States and European patents discussed in this paragraph, relating to our proprietary products, no one patent or license is currently of material importance to our business. We have two U.S. patents covering satraplatin, a compound patent that expires in 2008 and a medical use patent that expires in 2010, and an issued compound patent in Europe that expires in various countries between 2008 and 2009. There is a possibility, under the Hatch-Waxman Act, to obtain up to a 5-year extension of one of the U.S. patents for the time spent during the FDA regulatory process. There are similar extension possibilities in Europe. For EOquin™, the U.S. compound patent expires in 2009, however, we recently received from the U.S. Patent and Trademark Office a Notice of Allowance for a patent application for EOquin™ that, when issued, will cover EOquin™ for use in the treatment of superficial bladder cancer and will not expire until November 2022. In Europe, we have an issued compound patent that expires in various countries in 2007 and we have a patent application pending for the treatment of bladder cancer. For elsamitrucin, the U.S. and Europe patents have already expired, however, we anticipate filing future U.S. and European patent applications covering new formulations or uses for this product. For SPI-153, we have a U.S. compound patent issued that will expire in 2020, and in Europe we have a patent application pending. For RenaZorb™, there are compound patents pending in the United States and Europe. For SPI-1620, we have filed method of use patent applications in U.S. and Europe. We are constantly evaluating our patent portfolio and considering new patent applications in order to maximize the life cycle of each of our products.

While the United States and the European Union are currently the largest markets for most our proprietary products, we also have patents issued and patent applications pending outside of the United States and Europe. Limitations on patent protection in these countries, and the differences in what constitutes patentable subject matter in countries outside the United States, may limit the protection we have on patents issued or licensed to us outside of the United States. In addition, laws of foreign countries may not protect our intellectual property to the same extent as would laws in the United States. To minimize our costs and expenses and to maintain effective protection, we usually focus our patent and licensing activities within the United States, the European Union, Canada and Japan. In determining whether or not to seek a patent or to license any patent in a certain foreign country, we weigh the relevant costs and benefits, and consider, among other things, the market potential and profitability, the scope of patent protection afforded by the law of the jurisdiction and its enforceability, and the nature of terms with any potential licensees. Failure to obtain adequate patent protection for our proprietary drugs and technology would impair our ability to be commercially competitive in these markets.

We also hold U.S. and foreign patent rights related to our neurology drug candidates. All neurology patents were assigned to us by the inventors, including Dr. Alvin Glasky, our former Chairman and CEO, and McMaster University, for certain royalty payments. We may out-license these patent rights for further development.

In addition to the specific intellectual property subjects discussed above, we have trademark protection for EOquin™ and RenaZorb™. We will likely register trademarks for the branded names of our proprietary drug products.

In conducting our business generally, we rely upon trade secrets, know-how, licensing arrangements and customary practices for the protection of our confidential and proprietary information such as confidentiality agreements. It is possible that these agreements will be breached or will not be enforceable in every instance, and that we will not have adequate remedies for any such breach. It is also possible that our trade secrets or know-how will otherwise become known or independently developed by competitors. The protection of know-how is particularly important because the know-how is often the necessary or useful information that allows us to practice the claims in the patents related to our proprietary products.

We may find it necessary to initiate litigation to enforce our patent rights, to protect our trade secrets or know-how or to determine the scope and validity of the proprietary rights of others. Litigation concerning patents, trademarks, copyrights and proprietary technologies can often be protracted and expensive and, as with litigation generally, the outcome is inherently uncertain. See "Risk Factors" for more information.

In connection with ANDAs filed on behalf of JBCPL and FDC, we have the exclusive license to market and distribute those drugs within the United States, if and when approved by the FDA. We own the ANDAs for carboplatin and sumatriptan succinate injection.

Paragraph IV Certification

In 1984, Congress enacted the Hatch-Waxman Act in part to establish a streamlined approval process for the FDA to use in approving generic versions of previously approved branded drugs. Under the Hatch-Waxman Act, for each patent listed in the Orange Book, where branded companies are required to list their patents for branded products, for the relevant branded drug, an ANDA applicant must certify one of the following claims: (1) that there is no patent information listed; (2) that such patent has expired; (3) that the proposed drug will not be marketed until expiration of the patent; or (4) that either the proposed generic drug does not infringe the patent or the patent is invalid, otherwise known as Paragraph IV certification.

If an ANDA applicant files a paragraph IV certification, the Hatch-Waxman Act requires the applicant to provide the patent holder with notice of that certification and provides the patent holder with a 45-day window, during which it may bring suit against the applicant for infringement. If patent litigation is initiated during this period, the FDA may not approve the ANDA until the earlier of (1) 30 months from the patent holder's receipt of the notice (the 30-month stay) or (2) the issuance of a final, non-appealed, or non-appealable court decision finding the patent invalid, unenforceable or not infringed. If the patent is found to be infringed by the filing of the ANDA, the patent holder could seek an injunction to block the launch of the generic product until the patent expires.

Often more than one company will file an ANDA that includes a paragraph IV certification. However, the Hatch-Waxman Act provides that such subsequent ANDA applications will not be approved until 180 days after the earlier of (1) the date of the first commercial marketing of the first-filed ANDA applicant's generic drug or (2) the date of a decision of a court in an action holding the relevant patent invalid, unenforceable, or not infringed. Thus, the Hatch-Waxman Act effectively grants the first-filed ANDA holder 180 days of marketing exclusivity for the generic product.

For more information on our ANDA with paragraph IV certification for sumatriptan succinate injection, please see "Our generic drug candidates — Sumatriptan succinate injection."

Please also read our discussion of patent and intellectual property matters in the "RISK FACTORS" section of this report.

Governmental Regulation

The production and marketing of our proprietary and generic drug products 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, including for drugs already at a clinical stage of development, can take many years and require 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 countries under reciprocal agreements with the FDA.

General Information about the Drug Approval Process

The United States system of new drug approval is one of the most rigorous in the world. Only a small percentage of compounds that enter the pre-clinical testing stage are ever approved for commercialization. Our proprietary drug strategy focuses on in-licensing clinical stage drug candidates that are already in or about to enter human clinical trials. This strategic focus on clinical stage drug candidates (those eligible for human trials) is designed to address certain risks of drug development by shortening the timeline to marketability and reducing the risk of failure, both of which are higher with an early stage product.

The following general comments about the drug approval process are relevant to the development activities we are undertaking with our proprietary drugs.

Pre-clinical Testing: During the pre-clinical testing stage, laboratory and animal studies are conducted to show biological activity of a drug compound against the targeted disease and the compound is evaluated for safety.

Investigational New Drug Application: After pre-clinical testing, an Investigation New Drug Application is submitted to the FDA to begin human testing of the drug.

Phase 1 Clinical Trials: After an Investigational New Drug Application becomes effective, Phase 1 human clinical trials can begin. These trials, involving small numbers of healthy volunteers or patients usually define a drug candidate's safety profile, including the safe dosage range.

Phase 2 Clinical Trials: In Phase 2 clinical trials, controlled studies of volunteer human patients with the targeted disease are conducted to assess the drug's effectiveness. These studies are designed primarily to determine the appropriate dose levels, dose schedules and route(s) of administration, and to evaluate the effectiveness of the drug on humans, as well as to determine if there are any side effects on humans to expand the safety profile following Phase 1.

Phase 3 Clinical Trials: This Phase usually involves large numbers of patients with the targeted disease. During the Phase 3 clinical trials, physicians monitor the patients to determine the drug candidate's efficacy and to observe and report any adverse reactions that may result from long-term use of the drug on a large, more widespread, patient population. During the Phase 3 clinical trials, the drug candidate is compared to either a placebo or a standard treatment for the target disease.

New Drug Application: After completion of all three clinical trial phases, if the data indicates that the drug is safe and effective, a New Drug Application is filed with the FDA. We estimate that approval of a New Drug Application for a cancer drug generally takes six months to three years.

Fast Track Review: The FDA has established procedures for accelerating the approval of drugs to be marketed for serious life threatening diseases for which the manufacturer can demonstrate the potential to address unmet medical needs. One of our drug candidates, satraplatin, has been given a fast track designation for the hormone refractory prostate cancer indication.

Phase 4 Clinical Trials: After a drug has been approved by the FDA, Phase 4 studies are conducted to explore additional patient populations, compare the drug to a competitor, or to further study the risks, benefits and optimal use of a drug. These studies may be a requirement as a condition of the initial approval of the NDA.

Abbreviated New Drug Application (ANDA): The Abbreviated New Drug Application is particularly relevant for our business strategy. An ANDA is the abbreviated review and approval process created by the Drug Price Competition and Patent Term Restoration Act of 1984 signed into law in part for the accelerated approval of generic drugs. When a company files an ANDA, it must make a patent certification if there are any patents covering the branded product listed in the FDA's Orange Book. An ANDA applicant must make one of four certifications: (1) that there is no patent information listed in the Orange Book; (2) that the listed patent has expired; (3) that the listed patent will expire on a stated date or (4) that the listed patent is invalid or will not be infringed by the generic product. The ANDA must also demonstrate both chemical equivalence and bio-equivalence (the rate and extent of absorption of the generic drug in the body is substantially equivalent to the brand name product), unless a bio-equivalence waiver is granted by the FDA in the case of an injectable generic drug to the brand name product. The ANDA drug development and approval process generally takes less time than the NDA drug development and approval process since the ANDA process does not require new clinical trials establishing the safety and efficacy of the drug product. We estimate that approval of an Abbreviated New Drug Application generally takes one to two years.

Approval: If the FDA approves the New Drug Application, the drug becomes available for physicians to prescribe to patients for treatment. The marketing of a drug after FDA approval is subject to substantial continuing regulation by the FDA, including regulation of adverse event reporting manufacturing practices and the advertising and promotion of the drug.

Failure to comply with FDA and other governmental regulations can result in fines, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA's review of NDAs, ANDAs or other product applications enforcement actions, injunctions and criminal prosecution. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals. Although we have internal compliance programs, if these programs do not meet regulatory agency standards or if our compliance is deemed deficient in any significant way, it could have a material adverse effect on us. See "Risks Factors — Our failure to comply with extensive governmental regulation to which we are subject may delay or prevent approval of our product candidates and may subject us to penalties."

The Generic Drug Enforcement Act of 1992 established penalties for wrongdoing in connection with the development or submission of an ANDA. Under this Act, the FDA has the authority to permanently or temporarily bar companies or individuals from submitting or assisting in the submission of an ANDA, and to temporarily deny approval and suspend applications to market generic drugs. The FDA may also suspend the distribution of all drugs approved or developed in connection with certain wrongful conduct and/or withdraw approval of an ANDA and seek civil penalties. The FDA can also significantly delay the approval of any pending NDA, ANDA or other regulatory submissions under its Fraud, Untrue Statements of Material Facts, Bribery and Illegal Gratuities Policy.

As part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, companies are now required to file with the Federal Trade Commission and the Department of Justice certain types of agreements entered into between branded and generic pharmaceutical companies related to the manufacture, marketing and sale of generic versions of branded drugs. This new requirement could affect the manner in which generic drug manufacturers resolve intellectual property litigation and other disputes with branded pharmaceutical companies, and could result generally in an increase in private-party litigation against pharmaceutical companies. The impact of this new requirement, and the potential private-party lawsuits associated with arrangements between brand name and generic drug manufacturers, is uncertain and could adversely affect our business.

Continuing studies of the proper utilization, safety and efficacy of pharmaceuticals and other health care products are being conducted by industry, government agencies and others. Such studies, which increasingly employ sophisticated methods and techniques, can call into question the utilization, safety and efficacy of previously marketed products and in some cases have resulted, and may in the future result, in the discontinuance of their marketing.

Employees

The efforts of our employees are critical to our success. We believe we have assembled a strong management team with the experience and expertise needed to execute our business strategy. However, we are constantly looking for talented individuals that provide the right mix of skills to join our company. We anticipate hiring additional personnel as needs dictate to implement our growth strategy. As of December 31, 2004, we had 25 employees, of which four held M.D. degrees and four held a Ph.D. degree. 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.

Available Information

We file with the Securities and Exchange Commission (SEC) our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and registration statements, and all amendments to those reports, proxy statements and registration statements. The public may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. The public may also obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains an internet site at *http://www.sec.gov* that contains reports, proxy and information statements and other information regarding registrants, including us, that file electronically.

We also maintain a website located at *http://www.spectrumpharm.com,* and electronic copies of our periodic and current reports, and any amendments to those reports, are available, free of charge, under the "Investor Relations" link on our website as soon as practicable after such material is filed with, or furnished to, the SEC.

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

RISK FACTORS

An investment in our common stock involves a high degree of risk. Our business, financial condition, operating results and prospects can be impacted by a number of factors, any one of which could cause our actual results to differ materially from recent results or from our anticipated future results. As a result, the trading price of our common stock could decline, and you could lose a part or all of your investment. You should carefully consider the risks described below with all of the other information included in this Annual Report. Failure to satisfactorily achieve any of our objectives or avoid any of the risks below would likely have a material adverse effect on our business and results of operations.

Risks Related to Our Business

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

Our cumulative losses since our inception in 1987 through December 31, 2004 were in excess of $165 million. We lost approximately $12 million in 2004, $10 million in 2003 and $18 million in 2002. We expect to continue to incur losses in the future, particularly as we continue to invest in the development of our drug product candidates, acquire additional drug candidates and expand the scope of our operations. We recently received approval to market our first generic drug product, ciprofloxacin, in the United States and recorded modest revenue in 2004. However, we currently do not sell any other products or services and we may never achieve significant revenues from sales of products or become profitable. Even if we eventually generate significant revenues from sales, we will likely continue to incur losses over the next several years.

Our business does not generate the cash needed to finance our ongoing operations and therefore, we will need to raise additional capital.

Our current business operations do not generate sufficient operating cash to finance the clinical development of our drug product candidates. We have historically relied primarily on raising capital through the sale of our securities, and/or out-licensing our drug candidates and technology, to meet our financial needs. While anticipated profits from the sale of generic drugs, if we are successful in generating significant revenues from generics, may help defray some of the expenses of operating our business, we believe that in order to prepare the company for continued future drug product development and acquisition, and to capitalize on growth opportunities, we will, for the foreseeable future, need to continue to raise funds through public or private financings.

We may not be able to raise additional capital on favorable terms, if at all. Accordingly, we may be forced to significantly change our business plans and restructure our operations to conserve cash, which would likely involve out-licensing or selling 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 and/or reducing the scope and nature of our currently planned research and drug development activities. An inability to raise additional capital would also impact our ability to expand operations.

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

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

All of our product candidates are prone to the risks of failure inherent in drug development. The results of pre-clinical studies and early-stage clinical trials of our product candidates do not necessarily predict the results of later-stage clinical trials. Later-stage clinical trials may fail to demonstrate that a product candidate

is safe and effective despite having progressed through initial clinical testing. Even if we believe the data collected from clinical trials of our drug candidates are promising, such data may not be sufficient to support approval by the FDA or any other United States or foreign regulatory approval. Pre-clinical and clinical data can be interpreted in different ways. Accordingly, FDA officials could interpret such data in different ways than we or our partners do, which could delay, limit or prevent regulatory approval. The FDA, other regulatory authorities, our institutional review boards, our contract research organization, or we may suspend or terminate our clinical trials for our drug candidates. Any failure or significant delay in completing clinical trials for our product candidates, or in receiving regulatory approval for the sale of any drugs resulting from our drug candidates, may severely harm our business and reputation. Even if we receive FDA and other regulatory approvals, our product candidates may later exhibit adverse effects that may limit or prevent their widespread use, may cause FDA to revoke, suspend or limit their approval, or may force us to withdraw products derived from those candidates from the market.

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

Drug Candidate	Target Indication	Development Status
Satraplatin	Hormone Refractory Prostate Cancer	Late Phase 3 clinical trial
EOquin™ (EO9)	Refractory Superficial Bladder Cancer	Late Phase 2 clinical trial
Elsamitrucin	Refractory non-Hodgkin's Lymphoma	Phase 2 clinical trial
SPI-153.....	Hormone Dependent Cancers	Phase 2 clinical trial
SPI-153.....	Benign Prostatic Hypertrophy	Phase 2 clinical trial
Satraplatin	Non-small cell lung cancer	Phase 1/2 clinical trial
EO9.....	Radiation Sensitizer	Pre-clinical
RenaZorb™	End-stage Renal Disease, Chronic Kidney Disease	Pre-clinical
SPI-1620.....	Adjunct to Chemotherapy	Pre-clinical

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

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

The development of our drug candidate, SPI-153, may be adversely affected by the development efforts of Zentaris GmbH who retained certain rights to the product.

Zentaris GmbH licensed the rights to us to develop and market SPI-153 in the United States, Canada, Mexico and India. Zentaris may conduct their own clinical trials on SPI-153 for regulatory approval in other parts of the world. We will not have control over Zentaris' efforts in this area and our own development efforts for SPI-153 may be adversely impacted if their efforts are not successful.

From time to time we may need to license proprietary technologies from third parties, which may be difficult or expensive to obtain.

We may need to obtain licenses to patents and other proprietary rights held by third parties to successfully develop, manufacture and market our drug products. As an example, it may be necessary to utilize a third party's proprietary technology to reformulate one of our drug products in order to improve upon

the capabilities of the drug product. If we are unable to timely obtain these licenses on reasonable terms, our ability to commercially exploit our drug products may be inhibited or prevented.

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. While some of our management has had experience at conducting clinical trials, we have limited experience in doing so as a company. If we move forward with self-conducted clinical trials, our limited experience may delay the completion of our clinical trials and increase our costs.

The inability to retain and attract key personnel could significantly hinder our growth strategy and might cause our business to fail.

Our success depends upon the contributions of our key management and scientific personnel, especially Dr. Rajesh C. Shrotriya, our Chairman, President and Chief Executive Officer and Dr. Luigi Lenaz, our Chief Scientific Officer. Dr. Shrotriya has been President since 2000 and Chief Executive Officer since 2002, and has spearheaded the major changes in our business strategy and coordinated our structural reorganization. Dr. Lenaz has been President of our Oncology Division since 2000 and Chief Scientific Officer since 2005, and has played a key role in the identification and development of our proprietary drug candidates. The loss of the services of Dr. Shrotriya, Dr. Lenaz or any other key personnel could delay or preclude us from achieving our business objectives. Dr. Shrotriya has an employment agreement with us that will expire on December 31, 2005, with automatic one-year renewals thereafter unless we, or Dr. Shrotriya, give notice of intent not to renew at least 90 days in advance of the renewal date. Dr. Lenaz has an employment agreement with us that will expire on July 1, 2005, with automatic one year renewals thereafter unless Dr. Lenaz or we give 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 delay or inability to attract and retain the additional skilled personnel required for the expansion of our business, could significantly damage our business.

We are dependent on third parties for clinical testing, manufacturing and marketing our proposed proprietary products. If we are not able to secure favorable arrangements with such third parties, our business and financial condition could be harmed.

We may not conduct clinical trials ourselves, and we will not manufacture any of our proposed proprietary products for commercial sale nor do we have the resources necessary to do so. In addition, we currently do not have the capability to market our drug products ourselves. 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-promotional and/or co-marketing rights to certain of our proprietary 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 may not be able to enter into any partnering arrangements on this or any other basis. If we are not able to secure adequate partnering arrangements, our business and financial condition could be harmed. In addition, we will have to hire additional employees or consultants, since our current employees have limited experience in these areas. Sufficient employees with relevant skills may not be available to us. Any increase in the number of our employees would increase our expense level, and could have an adverse effect on our financial position.

In addition, we, or our potential corporate partners, may not successfully introduce our proposed proprietary products or our proposed proprietary products may not 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 proprietary 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.

Our efforts to acquire or in-license and develop additional proprietary drug candidates may fail, which would limit our ability to grow our proprietary business.

The long-term success of our strategy depends in part on obtaining drug candidates in addition to our existing portfolio. We are actively seeking to acquire, or in-license, additional proprietary drug candidates that demonstrate the potential to be both medically and commercially viable. We have certain criteria that we are looking for in any drug candidate acquisition and therefore, we may not be successful in locating and acquiring, or in-licensing, additional desirable drug candidates on acceptable terms.

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

Many companies, both public and private, including well-known pharmaceutical companies and smaller niche-focused companies, are developing products to treat all of the diseases we are pursuing, or distributing generic drug products directly competitive to the generic drugs we intend to market and distribute. 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.

Competition for branded drugs is less driven by price and is more focused on innovation in treatment of disease, advanced drug delivery and specific clinical benefits over competitive drug therapies. We have six proprietary drug candidates currently under development. We may not be successful in any or all of these studies; or if successful, and if one or more of our proprietary drug candidates is approved by the FDA, we may encounter direct competition from other companies who may be developing products for similar or the same indications as our drug candidates. Companies active in the areas of oncology which is our focus include Astra Zeneca, Amgen, Inc., Bayer AG, Eli Lilly and Co., Genentech, Inc., Novartis Pharmaceuticals Corporation, Bristol-Myers Squibb Company, GlaxoSmithKline, Biogen-IDEC Pharmaceuticals, Inc., Guilford Pharmaceuticals, Inc., Cephalon, Inc., Sanofi-Aventis Inc., Pfizer, Inc., Chiron Corp., Genta Inc., Imclone Systems Incorporated, MGI Pharma, Inc., SuperGen, Inc., Roche Pharmaceuticals and others who are more established and are currently marketing products for the treatment of various forms of cancer including the forms our oncology drug candidates target. Many of our competitors are large and well capitalized companies focusing on a wide range of diseases and drug indications, and 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

Any proprietary product for which we obtain FDA approval must compete for market acceptance and market share. For example, cisplatin injection and carboplatin injection 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 approves it for sale, 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 may never be successful commercially.

With regard to our drug product candidate, RenaZorb™, in treating hyperphosphatemia, under the new National Kidney Foundation K/DOQI guidelines, non-calcium, non-aluminum binders, are the recommended first-line long-term therapy for managing high phosphate levels. Genzyme corporations's Renagel® and Shire Pharmaceutical's Fosrenol® are the only two FDA approved non-calcium, non-aluminum, branded pharmaceuticals specifically for the treatment of hyperphosphatemia in end stage renal disease. We expect to compete with these products and potentially others based upon phosphate binding capacity, patient compliance, side effects and cost. While we believe RenaZorb™ has the potential to perform better than these competitors, if RenaZorb™ is successfully developed and receives FDA approval, it will be a number of years after Renagel® and Fosrenol® have been FDA approved and marketed. In addition, Genzyme and Shire may seek to modify their products or create new therapies that could reduce or eliminate any perceived benefit we believe RenaZorb™ may have over these products.

Our success in the marketing of our generic drug products will depend significantly upon our ability to forecast market conditions that may prevail after we obtain ANDA approval and identify generic drugs that our strategic partners and associated suppliers can produce for us cost-effectively. In addition, we must be able to expand our marketing, selling and distribution relationships in the United States since we currently do not have any internal distribution capabilities and an alliance with a single product distributor. Furthermore, as a new generic competitor entering the marketplace which is made up of many well-established companies, with established customers as well as established sales, marketing and distribution organizations we may not be able to successfully compete.

Since price is the primary basis for competition among generic versions of a given drug, any ability by our competitors to reduce production costs can provide them with a significant competitive advantage, and our ability to compete will be largely dependent on our ability to obtain supplies of our generic drug product from manufacturers at favorable prices. As a new generic competitor, we will be competing against established generic companies such as Teva Pharmaceuticals, Sandoz, Barr Laboratories, Mylan Laboratories Inc., Watson Pharmaceuticals, Inc., Genpharm, Dr. Reddy's, Ranbaxy, American Pharmaceutical Partners, Bedford Laboratories and others. These companies may have greater economies of scale in the production of their products and in certain cases may produce their own product supplies, such as active pharmaceutical ingredients, or can procure product supplies on more favorable terms which may provide significant cost and supply advantages to customers in the retail prescription market We expect that the generic market will be competitive and will be largely dominated by the competitors listed above who will target many if not all of the same products for development as Spectrum.

We currently have eight generic drug candidates under review at the FDA. For ciprofloxacin tablets, our first generic product candidate filed with FDA, and for which we obtained approval in September 2004, there are currently fifteen generic manufacturers approved to sell versions of ciprofloxacin tablets, which include Apotex, Barr, Cobalt, Taro, Teva, West Ward, Eon Labs, Carlsbad Technology, IVAX, Sandoz, Genpharm, Ranbaxy, Dr. Reddy's, Martec and Mylan Laboratories, Inc. The pediatric exclusivity for Diflucan, the branded form of fluconazole, our second generic product filed with the FDA, expired on July 29, 2004. The market is very competitive with versions from generic drug manufacturers such as Taro Pharmaceutical Industries, Mylan Laboratories, Inc, Sandoz, Ranbaxy, IVAX, Genpharm, Gedeon Richter, TEVA, Torpharm, Roxane and Pliva approved by the FDA for sale in the U.S. We have not yet obtained approval from the FDA for fluconazole tablets and can give no assurance for when approval is likely to come, if at all. Carboplatin injection, our third generic drug ANDA filed with FDA, is the generic equivalent of Bristol Meyers Squibb's brand Paraplatin, for which the patent expired in April 2004. The FDA granted approval, following the expiration of pediatric exclusivity in October 2004, for carboplatin injection to five generic companies, including Pharmachemie, APP, Bedford, Mayne and Pliva. TEVA Pharmaceuticals, through an agreement with Bristol Myers Squibb, is currently selling carboplatin injection produced by Bristol Myers Squibb as a generic drug. We have not yet obtained approval from the FDA for carboplatin injection and can give no assurance for when approval is likely to come, if at all. The patent for Imitrex® injection, the brand name for sumatriptan succinate injection, for which we filed an ANDA with paragraph IV certification, has not yet expired. However, we have initiated a challenge of the patent and are currently in litigation with GlaxoSmithKline, the patent holder for Imitrex® injection. Based on the guidelines available to us, and our experience with the FDA approval process, we do not anticipate receiving approval for our five other ANDAs, filed in 2004 and in 2005, before the first quarter of 2006, if at all, and all approvals will come after patents and/or exclusivities expire and after some of our competitors have already obtained approval.

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

Drugs produced by other companies are currently on the market for each disease type we are pursuing. Even if one or more of our drug candidates ultimately received FDA approval, our drug candidates may not have better efficacy in treating the target indication than a competing drug, may not have a more favorable side-effect profile than a competing drug, may not be more cost efficient to manufacture or apply, or otherwise

may not demonstrate a competitive advantage over competing therapies. Accordingly, even if FDA approval is obtained for one or more of our drug candidates, they may not gain acceptance by the medical field or become commercially successful.

Price and other competitive pressures may make the marketing and sale of our generic drugs not commercially feasible and not profitable.

The generic drug market in the United States is extremely competitive, characterized by many participants and constant downward price pressure on generic drug products. Consequently, margins are continually reduced and it is necessary to continually introduce new products to achieve and maintain profitability. We have only obtained regulatory approval for one of our generic drug candidates. While we have entered into agreements with third parties to manufacture the drug products for us, given the price volatility of the generic market, we believe it is imprudent to enter into definitive agreements on transfer prices with the manufacturers of our generic drug product candidates prior to FDA approval, and we do not expect to do so until we receive FDA approval and are ready to begin selling the generic drug products. Our ability to compete effectively in the generic drug market depends largely on our ability to obtain transfer price agreements that ensure a supply of our generic drug products at favorable prices. Even if we obtain regulatory approval to market one or more generic drug candidates in the United States, we may not be able to complete a transfer price arrangement with the manufacturers of the drug candidates that will allow us to market any generic drug products in the United States on terms favorable to us, or at all.

Also, if we fail to obtain approval of our ANDAs from the FDA in a timely manner, preferably before the patent and any additional exclusivity granted by the FDA to the branded drug product expire, our profitability will be significantly affected due to the significant price erosion caused by the typically large number of the generic companies entering the market. The U.S. patent and pediatric exclusivity for Cipro®, the branded form of our generic drug product ciprofloxacin, had both expired by June 2004. We received approval from the FDA of our ANDA for ciprofloxacin tablets in September 2004, however, fifteen other companies have received FDA approval to market generic versions of ciprofloxacin tablets, and we have observed a significant reduction in the market price for ciprofloxacin since June 2004. The patents and all exclusivities for our four ophthalmic products and our one undisclosed product have previously expired, and a number of other companies are currently selling their own generic versions of the products. In addition, we did not obtain approval of our ANDAs for fluconazole tablets and carboplatin injection prior to the expirations in July and October 2004, respectively, of the patents and exclusivities granted by the FDA to the corresponding branded products. Consequently, our ability to achieve a profit may be significantly harmed as we have observed significant reductions in the market prices for these products as well. The patents for sumatriptan succinate injection, the generic version of Imitrex®, marketed by GlaxoSmithKline, for which we filed an ANDA with paragraph IV certification in October 2004, have not yet expired. On February 18, 2005, GlaxoSmithKline filed suit in U.S. federal court to prevent us from proceeding with the commercialization of our generic product which action formally initiates our challenge of the patent listed by GlaxoSmithKline in connection with Imitrex® injection. For information regarding the risks of this litigation, please see the next risk factor below.

In addition to competitive pressures related to price, we may face opposition from the producers of the branded versions of the generic drugs for which we obtain approval. Branded pharmaceutical companies have aggressively sought 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 years or otherwise delay the launch of generics;
- using the citizen petition process, a process by which any person can submit a petition to the Commissioner of the FDA to issue, amend or revoke a regulation or order or take or refrain from taking any other administrative action, to request amendments to FDA standards;

- seeking changes to the United States Pharmacopoeia, an organization which publishes industry recognized compendia of drug standards; and
- attaching patent extension amendments to non-related federal legislation.

We may not be successful in expanding our generic drug distribution capabilities in the United States, our only target market for generic drugs, which would limit our ability to grow our generic drug business.

Many of our competitors have substantial, established direct and indirect distribution channels. We have not yet undertaken the marketing and distribution of a generic drug product ourselves and we currently have no direct sales and marketing organization and our limited sales and marketing resources are devoted to establishing and enhancing our third party distribution relationships.

We have established a relationship with a distributor for the distribution of ciprofloxacin; and commenced distribution of ciprofloxacin tablets during the fourth quarter of 2004. The long-term success in the marketing of our generic drugs will depend in part on our drug distribution capabilities in the U.S., our only target market for generic drugs. We may not be successful in expanding our existing distribution channel, establishing new, additional distribution channels or establishing a direct generic drug marketing capability sufficient to effectively and successfully compete in the generic drug market.

We may not be successful in establishing additional generic drug supply relationships, which would limit our ability to grow our generic drug business.

Long-term success in the marketing of generic drugs depends in part on our ability to expand and enhance our existing relationships and establish new relationships for supplying generic drug products. We do not presently intend to focus our research and development efforts on developing active pharmaceutical ingredients or the dosage form for generic drugs. In addition, we currently have no capacity to manufacture generic drug products and do not intend to spend our capital resources to develop the capacity to do so. Therefore, we must rely on relationships with other companies to supply our generic drug products. We may not be successful in expanding or enhancing our existing relationships or in securing new relationships. If we fail to expand our existing relationships or secure new relationships, our ability to expand our generic drug business will be harmed.

Our supply of drug products will be dependent upon the production capabilities of our supply sources, which may limit our ability to meet demand for our products and ensure regulatory compliance.

We have no internal manufacturing capacity for our drug product candidates, and therefore, we have entered into agreements with third-party manufacturers to supply us with our drug products, subject to further agreement on pricing for particular drug products. Consequently, we will be dependent on our manufacturing partners for our supply of drug products. Some of these manufacturing facilities are located outside the United States. The manufacture of drug products, including the acquisition of compounds used in the manufacture of the finished drug product, may require considerable lead times. Further, with regard to our generic drug products, sales of a new generic drug product may be difficult to forecast. We will have little or no control over the production process. Accordingly, while we do not currently anticipate shortages of supply, there could arise circumstances in which market demand for a particular generic product could outstrip the ability of our supply source to timely manufacture and deliver the product, thereby causing us to lose sales.

Reliance on a third-party manufacturers entails risks to which we would not be subject if we manufactured products ourselves, including reliance on the third party for regulatory compliance and adhering to FDA's current Good Manufacturing Practices, or cGMP, requirements, the possible breach of the manufacturing agreement by the third party because of factors beyond our control and the possibility of termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us. Before we can obtain marketing approval for our product candidates, our supplier's manufacturing facilities must pass an FDA pre-approval inspection. In order to obtain approval, all of the facility's manufacturing methods, equipment and processes must comply with cGMP requirements. The

cGMP requirements govern all areas of record keeping, production processes and controls, personnel and quality control. Any failure of our third party manufacturers or us to comply with applicable regulations, including an FDA pre-approval inspection and cGMP requirements, could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delay, suspension or withdrawal of approvals, license revocation, seizures or recalls of product, operation restrictions and criminal prosecutions, any of which could significantly and adversely affect our business.

GlaxoSmithKline filed suit in U.S. federal court asserting that Spectrum has infringed their patent for Imitrex® injection by filing our ANDA for sumatriptan injection, the generic form of Imitrex® injection. This challenge may prevent us from commercializing sumatriptan until after the patent has expired and may require us to incur substantial expense and the significant effort of technical and management personnel.

On February 18, 2005, GlaxoSmithKline filed suit in U.S. federal court to prevent us from proceeding with the commercialization of our generic form of sumatriptan injection. Since patent litigation has been initiated, the FDA will not approve our ANDA until the earlier of (1) 30 months from the GlaxoSmithKline's receipt of our notice of ANDA acceptance (the 30-month stay) or (2) the issuance of a final non-appealed, or non-appealable court decision finding the Imitex® patent invalid, unenforceable or not infringed. If the patent is found to be infringed by the filing of our ANDA, GlaxoSmithKline could seek an injunction to block the launch of our generic product until the patent expires. This would prohibit us from obtaining the 180-day marketing exclusivity afforded by the FDA to companies who are the first to file an ANDA with a paragraph IV certification for a generic equivalent to a brand name product. We believe we are the first to file the ANDA for sumatriptan injection.

Our defense against the charge of infringement by GlaxoSmithKline could require us to incur substantial legal expense and to divert significant effort of our technical and management personnel away from their regular activities in our business, which could substantially hinder our ability to conduct, advance and grow our business.

Risks Related to Our Industry

Rapid technological advancement may render our drug candidates obsolete before we recover expenses incurred in connection with their development. As a result, certain drug products may never become profitable.

The pharmaceutical industry is characterized by rapidly evolving technology. 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. A competitor could develop a new technology, product or therapy that has better efficacy, a more favorable side-effect profile or is more cost effective than one or more of our drug candidates and thereby cause our drug candidate to become commercially obsolete. Some drug candidates may become obsolete before we recover the expenses incurred in their development. As a result, such products may never become profitable.

Competition for patients in conducting clinical trials may prevent or delay product development and strain our limited financial resources.

Many pharmaceutical companies are conducting clinical trials in patients with the disease indications that our 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 do not know how many of the eligible patients may be enrolled in competing studies and consequently not available to us. Our clinical trials may be delayed or terminated due to the inability to enroll enough patients to complete our clinical trials. Patient enrollment depends on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to

clinical sites and the eligibility criteria for the study. The delay or inability to meet planned patient enrollment may result in increased costs and delays or termination of the trial, which could have a harmful effect on our ability to develop products.

We may not be successful in obtaining regulatory approval to market and sell our proprietary or generic drug candidates.

Before our proprietary drug candidates can be marketed and sold, regulatory approval must be obtained from the FDA and comparable foreign regulatory agencies. We must demonstrate to the FDA and other regulatory authorities in the United States and abroad that our product candidates satisfy rigorous standards of safety and efficacy. We will need to conduct significant additional research, pre-clinical testing and clinical testing, before we can file applications with the FDA for approval of our product candidates. The process of obtaining FDA and other regulatory approvals is time consuming, expensive, and difficult to design and implement. The review and approval, or denial, process for an application can take years. The FDA, or comparable foreign regulatory agencies, may not timely, or ever, approve an application. Among the many possibilities, the FDA may require substantial additional testing or clinical trials or find our drug candidate is not sufficiently safe or effective in treating the targeted disease. This could result in the denial or delay of product approval. Our product development costs will increase if we experience delays in testing or approvals. Further, a competitor may develop a competing drug or therapy that impairs or eliminates the commercial feasibility of our drug candidates.

In order to obtain approval for our generic drug candidates, we will need to scientifically demonstrate that our drug product is safe and bioequivalent to the innovator drug. Bioequivalency may be demonstrated by comparing the generic drug candidate to the innovator drug product in dosage form, strength, route of administration, quality, performance characteristics and intended use. We plan to use our management's experience with the regulatory approval process in the United States to prepare, file and prosecute appropriate Abbreviated New Drug Applications, or ANDAs, for our current and future generic drug candidates. Since 2003 we have filed nine ANDAs with the FDA. In September 2004, we received approval from the FDA to market ciprofloxacin tablets in the United States. We intend to file additional ANDAs in the foreseeable future. The FDA may not agree that our safety and bioequivalency studies provide sufficient support for approval. This could result in denial or delay of FDA approval of our generic products. Generic drugs generally have a relatively short window in which they can be profitable before other manufacturers introduce competing products that impose downward pressure on prices and reduce market share for other versions of the generic drug. Consequently, delays in obtaining FDA approval may also significantly impair our ability to compete.

Our failure to comply with extensive governmental regulation to which we are subject may delay or prevent approval of our product candidates and may subject us to penalties.

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. While we believe that we are currently in compliance with applicable FDA regulations, if we, our partners, or contract research organizations 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, an institutional review board at our clinical trial sites, our third-party investigators, any comparable regulatory agency in another country, or we, may suspend clinical trials at any time if 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.

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. Even if we obtain regulatory approval for our product candidates, we, our partners, our manufacturers, and other contract entities will continue to be subject to extensive requirements by a number of national, foreign, state and local agencies. These regulations will impact many aspects of our operations, including testing, research and development, manufacturing, safety, effectiveness, labeling, storage, quality control, adverse event reporting, record keeping, approval, advertising and promotion of our future products. Failure to comply with applicable regulatory requirements could, among other things, result in:

- fines;
- changes in advertising;
- revocation or suspension of regulatory approvals of products;
- product recalls or seizures;
- delays, interruption, or suspension of product distribution, marketing and sale;
- civil or criminal sanctions; and
- refusals to approve new products.

The later discovery of previously unknown problems with our products may result in restrictions of the product candidate, including withdrawal from manufacture. In addition, the FDA may revisit and change its prior determinations with regard to the safety and efficacy of our future products. If the FDA's position changes, we may be required to change our labeling or to cease manufacture and marketing of the challenged products. Even prior to any formal regulatory action, we could voluntarily decide to cease the distribution and sale or recall any of our future products if concerns about their safety or effectiveness develop.

In their regulation of advertising, the FDA and the Federal Trade Commission from time to time issue correspondence alleging that some advertising or promotional practices are false, misleading or deceptive. The FDA has the power to impose a wide array of sanctions on companies for such advertising practices, and the receipt of correspondence from the FDA alleging these practices could result in any of the following:

- incurring substantial expenses, including fines, penalties, legal fees and costs to comply with the FDA's requirements;
- changes in the methods of marketing and selling products;
- taking FDA-mandated corrective action, which may include placing advertisements or sending letters to physicians, rescinding previous advertisements or promotions; and
- disruption in the distribution of products and loss of sales until compliance with the FDA's position is obtained.

If we were to become subject to any of the above requirements, it could be damaging to our reputation, and our business condition could be adversely affected.

Physicians may prescribe pharmaceutical products for uses that are not described in a product's labeling or differ from those tested by us and approved by the FDA. While such "off-label" uses are common and the FDA does not regulate physicians' choice of treatments, the FDA does restrict a manufacturer's communications on the subject of off-label use. Companies cannot actively promote FDA-approved pharmaceutical products for off-label uses, but they may disseminate to physicians articles published in peer-reviewed journals. If our promotional activities fail to comply with the FDA's regulations or guidelines, we may be subject to warnings from, or enforcement action by, the FDA.

Legislative or regulatory reform of the healthcare system and pharmaceutical industry may hurt our ability to sell our products profitably or at all.

In both the United States and certain foreign jurisdictions, there have been and may continue to be a number of legislative and regulatory proposals to change the healthcare system and pharmaceutical industry in

ways that could impact upon our ability to sell our products profitably. For example, sales of our products will depend in part on the availability of reimbursement from third-party payers such as government health administration authorities, private health insurers, health maintenance organizations including pharmacy benefit managers and other health care-related organizations. Both the federal and state governments in the United States and foreign governments continue to propose and pass new legislation, rules and regulations designed to contain or reduce the cost of health care. As an example, the Medicare Prescription Drug, Improvement and Modernization Act of 2003, the Medicare Modernization Act, was recently enacted. This legislation provides a new Medicare prescription drug benefit beginning in 2006 and mandates other reforms. Also, the passage of the Medicare Modernization Act reduces reimbursement for certain drugs used in the treatment of cancer. Although we cannot predict the full effects on our business of the implementation of this new legislation, it is possible that the new benefit, which will be managed by private health insurers, pharmacy benefit managers and other managed care organizations, will result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce the prices charged for prescription drugs. This could harm our ability to market our products and generate revenues.

It is also possible that other proposals will be adopted. As a result of the new Medicare prescription drug benefit, or any other proposals, we may determine to change our current manner of operation which could harm our ability to operate our business efficiently. Existing regulations that affect the price of pharmaceutical and other medical products may also change before any of our products are approved for marketing. Cost control initiatives could decrease the price that we receive for any of our products we are developing. In addition, third-party payers are increasingly challenging the price and cost-effectiveness of medical products and services. Significant uncertainty exists as to the reimbursement status of newly approved pharmaceutical products. Our products may not be considered cost effective, or adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize a return on our investments.

In addition, new court decisions, FDA interpretations, and legislative changes have modified the rules governing eligibility for and the timing of 180-day market exclusivity periods, a period of marketing exclusivity that the FDA may grant to an ANDA applicant who is the first to file a legal challenge to patents of branded drugs. We believe we were the first to file an ANDA for sumatriptan succinate injection, the generic form of GlaxoSmithKline's Imitrex® injection, and are currently in litigation with GlaxoSmithKline regarding the patent that covers this product. However, it is difficult to predict the effects such changes may have on our business or our current case. Any changes in FDA regulations, procedures, or interpretations may make ANDA approvals of generic drugs more difficult or otherwise limit the benefits available to us through the granting of 180-day marketing exclusivity. If we are not able to exploit the 180-day exclusivity period for our sumatriptan succinate injection ANDA or one of our generic product candidates that we were first to file, for any reason, our product may not gain market share, which could materially adversely affect our results of operations.

As part of the Medicare Modernization Act, companies are now required to file with the Federal Trade Commission and the Department of Justice certain types of agreements entered into between branded and generic pharmaceutical companies related to the manufacture, marketing and sale of generic versions of branded drugs. This new requirement could affect the manner in which generic drug manufacturers resolve intellectual property litigation and other disputes with branded pharmaceutical companies, and could result generally in an increase in private-party litigation against pharmaceutical companies. The impact of this new requirement, and the potential private-party lawsuits associated with arrangements between brand name and generic drug manufacturers, is uncertain and could adversely affect our business.

Additional government regulations, legislation, or policies may be enacted which could prevent or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of adverse government action that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we might not be permitted to market our products and our business could suffer.

If we are unable to adequately protect our technology or enforce our patents, our business could suffer.

Our success with proprietary products that we develop will depend, in part, on our ability to obtain and maintain patent protection for these products. We currently have a number of U.S. and foreign patents issued and pending. We cannot be sure that we will receive patents for any of our pending patent applications or any patent applications we may file in the future. If our pending and future patent applications are not approved or, if approved, if such patents are not upheld in a court of law, it may reduce our ability to competitively exploit our patented products. Also, such patents may or may not provide competitive advantages for their respective products or they may be challenged or circumvented by our competitors, in which case our ability to commercially exploit these products may be diminished.

We also rely on trade secret protection and contractual protections for our unpatented, confidential and 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 confidential and proprietary information. It is possible that these agreements will be breached, or that they will not be enforceable in every instance, and that we will not have adequate remedies for any such breach. It is also possible that our trade secrets will become known or independently developed by our competitors.

If we are unable to adequately protect our technology, trade secrets or proprietary know-how, or enforce our patents, our business, financial condition and prospects could suffer.

Intellectual property rights are complex and uncertain and therefore may subject us to infringement claims.

The patent positions related to our proprietary and generic drug candidates are inherently uncertain and involve complex legal and factual issues. Although we are not aware of any infringement by any of our drug candidates on the rights of any third party, there may be third party patents or other intellectual property rights relevant to our drug candidates of which we are not aware. Third parties may assert patent or other intellectual property infringement claims against us with respect to our proprietary drug candidates or our generic drug products. This could draw us into costly litigation as well as result in the loss of our use of the intellectual property that is critical to our business strategy.

Intellectual property litigation is increasingly common and increasingly expensive and may result in restrictions on our business and substantial costs, even if we prevail.

Patent and other intellectual property litigation is becoming more common in the pharmaceutical industry. Litigation is sometimes necessary to defend against or assert claims of infringement, to enforce our patent rights, to protect trade secrets or to determine the scope and validity of proprietary rights of third parties. Other than the lawsuit filed against us by GlaxoSmithKline related to our ANDA for sumatriptan injection, currently no third party has asserted that we are infringing upon their patent rights or other intellectual property, nor are we aware or believe 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. In addition, if we infringe the intellectual property rights of others, we could lose our right to develop, manufacture or sell our products or could be required to pay monetary damages or royalties to license proprietary rights from third parties. An adverse determination in a judicial or administrative proceeding or a failure to obtain necessary licenses could prevent us from manufacturing or selling our products, which could harm our business, financial condition and prospects.

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 develop or market certain of our drug candidates.

We may be subject to product liability claims, and may not have sufficient product liability insurance to cover any such 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 from consumers of our products. Although we currently carry product liability insurance in the amount of at least $3 million in the aggregate, it is possible that this coverage will be insufficient to protect us from future claims.

Further, we may not 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 involved and may 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 for injuries resulting from the hazardous materials we use, and for pollution clean up and removal; however, future claims may exceed the amount of our coverage. Currently the costs of complying with federal, state and local regulations are not significant, and consist primarily of waste disposal expenses.

Risks Related to Our Stock

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.

As of March 1, 2005, there were approximately 15.3 million shares of our common stock outstanding, and in addition, security holders held options, warrants and preferred stock which, if exercised or converted, would obligate us to issue up to approximately 10 million additional shares of common stock. A substantial number of those shares, when we issue them upon conversion or exercise, will be available for immediate resale in the public market. In addition, we have filed a shelf registration statement that allows us to sell up to $100 million of our securities, some or all of which may be shares of our common stock or securities convertible into or exercisable for shares of our common stock, and all of which would be available for immediate resale in the market. We may issue and sell all of these securities within two years after January 24, 2005, the date of the effectiveness of the registration statement. If we were to sell the full $100 million available under the registration statement as common stock at a price equal to the current market price of our common stock as of the date of the effectiveness of the registration statement, we would issue approximately 16.0 million new shares of our common stock. The market price of our common stock could fall as a result of resales of any of these shares of common stock due to the increased number of shares available for sale in the market.

We have financed our operations, and for the foreseeable future we expect to continue to finance a substantial portion of our operating cash requirements, 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, to decrease or our 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 2004, the price of our common stock ranged between $3.92 and $10.13, and the daily trading volume was as high as 1,391,800 shares and as low as 9,900 shares. During 2005 through March 1, 2005, the price of our common stock has ranged between $5.82 and $7.00, and the daily trading volume has been as high as 360,200 shares and as low as 25,700 shares.

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

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

- the ability of our board of directors to amend our bylaws without stockholder approval;
- the inability of stockholders to call special meetings;
- the ability of members of the board of directors to fill vacancies on the board of directors;
- the inability of stockholders to act by written consent, unless such consent is unanimous;
- the establishment of advance notice requirements for nomination for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

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

In December 2000, we adopted a stockholder rights plan pursuant to which we distributed rights to purchase units of our Series B junior participating preferred stock. The rights become exercisable upon the earlier of ten days after a person or group of affiliated or associated persons has acquired 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. We currently have no stockholders who own 20% or more of the outstanding shares of our common stock.

We do not anticipate declaring any cash dividends on our common stock.

We have never declared or paid cash dividends on our common stock and do not plan to pay any cash dividends in the near future. Our current policy is to retain all funds and any earnings for use in the operation and expansion of our business.

Item 2. ***Properties***

Our corporate administrative offices are located in a two-story 34,320 square foot facility containing office and laboratory space, constructed for us in Irvine, California. The lease on this facility was renewed effective July 1, 2004 for a five-year period through June 30, 2009, at an average base monthly rental rate of approximately $33,000 over the five-year term, plus taxes, insurance and common area maintenance. At the end of the lease term we have one five-year renewal option. This facility is suitable and adequate to undertake our current and anticipated future operations. Currently we have sub-leased, through November 2007, approximately half the facility consisting of laboratory space. We also lease a small administrative office in Zurich, Switzerland on an expense-sharing basis. The financial and other terms of this lease are not material to our business.

Item 3. ***Legal Proceedings***

Sumatriptan succinate injection Paragraph IV Litigation

In October 2004, we filed with the FDA an ANDA for sumatriptan succinate injection 6mg/0.5mL, seeking approval to engage in the commercial manufacture, sale, and use of the sumatriptan succinate injection product in the United States. Sumatriptan succinate is marketed by GlaxoSmithKline under the brand name Imitrex® and is used for the acute treatment of migraine attacks with or without aura and the acute treatment of cluster headache episodes in adults.

GlaxoSmithKline has two patents for sumatriptan succinate injection listed in the FDA's Orange Book, which is the FDA's listing of approved drug products. The exclusivity afforded the patents listed in the Orange Book for Imitrex® injection expire on June 28, 2007 and February 6, 2009, in each case including extensions for pediatric exclusivity. Our ANDA includes a paragraph IV certification that the later to expire patent associated with GlaxoSmithKline's Imitrex® injection, is invalid, unenforceable and/or or will not be infringed by our generic product candidate.

On February 18, 2005, GlaxoSmithKline filed a lawsuit against us in the United States District Court for the District of Delaware, alleging infringement of the patent on Imitrex®. Pursuant to the Hatch-Waxman Act, the FDA is stayed for 30 months from approving our ANDA until the earlier of a final, non-appealed or non-appealable court decision finding the patent invalid, unenforceable or not infringed or the expiration of the 30 month stay. The 30 month stay began running when GlaxoSmithKline filed suit in federal court alleging patent infringement of their Orange Book-listed patent. Often more than one company will file an ANDA that includes a paragraph IV certification. However, the Hatch-Waxman Act provides that such subsequent ANDA applications will not be approved until 180 days after the earlier of (1) the date of the first commercial marketing of the first-filed ANDA applicant's generic drug or (2) the date of a decision of a court in an action holding the relevant patent invalid, unenforceable, or not infringed. Thus, the Hatch-Waxman Act effectively grants the first-filed ANDA holder 180 days of marketing exclusivity for the generic product. We believe that our ANDA was the first filed ANDA in connection with sumatriptan succinate injection 6mg/0.5mL. If the patent is found to be infringed by the filing of our ANDA, GlaxoSmithKline could seek an injunction to block the launch of our generic product until the patent expires.

While it is not possible to determine with any degree of certainty the ultimate outcome of the foregoing legal proceedings, we believe that we have substantial and meritorious basis with respect to our Paragraph IV challenge of GlaxoSmithKline patent for sumatriptan succinate injection 6mg/0.5mL.

Other

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

Item 4. ***Submission of Matters to a Vote of Security Holders***

No matters were submitted to a vote of security holders during the quarter ended December 31, 2004.

PART II

Item 5. ***Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

Common Stock

As of March 1, 2005 there were 15,326,484 shares of common stock outstanding and 378 shareholders of record. On March 1, 2005, the closing sale price of our common stock was $6.66 per share.

Market for Securities

Our common stock is traded on the NASDAQ National Market under the symbol "SPPI." The high and low sale prices of our common stock reported by NASDAQ during each quarter ended in 2004 and 2003 were as follows:

	High	Low
Year 2004		
Quarter Ended		
March 31	$10.13	$7.53
June 30	$ 8.50	$5.15
September 30	$ 7.64	$3.92
December 31	$ 6.68	$5.10
Year 2003		
Quarter Ended		
March 31	$ 2.40	$1.66
June 30	$ 6.40	$1.90
September 30	$10.37	$3.57
December 31	$ 8.60	$5.42

The high and low sales prices of our common stock reported by NASDAQ reflect inter-dealer prices, without retail mark-ups, markdowns or commissions, and may not represent actual transactions.

Dividends

We have never paid cash dividends on our common stock and we do not intend to pay cash dividends in the foreseeable future. We currently intend to retain our earnings, if any, to finance future growth.

Unregistered Sales of Equity Securities

In connection with a private placement transaction in August 2003, we issued warrants exercisable through August 2008. Since our last current report, a warrant was exercised for the purchase of 19,654 shares of our common stock for cash consideration of $93,356. We believe the sale of the shares was exempt from registration under the Securities Act of 1933 (the "Act") pursuant to Section 4(2) of the Act. We made no solicitation in connection with the exercise of the warrant; we obtained representations from the holder regarding its status as an accredited investor; and the holder had access to adequate information about Spectrum in order to make an informed investment decision. No underwriting discounts or commissions were paid in conjunction with the issuances.

Item 6. ***Selected Financial Data***

The following table presents our selected financial data. Financial data for the years ended December 31, 2004, 2003 and 2002 and as of December 31, 2004 and 2003 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 December 31, 2001 and 2000 and as of December 31, 2002, 2001 and 2000 has been derived from our audited financial statements not included herein.

CONSOLIDATED FINANCIAL INFORMATION
(In thousands, except Share data)

Statement of Operations Data for the Years Ended December 31:	**2004**	**2003**	**2002**	**2001**	**2000**
Revenues	$ 258	$ 1,000	$ 2,371	$ 41	$ -
Operating expenses:					
Cost of product sold	$ 123	$ –	$ –	$ –	$ –
Research and development	6,954	3,683	11,706	20,611	38,767
General and administrative	5,096	5,049	3,691	5,475	4,352
Stock-based charges (see supplement below)	885	2,573	1,431	2,105	755
Restructuring expenses	–	163	3,050	–	–
Loss from operations	(12,800)	(10,468)	(17,507)	(28,150)	(43,874)
Other income (expense)	514	78	(127)	315	(2,553)
Net loss	$(12,286)	$(10,390)	$(17,634)	$(27,835)	$(46,427)
Basic and diluted net loss per share	$ (0.98)	$ (4.83)	$ (12.34)	$ (36.50)	$(109.25)
Cash Dividends on common stock	$ –	$ –	$ –	$ –	$ –
Supplemental Information					
Stock-based charges — Components:					
Research and development	$ 634	$ 1,000	$ 1,020	$ –	$ –
General and administrative	251	1,573	411	2,105	755
Total stock based charges	$ 885	$ 2,573	$ 1,431	$ 2,105	$ 755

Balance Sheet Data at December 31:	**2004**	**2003**	**2002**	**2001**	**2000**
Cash, cash equivalents and marketable securities	$ 39,206	$ 26,351	$ 1,578	$ 7,157	$ 11,470
Property and equipment, net	$ 687	$ 560	$ 802	$ 4,689	$ 3,416
Total assets	$ 40,758	$ 27,389	$ 3,453	$ 12,825	$ 15,781
Current liabilities	$ 2,666	$ 3,108	$ 2,522	$ 5,212	$ 5,110
Long-term debt, less current portion	$ –	$ –	$ 158	$ 464	$ 474
Other non-current-liabilities	$ 178	$ –	$ 101	$ 362	$ 87
Minority interest in consolidated subsidiaries	$ 24	$ –	$ –	$ –	$ 7,280
Total stockholders' equity	$ 37,890	$ 24,281	$ 672	$ 6,787	$ 2,830

Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations*

You should read the following discussion of the financial condition, changes in 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 might cause such a difference include, but are not limited to, those discussed below and elsewhere, including "Risk Factors". These factors include, but are not limited to:

- our ability to successfully develop, obtain regulatory approvals for and market our products;
- our ability to generate and maintain sufficient cash resources to increase investment in our business;
- our ability to identify new product candidates;
- the timing or results of pending or future clinical trials;
- actions by the FDA and other regulatory agencies;
- demand and market acceptance for our approved products and
- the effect of changing economic conditions.

Overview

Spectrum Pharmaceuticals, Inc. is a specialty pharmaceutical company engaged in the business of acquiring, developing and commercializing prescription drug products for various indications. While we own patent rights to certain product candidates, the drug products we are currently developing, which are focused on the treatment of cancer and other unmet medical needs, are in-licensed from third parties whereby we acquired exclusive development and commercialization rights from the holders of patents for those compounds. We are also actively engaged in seeking FDA approval for marketing generic versions of branded drugs whose patent protection is scheduled to expire in the near-term, or has already expired. In September 2004, the FDA granted us approval to market ciprofloxacin, the generic version of the anti-bacterial drug Cipro®, which is marketed by Bayer.

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

Business Outlook

Our primary business focus for 2005, and beyond, will be to continue to acquire and develop a portfolio of marketable prescription drug products with a mix of near-term and long-term revenue potential.

As of the date of filing this report, we have six proprietary drug product candidates under development: satraplatin, EOquin™, elsamitrucin, SPI-153; RenaZorb™; and SPI-1620, and to-date have filed nine ANDAs with the FDA, including that for ciprofloxacin, which was approved in September 2004.

- Funding for satraplatin clinical trials is being borne entirely by our co-development partner GPC Biotech. We are funding the Phase 2 clinical trials of EOquin and elsamitrucin; and plan to fund the development, including clinical trials, of SPI-153, RenaZorb™and SPI-1620.
- We have eight drug products for which we have ANDAs pending with the FDA: fluconazole tablets, injectable carboplatin and sumatriptan succinate, and five other drug products.
- We expect to receive approval by the FDA of our ANDAs for carboplatin and fluconazole in the first half of 2005. We may not receive approval for our other pending ANDAs, filed in 2004 and early 2005, before the first quarter of 2006, if at all.

Our goal is to continue to acquire or license additional promising drug product candidates for clinical stage development, and to pursue additional ANDA filings, including several injectable products, and to have several generic drugs FDA approved and marketed in the U.S. over the next 5 years. In this regard we are evaluating several general drug candidates for feasibility. The evaluation of feasibility includes many factors, including, but not limited to, evaluation of market potential, competition, potential patent extensions, and availability of active pharmaceutical ingredients and manufacturing capacity.

Financial Condition

Liquidity and Capital Resources

Our current business operations do not generate sufficient operating cash to finance the clinical development of our drug product candidates. Our cumulative losses, since inception in 1987, through December 31, 2004, have exceeded $165 million. We expect to continue to incur significant additional losses as we implement our growth strategy of developing marketable drug products for at least the next several years unless they are offset, if at all, by licensing revenues under our out-license agreement with GPC Biotech AG and any profits from the sale of generic products.

We believe that the approximately $39 million in cash, cash equivalents and marketable securities that we had on hand as of December 31, 2004, will allow us to fund our current planned operations for at least the next twelve months. While anticipated profits from the sale of generic drugs, if we are successful in generating revenues from generics, may help defray some of the expenses of operating our business, we believe that in order to prepare the company for future drug product acquisition and development, and to capitalize on growth opportunities, we will, for the foreseeable future, need to continue to raise funds through public or private financings. Our operations have historically been financed by the issuance of capital stock because it is generally difficult to fund pharmaceutical research and development via borrowings due to the significant expenses involved, lack of revenues sufficient to service debt and the significant inherent uncertainty as to results of research and the timing of those results. In this regard, while we have no imminent need for additional funding, we filed a shelf registration statement, in January 2005, that would enable to raise $100 million, should we elect to do so.

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

Over the past two years, since the inception of our current business strategy in August 2002, our expenditures for research and development and general and administrative expenses, excluding license acquisition costs, have been largely incurred on non-product-specific, or indirect, costs such as personnel, occupancy and other fixed costs representing approximately 80% of total expenditures. We anticipate that over the next twelve months, such indirect costs will range between approximately $8 million and $9 million. In

addition, we incur product-specific development costs such as upfront license fees, milestone payments, active pharmaceutical ingredient (API), clinical trials, patent search legal costs, and product liability insurance, among others. The following describes our current assessment of product specific development costs for each significant proprietary product, and generics as a group, currently under development. As we mentioned above, these costs are subject to uncertainties inherent in new drug development. In addition, the expenses are not necessarily cumulative. We may reduce the amount we spend on one product to shift our cash resources to another product. Therefore, what we actually spend to develop a particular product may not fall within the estimated range and the estimated ranges may change from quarter to quarter based upon changes in priorities or strategy and/or the results of the development. While we do not receive any funding from third parties for research and development we conduct, our estimated costs could be mitigated should we enter into co-development agreements for any of our drug product candidates.

- *Satraplatin:* The costs of conducting clinical trials are being borne entirely by our co-development partner GPC Biotech. While we have licensed the development of satraplatin to GPC Biotech, we are not obligated to reimburse GPC Biotech for development costs they incur or to refund any license or milestone payments we receive.
- *EOquin:* Through December 31, 2004, excluding indirect costs described earlier, we have spent approximately $1.3 million on the development of EOquin, including approximately $800,000 during the year ended December 31, 2004. Estimated expenditures for the next twelve months are subject to considerable uncertainty, and are largely dependent on the analysis of Phase 2 clinical trial data that is expected to be available in the first half of 2005. We anticipate that over the next twelve months we may incur development costs ranging between approximately $1.5 million and $3 million.
- *Elsamitrucin:* Through December 31, 2004, excluding indirect costs described earlier, we have spent approximately $900,000 on the development of Elsamitrucin, including approximately $500,000 during the year ended December 31, 2004. Estimated expenditures for the next twelve months are subject to considerable uncertainty, and are largely dependent on the completion of enrollment in the Phase 2 clinical trial and positive results. We anticipate that over the next twelve months we may incur development costs ranging between approximately $1.5 million and $3 million.
- *SPI-153:* Through December 31, 2004, excluding indirect costs described earlier, we have spent approximately $1.8 million in cash and equity on the acquisition of SPI-153. Because we acquired rights to this compound recently, estimated expenditures for the next twelve months are subject to considerable uncertainty. Depending on the indications we develop the product for, we may incur development costs ranging between approximately $2 million and $5 million over the next twelve months.
- *RenaZorb*™: In January 2005, we entered into a license agreement with Altair Nanotechnologies, Inc., whereby we acquired an exclusive worldwide license to develop and commercialize for all human therapeutic and diagnostic uses, RenaZorb™, two second-generation lanthanum-based phosphate binding agents, which utilize Altair's proprietary lanthanum nanoparticle technology and have the potential to treat hyperphosphatemia, or high phosphate levels in blood, in patients with end-stage renal disease and chronic kidney disease. We paid Altair an upfront payment of 100,000 shares of restricted Spectrum common stock and made an equity investment of $200,000 for 38,314 shares of Altair common stock, and are obligated to make future payments contingent upon the successful achievement of certain development and regulatory milestones. In addition, we will pay royalties and sales milestones on net sales, if any, after marketing approval is obtained from regulatory authorities. As of the date of this report we are unable to reliably estimate the development costs for RenaZorb™ because we only recently acquired the rights to the compound and we are still in the early stages of planning for future development. However, upon successful achievement of one of the development milestones, which is anticipated to occur in 2005, we will be obligated to issue Altair 100,000 shares of our restricted common stock.
- *SPI-1620:* In February 2005, we entered into a license agreement with Chicago Labs, Inc., whereby we acquired an exclusive worldwide license to develop and commercialize SPI-1620, an endothelinB

agonist, which we believe may selectively dilate tumor blood vessels and thereby selectively increase the delivery of anti-cancer drugs to cancer tissue, for the prevention and treatment of cancer. We paid Chicago Labs an upfront fee of $100,000, and are obligated to make future payments contingent upon the successful achievement of certain development and regulatory milestones. In addition, we will pay royalties and sales milestones on net sales, if any, after marketing approval is obtained from regulatory authorities. As of the date of this report we are unable to reliably estimate the development costs for SPI-1620 because we only recently acquired the rights to the compound and we are still in the early stages of planning for future development.

- In addition to the foregoing drug product candidates, we continually evaluate proprietary products for acquisition. If we are successful in licensing additional products, our research and development expenditures would increase.

- While we are contingently obligated to make cash milestone payments, aggregating approximately $25 million as of December 31, 2004, under our licensing agreements given the unpredictability of the results to be derived from those trials, we believe that it is unlikely that any material cash milestone payment obligation will be triggered in the next 12 months. Further, if we reach a milestone, it will likely occur prior to revenues being generated from the related compound. However, in connection with the milestone obligations related to one of our drug product candidates, satraplatin, each of our contingent future cash payment obligations is generally matched by a corresponding, greater cash payment milestone obligation of GPC Biotech to us.

- *Generic drugs:* Through December 31, 2004, we have spent approximately $1.7 million on the development of generic drugs, including costs for products that we anticipate filing ANDAs for in the future. Over the next twelve months we expect to incur development costs ranging between $2 million and $3 million. We do not receive any funding from third parties for research and development we conduct for generic products, nor do we pay our generic alliance partners for any research and development they incur in the development of ANDAs for regulatory approval.

  Marketing of ciprofloxacin tablets, our first generic drug, commenced in the fourth quarter of 2004. Fifteen other companies have received FDA approval to market generic versions of ciprofloxacin tablets, and we have observed a significant reduction in the market price for ciprofloxacin tablets since June 2004, when the pediatric exclusivity for ciprofloxacin expired. We expect to receive approval by the FDA of our ANDAs for carboplatin injection and fluconazole tablets in the first half of 2005. The marketing exclusivity for Bristol Myers Squibb's branded form of carboplatin injection expired in October 2004, and the FDA has granted ANDA approval to five generic companies, including Pharmachemie, APP, Bedford, Mayne and Pliva. TEVA Pharmaceuticals, through an agreement with Bristol Myers Squibb, is currently selling carboplatin injection produced by Bristol Myers Squibb as a generic drug. The marketing exclusivity for Pfizer's branded form of fluconazole tablets expired in July 2004, and the FDA has approved generic versions from several companies, including Taro Pharmaceutical Industries, Mylan, Sandoz, Ranbaxy, IVAX, Genpharm, Gedeon Richter, TEVA, Torpharm, Roxane and Pliva. We have observed significant price declines in the marketplace for each of the foregoing products. Accordingly, given the competition faced by these products and the fact that we are still seeking alliances with third parties to assist us in the marketing and sale of flucanazole tablets and carboplatin injection, we are unable at this time to reasonably estimate potential revenues or profits from these generic products in the foreseeable future.

Net Cash used in Operating activities

During the years ended December 31, 2004 and 2003, the net cash used in operations, for research and development and general and administrative expenses, was approximately $11.8 million and $6.6 million respectively. The increase of $5.2 million is primarily due to an increase in 2004 in research and development expenditures of approximately $3.3 million, combined with a decrease of approximately $1 million in licensing fee revenue, payment in 2004 of compensation accrued at December 31, 2003, and increases in accounts receivable and inventory.

Net Cash used in Investing Activities

As described in our accounting policy for cash, cash equivalents and marketable securities, we invest our cash in a variety of investments pending its use in our business. In order to maximize the interest yield on our investments, we invested in investments which do not meet the definition of cash equivalents, and are classified as marketable securities on the balance sheet. As of December 31, 2004 and 2003, the change in the carrying amount of marketable securities predominantly accounted for the net cash used in investing activities during the years ended December 31, 2004 and 2003, approximately $34.4 million and $1.3 million, respectively. The increase of approximately $33.1 million in 2004 was primarily due to the investment in marketable securities of excess funds, including the approximately $25 million cash provided by financing activities during 2004.

Net Cash provided by Financing Activities

Cash provided by financing activities was approximately $25 million and $31 million, for the years ended December 31, 2004 and 2003, respectively. The approximately $25 million in 2004 was comprised of approximately $22.6 million from the issuance in April 2004 of approximately 3.2 million shares of common stock and warrants to purchase approximately 1.1 million shares of common stock, plus $2.4 million from the exercise of options and warrants for approximately 717,000 shares of our common stock. Offsetting these cash inflows was a $145,000 payment of our capital lease obligations during the year.

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, from assessing: planned research and development activities and general and administrative requirements, required clinical trial activity, market need for our drug candidates and other major business assumptions.

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

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and disclosure of contingent obligations in the financial statements and accompanying notes. Our most significant assumptions are employed in estimates used in estimating stock-based charges, determining values of financial instruments and accrued obligations, as well as in estimates used in applying the revenue recognition policy. The estimation process requires assumptions to be made about future events and conditions, and as such, is inherently subjective and uncertain. Actual results could differ materially from our estimates.

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

Cash, Cash Equivalents and Marketable Securities

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

Patents and Licenses

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

Revenue Recognition

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

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

Research and Development

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

Accounting for Stock-Based Employee Compensation

At December 31, 2004, we had three stock-based employee compensation plans, which are described more fully in Note 8 to the Financial Statements included in this Annual Report on Form 10-K. As permitted by FASB Statement No. 123, *"Accounting for Stock-Based Compensation"*, we account for grants pursuant to those plans under the intrinsic value method described in Accounting Principles Board (APB) Opinion No. 25, *"Accounting for Stock Issued to Employees"*, and related Interpretations. Under the intrinsic value method, no stock-based employee compensation cost is recorded when the exercise price is equal to, or higher than, the market value of the underlying common stock on the date of grant. We recognize stock-based compensation expense for all grants to consultants, and for those grants to employees where the exercise prices are below the market price of the underlying stock at the measurement date of the grant.

New Accounting Pronouncements

In November 2004, the FASB issued Statement No. 151, *"Inventory Costs — an amendment of ARB No. 43, Chapter 4"*. Statement No. 151 requires the current expensing of abnormal production costs, and

requires that allocation of fixed production overheads to the costs of conversion of inventory be based on the normal capacity of the production facilities. The adoption of Statement No. 151 is not expected to have any impact on our financial statements.

In December 2004, the FASB issued Statement No. 123(R), *"Share-Based Payment"*. This Statement eliminates the use of the intrinsic value method described in Accounting Principles Board (APB) Opinion No. 25, *"Accounting for Stock Issued to Employees"*, and requires a public entity to measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost will be recognized over the period during which an employee is required to provide service in exchange for the award. We expect to adopt the provisions of Statement No. 123(R) when it becomes a mandatory requirement, currently expected to be July 1, 2005. The adoption of this statement is expected to result in significantly higher reported operating expenses in our future financial statements. Had we adopted the provisions of Statement No. 123(R) as of January 1, 2004, our reported loss for the year-ended December 31, 2004 would have been $2,571,000 higher, or $14,857,000.

In December 2004, the FASB issued Statement No. 153, "Exchanges of Non-monetary Assets — an amendment of APB Opinion No. 29". Statement No. 153 eliminates certain exceptions from the principle that exchanges of non-monetary assets should be measured based on the fair value of the assets exchanged. The adoption of Statement No. 153 is not expected to have any impact on our financial statements.

Results of Operations

Results of Operations for Fiscal 2004 Compared to Fiscal 2003

In 2004, we incurred a net loss of approximately $12.3 million compared to a net loss of approximately $10.4 million in 2003. The increase of $1.9 million was primarily due to an increase of $3.3 million in research and development expenses including approximately $1.2 million in cash for the acquisition of an anticancer drug candidate (SPI-153) and a decrease of $1 million in licensing revenues from 2003. These increases in net loss were offset by the non-recurrence in 2004 of a non-cash charge in 2003 of $2.5 million stock options expense, which charge arose due to timing delays in awarding stock options to employees as a result of our compliance with state securities laws during a period where our stock price rose rapidly.

We recorded $258,000 of revenues in 2004 and $1.0 million revenues in the year ended December 31, 2003. The revenue in 2004 primarily represents $185,000 of product sales revenue, recorded from the first shipment of ciprofloxacin, after receipt of FDA approval in September 2004, and represents the cash received by us. The cost of the product sold was $123,000. In view of the competitive market for sales of ciprofloxacin, we are unable to assess the future revenue potential of this product. Also, in 2004 we received $73,000 from GPC Biotech under our co-development license agreement, representing commissions on drug products used by GPC Biotech in clinical trials. In connection with the revenue from GPC, we had no performance obligations or incurred costs. The timing and amount of similar revenues in the future is neither predictable nor assured. The revenue in 2003 was derived from the second licensing fee of $1 million under the licensing agreement with GPC, which became due in September 2003 upon dosing of the first patient in a registrational study. Future revenues from GPC are dependent upon the occurrence of milestones specified in the agreement. No milestone event occurred during 2004.

Research and development expenses increased by $3,271,000, from $3,683,000 in 2003 to $6,954,000 in 2004, primarily due to a cash payment of $1.2 million for the up-front licensing fee for SPI-153; and a $1.6 million increase in drug product expense as a result of the investigation and development of additional new products, and increased clinical trials activity for EOquin and elsamitrucin. Other notable increases in expenses over the comparative reporting period in 2003, were personnel costs of $200,000, insurance costs of $200,000, and patent-related legal expenses of $150,000, which were partially offset by a reduction in rent expense of $150,000 due to the termination of a lease on a research facility. These cost increases are the result of the increasing scope of our activities, which include the investigation and development of new prescription drug candidates. We expect continued increases in research and development expenses in 2005 and beyond as we develop and expand our product portfolio.

General and administrative expenses increased by approximately $47,000, from $5,049,000 in 2003 to $5,096,000 in 2004, primarily due to:

- Legal and professional fees, excluding financing related fees charged against the proceeds of the financing, and SEC reporting and compliance costs increased by approximately $200,000 in 2004 due primarily to the changes in our organization, compliance with new NASDAQ, SEC and Sarbanes-Oxley Act of 2002 rules and regulations, and evaluation of business alliances and opportunities in conjunction with expanding our product portfolio.
- Personnel costs, excluding the 2003 severance charge of approximately $500,000, increased by approximately $400,000, due to the hiring of additional personnel in the past twelve months to enable us to implement our planned growth.
- Partially offsetting the foregoing increased costs were reductions in rent expense primarily as a result of a more favorable facility lease effective July 1, 2004.

Stock-based charges, which are non-cash charges, decreased by approximately $1,688,000, from $2,573,000 in 2003 to $885,000 in 2004. The following describe the components of the charges in 2003 and 2004.

- $634,000 of the 2004 charge arose from recording the fair value of 251,896 shares of restricted common stock issued to Zentaris GmbH in connection with the in-licensing of SPI-153.
- The remainder of the 2004 relates to amortization of the fair value of warrants granted to consultants, primarily in 2003 and 2004.
- The 2003 charge arose due to timing delays in awarding stock options to employees as a result of our compliance with state securities laws during a period where our stock price rose rapidly.

We believe the use of stock options and similar equity-based awards is crucial for an early stage company like ours, as a means to conserve cash and to retain and motivate high-performance employees and consultants. We believe that such equity awards foster an alignment of employee and consultant interests with those of our stockholders. We expect stock-based charges to become increasingly significant to us. In December 2004, the FASB issued Statement No. 123(R), *"Share-Based Payment"*. The adoption of this statement will result in significantly higher reported operating expenses in our future financial statements. Had we adopted the provisions of Statement No. 123(R) as of January 1, 2004, our stock based charges for 2004 would have been $2,571,000 higher, or $3,456,000. We intend to adopt the provisions of Statement No. 123(R) when it becomes a mandatory requirement, currently expected to be July 1, 2005.

Other income, net for 2004 compared to 2003 increased by approximately $436,000 primarily due to interest income earned on significantly higher average cash, cash equivalents and marketable securities balances and rising short term interest rates during 2004.

Results of Operations for Fiscal 2003 Compared to Fiscal 2002

Revenue for 2003 of $1 million decreased by approximately $1.4 million as compared to 2002, and was derived from the second licensing fee of $1 million under the co-development and licensing agreement with GPC Biotech AG, which became due in September 2003 upon dosing of the first patient in a registrational study. Future GPC revenues are dependant upon the occurrence of milestones specified in the agreement.

Research and development expenses decreased by approximately $8.0 million, from $11.7 million in 2002 to $3.7 million in 2003 primarily as a result of the restructuring, initiated in August 2002, whereby all research activities related to Neotrofin™, functional genomics and neurology were eliminated. In 2003, research and development expenses included our ongoing clinical trial for EOquin™ in the treatment of patients with refractory superficial bladder cancer, procurement of elsamitrucin supplies for a clinical trial in patients with non-Hodgkin's lymphoma and expenses incurred in connection with the filing of our ANDAs for ciprofloxacin, carboplatin and fluconazole.

General and administrative expenses increased by approximately $1.3 million, from $3.7 million in 2002 to $5.0 million in 2003 due primarily to the following factors:

- Legal and professional fees increased by approximately $900,000 in 2003 due to the changes in our organization, expenses incurred in successfully addressing the NASDAQ delisting notice we received in March 2003, additional expenses for compliance with California and other state securities laws due to our listing on the NASDAQ SmallCap Market, compliance with new SEC and Sarbanes-Oxley Act rules and regulations, and evaluation of business alliances and opportunities in conjunction with expanding our product portfolio;

- Employee severance costs included in general and administrative expense in 2003 of approximately $500,000;

- As a result of the 2002 change in our business plan, and a dramatic reduction in the scope of our research and development activities, the allocation of general and administrative costs to research and development was $1.4 million lower in 2003 as compared to 2002; and

- Offsetting the foregoing increases was an aggregate decrease of approximately $1.5 million in payroll and occupancy costs, depreciation and other miscellaneous corporate overhead.

Stock-based compensation expense of $2,573,000 for 2003 represents non-cash charges as a result of stock awards and stock options granted to employees and consultants. The use of options as a means to compensate and retain employees is crucial for a company like ours. The increase of approximately $1.2 million in stock-based compensation from $2.6 million in 2003 as compared to $1.4 million in 2002 was primarily due to timing delays in 2003 in awarding stock options as a result of our compliance with state securities laws during a period where our stock price was rising rapidly.

- Stock awards and options granted to employees are accounted for under APB 25. All of the options granted by us have been made at fair market values on the dates originally authorized by the Board of Directors or the Compensation Committee. However, as described in Note 9 to the consolidated financial statements, certain grants to employees contemplated by the Board had later effective grant dates. Accordingly, we recorded a non-cash stock-based employee compensation expense of $2,296,000 during 2003.

- In accordance with SFAS 123, we expense the "fair value" of options granted to consultants. During 2003, we agreed to issue to a consultant engaged to generate retail interest in our stock, a warrant to purchase 130,000 shares of our common stock. The Black-Scholes value of the warrant, $480,000, is being amortized over the service period and $276,000 was charged to expense in 2003.

During 2002, approximately $1 million of stock-based compensation was charged in connection with the issuance of common stock and warrants to purchase common stock in settlement of accounts payable to certain vendors. In addition, during 2002, we recorded compensation expense of $411,000, as a result of the amortization of deferred compensation costs which were recorded in 2001 and prior years, when we granted stock options to employees with exercise prices less than the fair value of our common stock at the measurement date. The intrinsic values of the option grants were recorded as deferred compensation and were amortized to expense over the vesting period, in accordance with APB 25.

The restructuring charge of $163,000 in 2003 is related to an adjustment of the realizable value of assets held for sale as of December 31, 2003.

Other income for 2003 compared to 2002 increased approximately $200,000 due primarily to the elimination of miscellaneous expenses associated with the activities related to functional genomics and neurology.

Off-Balance Sheet Arrangements

None.

Contractual and Commercial Obligations

The following table summarizes our contractual and other commitments, including obligations under a facility lease and equipment leases, as of December 31, 2004:

Payment Due by Period

	Total	Less than 1 Year	1-3 Years	3-5 Years	After 5 Years
			(In thousands)		
Contractual Obligations(1)					
Capital Lease Obligations(2)	$ —	$ —	$ —	$ —	$ —
Operating Lease Obligations(3)	$ 1,980	$ 368	$ 897	$ 715	$ —
Purchase Obligations(4)	$ 3,103	$3,103	$ —	$ —	$ —
Contingent Milestone Obligations(5)	$24,600	$	$4,200	$6,900	$13,500
Total	$29,683	$3,471	$5,097	$7,615	$13,500

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

(2) As of December 31, 2004, we had no capital lease obligations.

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

(4) Purchase Obligations represent the amount of open purchase orders and contractual commitments to vendors, for products and services that have not been delivered, or rendered, as of December 31, 2004.

(5) Milestone Obligations are payable contingent upon successfully reaching certain development and regulatory milestones as further described below under "Licensing Agreements". While the amounts included in the table above represent all of our potential cash milestone obligations as of December 31, 2004, given the unpredictability of the drug development process, and the impossibility of predicting the success of current and future clinical trials, the timelines estimated above do not represent a forecast of when payment milestones will actually be reached, if at all. Rather, they assume that all milestones under all of our license agreements are successfully met, and represent our best estimates of the timelines. In the event that the milestones are met, we believe it is likely that the increase in the potential value of the related drug product will significantly exceed the amount of the milestone obligation.

Licensing Agreements

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

The potential contingent cash milestone obligations, aggregating approximately $25 million as of December 31, 2004, under all our licensing agreements are generally tied to progress through the FDA approval process, which approval significantly depends on positive clinical trial results. The following list is typical of milestone events: commencement of Phase 3 clinical trials, filing of new drug applications in the United States, Europe and Japan, and the approvals from those regulatory agencies.

Given the unpredictability of the drug development process, it is not possible to predict the probability of achieving successful results from the currently on-going clinical trials. We are, therefore, unable to predict the likelihood of any of the milestones occurring in the foreseeable future and, accordingly, the milestone payments represent contingent obligations, which will be recorded as expense when the milestone occurs.

If we reach a milestone, it will likely occur prior to revenues being generated from the related compound. However, in connection with the milestone obligations related to one of our drug product candidates, satraplatin, each of our contingent future cash payment obligations is generally matched by a corresponding, greater payment milestone obligation of GPC Biotech to us. In addition, upon successful achievement of one of the development milestones for RenaZorb™ under our licensing agreement with Altair Nanotechnologies, which is anticipated to occur in 2005, we will be obligated to issue Altair 100,000 shares of our restricted common stock.

Service Agreements

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

Employment Agreements

We have entered into employment agreements with two of our Executive Officers, Dr. Shrotriya, Chief Executive Officer, and Dr. Lenaz, Chief Scientific Officer, expiring December 31, 2005 and July 1, 2005, respectively. The employment agreements automatically renew for a one-year term unless either party gives written notice at least 90 days prior to the commencement of the next year of such party's intent not to renew the agreement. The agreements require each executive to devote his full working time and effort to the business and affairs of the Company during the term of the agreement. The agreements provide for an annual base salary with annual increases, periodic bonuses and option grants as determined by the Compensation Committee of our Board of Directors.

Each officer's employment may be terminated by us with or without cause as defined in the agreement. The agreements provide for certain guaranteed severance payments and benefits if the officer's employment is terminated without cause, if the officer's employment is terminated due to a change in control or is adversely affected due to a change in control and the officer resigns or if the officer decides to terminate his employment due to a disposition of a significant amount of assets or business units. The guaranteed severance payment includes a payment equal to twice the officer's then current annual base salary. In addition, all options held by the officer shall immediately vest and will be exercisable for one year from the date of termination; provided, however, if the Board determines that the officer's employment is being terminated for the reason that the shared expectations of the officer and the Board are not being met, in the Board's judgment, then the options currently held by the officer will vest in accordance with their terms for up to one year after the date of termination, with the right to exercise those options, when they vest, for approximately thirteen (13) months after the date of termination. The agreements also provide that, upon his retirement, all options held by the officer will become fully vested.

Related Party Transactions

Outsource Arrangement

Between November 2002 and November 2003, we had outsourced the administration, accounting and human resources functions, and SEC report preparation to McManus Financial Consulting (MFC) for a monthly fee of $15,000; and all investor relations activities to McManus & Co. (M&C) for a monthly fee of

$10,000 to $12,000 per month. Between January and June 2002, MFC also provided services to us at hourly rates, subject to a minimum annual retainer of $24,000. During the years ended December 31, 2004, 2003 and 2002, MFC and M&C received total fees and payments under severance arrangements amounting to $75,000, $539,000 and $106,000, respectively. MFC and M&C are co-owned by two of our former officers, John and Michael McManus, who are also brothers. John McManus received direct compensation from the Company as Vice President Finance and Strategic Planning and Assistant Corporate Secretary; however, Michael McManus received no direct compensation from us for his services as Controller. In November 2003, John and Michael McManus resigned their positions with the Company to return to their consulting business to pursue other opportunities. All payment obligations under these arrangements terminated in July 2004.

Director and Officer Notes for the Exercise of Equity Instruments

As of January 1, 2002, certain of our directors and officers owed us $616,000 previously loaned to them for the exercise of stock options or the purchase of stock. During 2002, we were repaid $391,000, which included all loans to officers. In February 2003, we agreed to forgive and terminate the remaining $225,000 and in return, the directors agreed to return the shares of common stock originally purchased under the loans. For accounting purposes, this arrangement was considered to be an uncompleted transaction and therefore, the common stock and related notes receivable were eliminated as of December 31, 2002.

Item 7A. *Quantitative and Qualitative Disclosures About Market Risk*

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

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

Our investments as of December 31, 2004 are primarily in 28 day auction rate notes. Because of our ability to redeem these investments at par within a 28-day period, changes in interest rates would have an immaterial effect on the fair value of these investments. If a 10% change in interest rates were to have occurred on December 31, 2004, any decline in the fair value of our investments would not be material. In addition, we are exposed to certain market risks associated with credit ratings of corporations whose corporate bonds we have purchased. If these companies were to experience a significant detrimental change in their credit ratings, the fair market value of such corporate bonds may significantly decrease. If these companies were to default on these corporate bonds, we may lose part or all of our principal. We believe that we effectively manage this market risk by diversifying our investments, and selecting securities that generally have third party insurance coverage in the event of default by the issuer.

Item 8. *Financial Statements and Supplementary Data*

Our annual consolidated financial statements are included in Item 15 of this report.

Item 9. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure*

None.

Item 9A. ***Controls and Procedures.***

(i) Disclosure Controls and Procedures.

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

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Vice President Finance, of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2004, the end of the period covered by this report (Evaluation Date). Based on the foregoing, our Chief Executive Officer and Vice President Finance concluded that our disclosure controls and procedures were effective and were operating at the reasonable assurance level.

(ii) Internal Control Over Financial Reporting.

(a) Management's annual report on internal control over financial reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f).

Our internal control system was designed to provide reasonable assurance to our management and board of directors regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Due to the small size of our company and the limited number of employees, it is not possible for us to fully segregate duties associated with the financial reporting process; accordingly, we rely on mitigating controls to reduce the risks from such lack of segregation of duties. Further, all internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Because of such inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in Internal Control — Integrated Framework, our management concluded that our internal control over financial reporting was effective as of the Evaluation Date.

Our management's assessment of the effectiveness of our internal control over financial reporting as of the Evaluation Date has been audited by Kelly & Company, an independent registered public accounting firm, as stated in their report which is included herein.

(b) Attestation report of the registered public accounting firm.

The integrated attestation report of Kelly & Company, the Company's independent registered public accounting firm, is set forth on page F-3. Presented below is an extract from that attestation report as to their audit of management's assessment of the effectiveness of our internal control over financial reporting:

". . . we have audited management's assessment, included in the accompanying Management's annual report on internal control over financial reporting, that the Company maintained effective internal control over financial reporting as of December 31, 2004 based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that Spectrum Pharmaceuticals, Inc. and Subsidiaries maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Spectrum Pharmaceuticals, Inc. and Subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria."

(c) Changes in internal control over financial reporting.

There was no change in the Company's internal control over financial reporting during the Company's fourth quarter ended December 31, 2004 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. ***Other Information***

In December 2004, the Compensation Committee of the Board of Directors approved changes to the annual compensation for the Company's board of directors as set forth in Exhibit 10.42 to this Annual Report on Form 10-K and is incorporated herein by reference.

PART III

Item 10. ***Directors and Executive Officers of the Registrant***

The information concerning our directors and executive officers required under this item is incorporated by reference from our definitive proxy statement related to our 2005 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A, on or before April 29, 2005 ("2005 Proxy Statement").

Item 11. ***Executive Compensation***

The information required under this item is incorporated by reference from our 2005 Proxy Statement.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

The information required under this item is incorporated by reference from our 2005 Proxy Statement.

Item 13. ***Certain Relationships and Related Transactions***

The information required under this item is incorporated by reference from our 2005 Proxy Statement.

Item 14. ***Principal Accountant Fees and Services***

The information required under this item is incorporated by reference from our 2005 Proxy Statement.

PART IV

Item 15. ***Exhibits, Financial Statement Schedules and Reports on Form 8-K***

(a)(1) *Consolidated Financial Statements:*

(a)(2) *Financial Statement Schedules:* All financial statement schedules are omitted because they are not applicable or the required information is included in the Consolidated Financial Statements or notes thereto.

(a)(3) *Exhibits.*

Exhibit No.	Description
3.1	Certificate of Incorporation of the Registrant, as filed on May 7, 1997. (Filed as Exhibit B to the Definitive Proxy Statement dated May 8, 1997, for the Annual Meeting of Shareholders of Spectrum Pharmaceuticals Colorado, the predecessor to Registrant, held on June 17, 1997, as filed with the Securities and Exchange Commission on May 9, 1997, and incorporated herein by reference.)
3.1.1	Certificate of Amendment to the Certificate of Incorporation of the Registrant. (Filed as Exhibit 3.1.1 to Form 10-K, as filed with the Securities and Exchange Commission on April 2, 2002, and incorporated herein by reference.)
3.1.2	Certificate of Designation of 5% Series A Preferred Stock with Conversion Features. (Filed as Exhibit 4.1 to Form 8-K, as filed with the Securities and Exchange Commission on February 9, 1999, and incorporated herein by reference.)
3.1.3	Certificate of Designation of Rights, Preferences and Privileges of Series B Junior Participating Preferred Stock of the Registrant. (Filed as Exhibit 3.1 to Form 8-A12G, as filed with the Securities and Exchange Commission on December 26, 2000, and incorporated herein by reference.)
3.1.4	Certificate of Designations of the Series C Preferred Stock of the Registrant. (Filed as Exhibit 4.7 to the Registration Statement on Form S-3, as amended (No. 333-64432), as filed with the Securities and Exchange Commission on July 2, 2001, and incorporated herein by reference.)
3.1.5	Certificate of Amendment of Certificate of Incorporation filed on September 5, 2002 (Filed as Exhibit 4.1 to Form 10-Q for the quarterly period ended September 30, 2002, as filed with the Securities and Exchange Commission on November 13, 2002, and incorporated herein by reference.)
3.1.6	Certificate of Designations, Rights and Preference of the Series D 8% Cumulative Convertible Voting Preferred Stock. (Filed as Exhibit 3.1 to Form 8-K, as filed with the Securities and Exchange Commission on May 16, 2003, and incorporated herein by reference.)
3.1.7	Certificate of Increase. (Filed as Exhibit 3.2 to Form 8-K, as filed with the Securities and Exchange Commission on May 16, 2003, and incorporated herein by reference.)
3.1.8	Certificate of Designations, Rights and Preference of the Series E Convertible Voting Preferred Stock (Filed as Exhibit 3.1 to Form 8-K, as filed with the Securities and Exchange Commission on September 30, 2003, and incorporated herein by reference.)

Exhibit No.	Description
3.2	Form of Amended and Restated Bylaws of the Registrant (Filed as Exhibit 4.2 to Form 10-Q for the quarterly period ended September 30, 2002, as filed with the Securities and Exchange Commission on November 13, 2002, and incorporated herein by reference.)
3.2.1	Form of Amended and Restated Bylaws of the Registrant. (Filed as Exhibit 3.1 to Form 10-Q, as filed with the Securities and Exchange Commission on August 16, 2004, and incorporated herein by reference.)
4.1	Registration Rights Agreement dated as of April 6, 2000, by and among the Registrant, Strong River Investments, Inc. and Montrose Investments Ltd. (Filed as Exhibit 4.2 to Form 8-K, as filed with the Securities and Exchange Commission on April 21, 2000, and incorporated herein by reference.)
4.2	Class A Warrant issued by the Registrant to Montrose Investments Ltd., dated as of April 6, 2000. (Filed as Exhibit 4.4 to Form 8-K, as filed with the Securities and Exchange Commission on April 21, 2000, and incorporated herein by reference.)
4.3	Class A Warrant issued by the Registrant to Strong River Investments, Inc., dated as of April 6, 2000. (Filed as Exhibit 4.5 to Form 8-K, as filed with the Securities and Exchange Commission on April 21, 2000, and incorporated herein by reference.)
4.4	Warrant issued by the Registrant to Brighton Capital, Ltd., dated as of April 6, 2000. (Filed as Exhibit 4.16 to the Registration Statement on Form S-3 (No. 333-37180), as filed with the Securities and Exchange Commission on May 16, 2000, and incorporated herein by reference.)
4.5	Registration Rights Agreement dated as of April 28, 2000, by and among the Registrant, Royal Canadian Growth Fund and Dlouhy Investments Inc. (Filed as Exhibit 4.2 to Form 8-K, as filed with the Securities and Exchange Commission on May 25, 2000, and incorporated herein by reference.)
4.6	Warrant issued by the Registrant to Royal Canadian Growth Fund, dated as of May 1, 2000. (Filed as Exhibit 4.3 to Form 8-K, as filed with the Securities and Exchange Commission on May 25, 2000, and incorporated herein by reference.)
4.7	Warrant issued by the Registrant to Dlouhy Investments Inc., dated as of May 1, 2000. (Filed as Exhibit 4.4 to Form 8-K, as filed with the Securities and Exchange Commission on May 25, 2000, and incorporated herein by reference.)
4.8	Registration Rights Agreement dated as of September 21, 2000, by and among the Registrant, Strong River Investments, Inc. and Montrose Investments Ltd. (Filed as Exhibit 4.4 to Form 8-K, as filed with the Securities and Exchange Commission on November 13, 2000, and incorporated herein by reference.)
4.9	Warrant issued by the Registrant to Montrose Investments Ltd., dated as of September 21, 2000. (Filed as Exhibit 4.7 to Form 8-K, as filed with the Securities and Exchange Commission on November 13, 2000, and incorporated herein by reference.)
4.10	Warrant issued by the Registrant to Strong River Investments, Inc., dated as of September 21, 2000. (Filed as Exhibit 4.8 to Form 8-K, as filed with the Securities and Exchange Commission on November 13, 2000, and incorporated herein by reference.)
4.11	Registration Rights Agreement dated as of September 29, 2000, by and among the Registrant, Strong River Investments, Inc. and Montrose Investments Ltd. (Filed as Exhibit 4.12 to Form 8-K, as filed with the Securities and Exchange Commission on November 13, 2000, and incorporated herein by reference.)
4.12	Closing Warrant issued by the Registrant to Montrose Investments, Ltd., dated as of September 29, 2000. (Filed as Exhibit 4.13 to Form 8-K, as filed with the Securities and Exchange Commission on November 13, 2000, and incorporated herein by reference.)
4.13	Closing Warrant issued by the Registrant to Strong River Investments, Inc., dated as of September 29, 2000. (Filed as Exhibit 4.14 to Form 8-K, as filed with the Securities and Exchange Commission on November 13, 2000, and incorporated herein by reference.)
4.14	Form of Warrants issued by the Registrant to Brighton Capital, Ltd., dated between September 18, 2000 and May 18, 2001. (Filed as Exhibit 4.32 to Form 10-K, as filed with the Securities and Exchange Commission on April 2, 2002, and incorporated herein by reference.)

Exhibit No.	Description
4.15	Rights Agreement, dated as of December 13, 2000, between the Registrant and U.S. Stock Transfer Corporation, as Rights Agent, which includes as Exhibit A thereto the form of Certificate of Designation for the Series B Junior Participating Preferred Stock, as Exhibit B thereto the Form of Rights Certificate and as Exhibit C thereto a Summary of Terms of Stockholder Rights Plan. (Filed as Exhibit 4.1 to Form 8-A12G, as filed with the Securities and Exchange Commission on December 26, 2000, and incorporated herein by reference.)
4.16	Registration Rights Agreement dated as of December 18, 2000, by and between the Registrant and Societe Generale. (Filed as Exhibit 4.4 to Form 8-K, as filed with the Securities and Exchange Commission on December 28, 2000, and incorporated herein by reference.)
4.17	Warrant issued by the Registrant to Societe Generale, dated as of December 18, 2000. (Filed as Exhibit 4.6 to Form 8-K, as filed with the Securities and Exchange Commission on December 28, 2000, and incorporated herein by reference.)
4.18	Warrant issued by the Registrant to Brighton Capital, Ltd., dated as of December 18, 2000. (Filed as Exhibit 4.36 to Form 10-K, as filed with the Securities and Exchange Commission on April 2, 2002, and incorporated herein by reference.)
4.19	Warrant issued by the Registrant to CroMedica Global, Inc., dated as of January 25, 2001. (Filed as Exhibit 4.37 to Form 10-K, as filed with the Securities and Exchange Commission on April 2, 2002, and incorporated herein by reference.)
4.20	Warrant issued by the Registrant to IAT ReInsurance Syndicate Ltd., dated as of March 8, 2001. (Filed as Exhibit 10.2 to Form 8-K, as filed with the Securities and Exchange Commission on March 14, 2001, and incorporated herein by reference.)
4.21	Warrant issued by the Registrant to Montrose Investments Ltd., dated as of May 18, 2001. (Filed as Exhibit 4.1 to Form 8-K, as filed with the Securities and Exchange Commission on May 21, 2001, and incorporated herein by reference.)
4.22	Warrant issued by the Registrant to Strong River Investments, Inc., dated as of May 18, 2001. (Filed as Exhibit 4.2 to Form 8-K, as filed with the Securities and Exchange Commission on May 21, 2001, and incorporated herein by reference.)
4.23	Form of Warrant issued by the Registrant to Gruntal & Co., L.L.C., dated as of August 10, 2001 (Filed as Exhibit 4.44 to Form 10-K, as filed with the Securities and Exchange Commission on April 2, 2002, and incorporated herein by reference.)
4.24	Form of Warrants issued by the Registrant to Cantor Fitzgerald & Co, dated as of December 6, 2001 and December 13, 2001. (Filed as Exhibit A to Schedule 1 to Exhibit 1.1 to Form 8-K, as filed with the Securities and Exchange Commission on October 24, 2001, and incorporated herein by reference.)
4.25	Warrant issued by the Registrant to Jefferies & Company, Inc., dated as of December 13, 2001. (Filed as Exhibit 4.46 to Form 10-K, as filed with the Securities and Exchange Commission on April 2, 2002, and incorporated herein by reference.)
4.26	Form of Warrant issued by the Registrant to certain purchasers, dated as of March 13, 2002. (Filed as Exhibit 4.47 to Form 10-K, as filed with the Securities and Exchange Commission on April 2, 2002, and incorporated herein by reference.)
4.27	Form of Warrant issued by the Registrant to certain purchasers, dated as of June 5, 2002. (Filed as Exhibit 4.1 to Form 8-K, as filed with the Securities and Exchange Commission on June 7, 2002, and incorporated herein by reference.)
4.28	Form of Warrant issued by the Registrant to certain purchasers, dated as of June 7, 2002. (Filed as Exhibit 4.1 to Form 8-K, as filed with the Securities and Exchange Commission on June 19, 2002, and incorporated herein by reference.)
4.29	Warrant Repurchase Agreement by and between the Registrant and BNC Bach International, Ltd., dated as of July 31, 2002. (Filed as Exhibit 10.3 to Form 10-Q for the quarterly period ended September 30, 2002, as filed with the Securities and Exchange Commission on November 13, 2002, and incorporated herein by reference.)

Exhibit No.	Description
4.30	Form of Warrant issued by the Registrant to five purchasers, dated as of November 21, 2002, to purchase up to an aggregate of 107,870 shares of our common stock. (Filed as Exhibit 4.1 to Form 8-K, as filed with the Securities and Exchange Commission on November 26, 2002, and incorporated herein by reference.)
4.31	Form of Warrant issued by the Registrant to certain purchasers, dated as of December 13, 2002, to purchase up to an aggregate of 65,550 shares of our common stock. (Filed as Exhibit 4.1 to Form 8-K, as filed with the Securities and Exchange Commission on December 13, 2002, and incorporated herein by reference.)
4.32	Form of Warrant issued by the Registrant to three purchasers, dated as of January 16, 2003, to purchase up to an aggregate of 55,555 shares of our common stock. (Filed as Exhibit 4.1 to Form 8-K, as filed with the Securities and Exchange Commission on January 17, 2003, and incorporated herein by reference.)
4.33	Form of Series D-1 Warrant. (Filed as Exhibit 4.1 to Form 8-K, as filed with the Securities and Exchange Commission on May 16, 2003, and incorporated herein by reference.)
4.34	Form of Series D-2 Warrant. (Filed as Exhibit 4.2 to Form 8-K, as filed with the Securities and Exchange Commission on May 16, 2003, and incorporated herein by reference.)
4.35	Series D-3 Warrant. (Filed as Exhibit 4.3 to Form 8-K, as filed with the Securities and Exchange Commission on May 16, 2003, and incorporated herein by reference.)
4.36	Registration Rights Agreement dated as of May 7, 2003, by and among the Registrant and the persons listed on Schedule 1 attached thereto. (Filed as Exhibit 4.4 to Form 8-K, as filed with the Securities and Exchange Commission on May 16, 2003, and incorporated herein by reference.)
4.37	Amendment No. 1 to the Rights Agreement dated as of December 13, 2000 by and between the Registrant and U.S. Stock Transfer Corporation. (Filed as Exhibit 4.1 to Form 10-Q, as filed with the Securities and Exchange Commission on August 14, 2003, and incorporated herein by reference.)
4.38	Registration Rights Agreement dated as of August 13, 2003, by and among the Registrant and the persons listed on Schedule 1 attached thereto. (Filed as Exhibit 4.1 to Form 8-K, as filed with the Securities and Exchange Commission on August 15, 2003, and incorporated herein by reference.)
4.39	Form of Series 2003-1 Warrant (Filed as Exhibit 4.2 to Form 8-K, as filed with the Securities and Exchange Commission on August 15, 2003, and incorporated herein by reference.)
4.40	Form of Series E-1 Warrant (Filed as Exhibit 4.1 to Form 8-K, as filed with the Securities and Exchange Commission on September 30, 2003, and incorporated herein by reference.)
4.41	Form of Series E-2 Warrant (Filed as Exhibit 4.2 to Form 8-K, as filed with the Securities and Exchange Commission on September 30, 2003, and incorporated herein by reference.)
4.42	Series E-3 Warrant (Filed as Exhibit 4.3 to Form 8-K, as filed with the Securities and Exchange Commission on September 30, 2003, and incorporated herein by reference.)
4.43	Registration Rights Agreement dated as of September 26, 2003, by and among the Registrant and the persons listed on Schedule 1 attached thereto. (Filed as Exhibit 4.4 to Form 8-K, as filed with the Securities and Exchange Commission on September 30, 2003, and incorporated herein by reference.)
4.44	Investor Rights Agreement, dated as of April 20, 2004, by and among the Registrant and the persons listed on Schedule 1 attached thereto. (Filed as Exhibit 4.1 to Form 8-K, as filed with the Securities and Exchange Commission on April 23, 2004, and incorporated herein by reference.)
4.45	Form of Warrant, dated as of April 21, 2004. (Filed as Exhibit 4.2 to Form 8-K, as filed with the Securities and Exchange Commission on April 23, 2004, and incorporated herein by reference.)
4.46	Amendment No. 2 to the Rights Agreement dated as of December 13, 2000 by and between the Registrant and U.S. Stock Transfer Corporation. (Filed as Exhibit 4.1 to Form 10-Q, as filed with the Securities and Exchange Commission on May 17, 2004, and incorporated herein by reference.)

Exhibit No.	Description
4.47	Amendment No. 3 to the Rights Agreement dated as of December 13, 2000 by and between the Registrant and U.S. Stock Transfer Corporation. (Filed as Exhibit 4.2 to Form 10-Q, as filed with the Securities and Exchange Commission on May 17, 2004, and incorporated herein by reference.)
4.48	Warrant issued by the Registrant to a consultant, dated as of September 17, 2003. (Filed as Exhibit 4.3 to Form 10-Q, as filed with the Securities and Exchange Commission on May 17, 2004, and incorporated herein by reference.)
4.49	Warrant issued by the Registrant to a consultant, dated as of April 21, 2004. (Filed as Exhibit 4.4 to Form 10-Q, as filed with the Securities and Exchange Commission on May 17, 2004, and incorporated herein by reference.)
4.50	Form of Warrant, dated as of September 30, 2004. (Filed as Exhibit 4.1 to Form 10-Q, as filed with the Securities and Exchange Commission on November 15, 2004, and incorporated herein by reference.)
4.51*	Form of Stock Option Agreement under the 2003 Amended and Restated Incentive Award Plan. (Filed as Exhibit 10.1 to Form 8-K, as filed with the Securities and Exchange Commission on December 17, 2004, and incorporated herein by reference.)
10.1*	1991 Stock Incentive Plan. (Filed as Exhibit 10.2 to the Registration Statement on Form SB-2, as amended (No. 333-05342-LA), and incorporated herein by reference.)
10.2	Industrial Lease Agreement dated as of January 16, 1997, between the Registrant and the Irvine Company. (Filed as Exhibit 10.11 to the Form 10-KSB for the fiscal year ended December 31, 1996, as filed with the Securities and Exchange Commission on March 31, 1997, and incorporated herein by reference.)
10.3*	Employee Stock Purchase Plan. (Filed as Exhibit 4.1 to the Registrant's Registration Statement on Form S-8 (No. 333-54246), and incorporated herein by reference.)
10.4*	Amendment 2001-1 to the Employee Stock Purchase Plan effective as of June 21, 2001. (Filed as Exhibit 10.22 to the Annual Report on Form 10-K, as amended, as filed with the Securities and Exchange Commission on April 25, 2001, and incorporated herein by reference.)
10.5*	Executive Employment Agreement for Rajesh C. Shrotriya, M.D., dated as of December 1, 2000. (Filed as Exhibit 10.35 to Form 10-K, as filed with the Securities and Exchange Commission on April 2, 2002, and incorporated herein by reference.)
10.6	License Agreement dated as of June 29, 2001, by and between the Registrant and NDDO Research Foundation. (Filed as Exhibit 10.4 to Form 10-Q, as filed with the Securities and Exchange Commission on November 14, 2001, and incorporated herein by reference.)
10.7	License Agreement dated as of August 28, 2001, by and between the Registrant and Johnson Matthey PLC. (Filed as Exhibit 10.5 to Form 10-Q, as filed with the Securities and Exchange Commission on November 14, 2001, and incorporated herein by reference.)
10.8	License Agreement dated as of October 24, 2001, by and between the Registrant and Bristol-Myers Squibb Company. (Filed as Exhibit 10.6 to Form 10-Q, as filed with the Securities and Exchange Commission on November 14, 2001, and incorporated herein by reference.)
10.9	Settlement Agreement and Release by and between the Registrant and Merck Eprova AG dated as of September 30, 2002. (Filed as Exhibit 10.7 to Form 10-Q for the quarterly period ended September 30, 2002, as filed with the Securities and Exchange Commission on November 13, 2002, and incorporated herein by reference.)
10.10	First Amendment to License Agreement dated August 28, 2001 by and between the Registrant and Johnson Matthey PLC dated as of September 30, 2002. (Filed as Exhibit 10.8 to Form 10-Q for the quarterly period ended September 30, 2002, as filed with the Securities and Exchange Commission on November 13, 2002, and incorporated herein by reference.)
10.11	Co-Development and License Agreement by and between the Registrant and GPC Biotech AG dated as of September 30, 2002. (Filed as Exhibit 10.9 to Form 10-Q for the quarterly period ended September 30, 2002, as filed with the Securities and Exchange Commission on November 13, 2002, and incorporated herein by reference.)

Exhibit No.	Description
10.12	Letter of Agreement by and between the Registrant and LEKAR Pharma Limited, dated as of March 26, 2003, for an investment of $1 million in the Registrant's common stock. (Filed as Exhibit 10.48 to Form 10-K, as filed with the Securities and Exchange Commission on March 28, 2003, and incorporated herein by reference.)
10.13	Limited Liability Agreement of NeoJB LLC, a Delaware limited liability company effective as of April 17, 2002. (Filed as Exhibit 10.1 to Form 10-Q, as filed with the Securities and Exchange Commission on May 14, 2003, and incorporated herein by reference.)
10.14	Supply Agreement dated April 16, 2002 by and between J.B. Chemicals & Pharmaceuticals Ltd. and NeoJB LLC. (Filed as Exhibit 10.2 to Form 10-Q, as filed with the Securities and Exchange Commission on May 14, 2003, and incorporated herein by reference.)
10.15	Management Agreement dated April 16, 2002 by and between NeoTherapeutics, Inc. and NeoJB LLC. (Filed as Exhibit 10.3 to Form 10-Q, as filed with the Securities and Exchange Commission on May 14, 2003, and incorporated herein by reference.)
10.16	Preferred Stock and Warrant Purchase Agreement dated as of April 29, 2003, by and among the Registrant and the purchasers listed on Schedule 1 attached thereto. (Filed as Exhibit 10.1 to Form 8-K, as filed with the Securities and Exchange Commission on May 16, 2003, and incorporated herein by reference.)
10.17	Amendment No. 1 of the Preferred Stock and Warrant Purchase Agreement and Registration Rights Agreement dated as of May 13, 2003 by and among the Registrant and the persons listed on Schedule 1B attached thereto. (Filed as Exhibit 10.2 to Form 8-K, as filed with the Securities and Exchange Commission on May 16, 2003, and incorporated herein by reference.)
10.18*	Form of Lock-up Agreement. (Filed as Exhibit 10.3 to Form 8-K, as filed with the Securities and Exchange Commission on May 16, 2003 and incorporated herein by reference.)
10.19*	Spectrum Pharmaceuticals, Inc. Amended and Restated 1997 Stock Incentive Plan. (Filed as Annex A to our Definitive Proxy Statement, as filed with the Securities and Exchange Commission on May 16, 2003, and incorporated herein by reference.)
10.20	Common Stock and Warrant Purchase Agreement dated as of August 13, 2003, by and among the Registrant and the purchasers listed on Schedule 1 attached thereto. (Filed as Exhibit 10.1 to Form 8-K, as filed with the Securities and Exchange Commission on August 15, 2003, and incorporated herein by reference.)
10.21	Preferred Stock and Warrant Purchase Agreement dated as of September 26, 2003, by and among the Registrant and the purchasers listed on Schedule 1 attached thereto. (Filed as Exhibit 10.1 to Form 8-K, as filed with the Securities and Exchange Commission on September 30, 2003, and incorporated herein by reference.)
10.22*	Form of Lock-up Agreement (Filed as Exhibit 10.2 to Form 8-K, as filed with the Securities and Exchange Commission on September 30, 2003, and incorporated herein by reference.)
10.23	Exclusive Supply, Marketing and Distribution Agreement between Lannett Company, Inc. and the Registrant dated August 15, 2003. (Filed as Exhibit 10.5 to Form 10-Q, as filed with the Securities and Exchange Commission on November 13, 2003, and incorporated herein by reference.)
10.24	Separation Agreement and General Release dated November 13, 2003 by and between Spectrum and John L. McManus. (Filed as Exhibit 10.6 to Form 10-Q, as filed with the Securities and Exchange Commission on November 13, 2003, and incorporated herein by reference.)
10.25	Separation Agreement and General Release dated November 7, 2003 by and between Spectrum and Michael P. McManus. (Filed as Exhibit 10.7 to Form 10-Q, as filed with the Securities and Exchange Commission on November 13, 2003, and incorporated herein by reference.)
10.26*	2003 Stock Incentive Plan. (Filed as Exhibit 10.8 to Form 10-Q, as filed with the Securities and Exchange Commission on November 13, 2003, and incorporated herein by reference.)

Exhibit No.	Description
10.27#	Exclusive Supply, Marketing and Distribution Agreement between FDC, Ltd. and the Registrant dated November 20, 2003. (Filed as Exhibit 10.44 to Form 10-K, as filed with the Securities and Exchange Commission on March 29, 2004, and incorporated herein by reference).
10.28*	Executive Employment Agreement for Luigi Lenaz, M.D., dated as of October 22, 2001. (Filed as Exhibit 10.45 to Form 10-K, as filed with the Securities and Exchange Commission on March 29, 2004, and incorporated herein by reference).
10.29	First Amendment dated March 25, 2004 to Industrial Lease Agreement dated as of January 16, 1997 by and between the Registrant and the Irvine Company. (Filed as Exhibit 10.1 to Form 10-Q, as filed with the Securities and Exchange Commission on May 17, 2004, and incorporated herein by reference.)
10.30*	2003 Amended and Restated Incentive Award Plan. (Filed as Exhibit 10.2 to Form 10-Q, as filed with the Securities and Exchange Commission on May 17, 2004, and incorporated herein by reference.)
10.31*	Form of Indemnity Agreement of the Registrant. (Filed as Exhibit 10.1 to Form 10-Q, as filed with the Securities and Exchange Commission on August 16, 2004, and incorporated herein by reference.)
10.32	Settlement Agreement and General Release By and Among NeoGene Technologies, Inc., the Registrant and The Regents of the University of California Dated as of March 26, 2004. (Filed as Exhibit 10.2 to Form 10-Q, as filed with the Securities and Exchange Commission on August 16, 2004, and incorporated herein by reference.)
10.33	Common Stock and Warrant Purchase Agreement, dated as of April 20, 2004, by and among Spectrum and the purchasers listed on Schedule 1 attached thereto. (Filed as Exhibit 10.1 to Form 8-K, as filed with the Securities and Exchange Commission on April 23, 2004, and incorporated by reference.)
10.34#	Co-Development and License Agreement by and between the Registrant and GPC Biotech AG, dated as of September 30, 2002. (Filed as Exhibit 10.1 to Form 10-Q, as filed with the Securities and Exchange Commission on November 15, 2004, and incorporated by reference.)
10.35#	Diagnostic and Drug Product Manufacturing, Supply and Marketing Agreement dated as of May 10, 2004 by and between the Registrant and Shantha Biotechnics Pvt. Ltd. (Filed as Exhibit 10.2 to Form 10-Q, as filed with the Securities and Exchange Commission on November 15, 2004, and incorporated by reference.)
10.36#	License and Collaboration Agreement by and between the Registrant and Zentaris GmbH, dated as of August 12, 2004. (Filed as Exhibit 10.3 to Form 10-Q, as filed with the Securities and Exchange Commission on November 15, 2004, and incorporated by reference.)
10.37	Settlement Agreement and Release by and between the Registrant and SCO Financial Group, LLC, dated as of September 30, 2004. (Filed as Exhibit 10.4 to Form 10-Q, as filed with the Securities and Exchange Commission on November 15, 2004, and incorporated by reference.)
10.38	Sublease Agreement dated September 28, 2004 by and between the Registrant and Concurrent Pharmaceuticals, Inc., and The Irvine Company. (Filed as Exhibit 10.1 to Form 8-K, as filed with the Securities and Exchange Commission on November 8, 2004, and incorporated herein by reference.)
10.39*	Form of Stock Option Agreement under the 2003 Amended and Restated Incentive Award Plan. (As filed as Exhibit 10.1 to Form 8-K, as filed with the Securities and Exchange Commission on December 17, 2004, and incorporated herein by reference.)
10.40#	License Agreement by and between the Registrant and Altair Nanomaterials, Inc. and Altair Nanotechnologies, Inc. (Filed as Exhibit 10.1 to Form 8-K, as filed with the Securities and Exchange Commission on February 3, 2005, and incorporated herein by reference.)
10.41#	License Agreement by and between the Registrant and Chicago Labs, Inc. (Filed as Exhibit 10.1 to Form 8-K, as filed with the Securities and Exchange Commission on February 25, 2005, and incorporated herein by reference.)
10.42+*	Summary of Director Compensation.

Exhibit No.	Description
21+	Subsidiaries of Registrant.
23.1+	Consent of Kelly & Company.
31.1+	Certification of Chief Executive Officer, pursuant to Rule 13a-14 promulgated under the Exchange Act, as created by Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification of Vice President Finance, pursuant to Rule 13a-14 promulgated under the Exchange Act, as created by Section 302 of the Sarbanes-Oxley Act of 2002.
31.1+	Certification of Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002.
32.2+	Certification of Vice President Finance, pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002

* Indicates a management contract or compensatory plan or arrangement.

+ Filed herewith

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

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

SPECTRUM PHARMACEUTICALS, INC.

By: /s/ RAJESH C. SHROTRIYA, M.D.
Rajesh C. Shrotriya, M.D.
Chief Executive Officer and President

Date: March 15, 2005

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ RAJESH C. SHROTRIYA, M.D. Rajesh C. Shrotriya, M.D.	Chairman of the Board, Chief Executive Officer President and Director (Principal Executive Officer)	March 15, 2005
/s/ SHYAM K. KUMARIA Shyam K. Kumaria	Vice President Finance (Principal Financial and Accounting Officer)	March 15, 2005
/s/ ANN C. KESSLER, PH.D. Ann C. Kessler, Ph.D.	Director	March 15, 2005
/s/ ARMIN M. KESSLER Armin M. Kessler	Director	March 15, 2005
/s/ STUART M. KRASSNER, SC.D., PSY.D. Stuart M. Krassner, Sc.D., Psy.D.	Director	March 15, 2005
/s/ ANTHONY E. MAIDA, III Anthony E. Maida, III	Director	March 15, 2005
/s/ DILIP J. MEHTA, M.D., PH.D. Dilip J. Mehta, M.D., Ph.D.	Director	March 15, 2005
/s/ JULIUS A. VIDA, PH.D. Julius A. Vida, Ph.D.	Director	March 15, 2005

SPECTRUM PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

As of December 31, 2004 and 2003 and
For Each of the Three Years in the Period Ended December 31, 2004

SPECTRUM PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS
As of December 31, 2004 and 2003 and
For Each of the Three Years in the Period Ended December 31, 2004

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
Spectrum Pharmaceuticals, Inc.

We have completed an integrated audit of Spectrum Pharmaceuticals, Inc and Subsidiaries' (the "Company") consolidated financial statements and of Management's annual report on internal control over financial reporting as of December 31, 2004 and audits of its 2003 and 2002 consolidated financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

Consolidated Financial Statements

We have audited the consolidated balance sheets of the Company as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity and comprehensive loss and cash flows for each of the three years in the period ended December 31, 2004. 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 audits.

We conducted our audits of these financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit of financial statements includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinions.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Spectrum Pharmaceuticals, Inc. and Subsidiaries as of December 31, 2004 and 2003, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2004 in conformity with accounting principles generally accepted in the United States.

Internal Control Over Financial Reporting

Also, we have audited management's assessment, included in the accompanying Management's annual report on internal control over financial reporting, that the Company maintained effective internal control over financial reporting as of December 31, 2004 based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company;

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that Spectrum Pharmaceuticals, Inc. and Subsidiaries maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Spectrum Pharmaceuticals, Inc. and Subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria.

/s/ Kelly & Company

Kelly & Company

Costa Mesa, California
February 25, 2005

Spectrum Pharmaceuticals, Inc. and Subsidiaries

Consolidated Balance Sheets

	December 31, 2004	December 31, 2003
	(In thousands, except share and per share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,241	$ 24,581
Marketable securities	35,965	1,770
Accounts receivable	199	–
Inventory	224	–
Prepaid expenses and other current assets	372	413
Total current assets	40,001	26,764
Property and equipment, net	687	560
Other assets	70	65
Total assets	$ 40,758	$ 27,389
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,609	$ 1,538
Accrued compensation	662	1,038
Accrued clinical study costs	300	–
Other accrued expenses	95	387
Capital lease obligations	–	145
Total current liabilities	2,666	3,108
Deferred rent and deposit	178	–
Total liabilities	2,844	3,108
Commitments and contingencies (Note 7)		
Minority interest	24	–
Stockholders' equity:		
Preferred stock, par value $0.001 per share, 5,000,000 shares authorized:		
Series B Junior Participating Preferred Stock, 200,000 shares authorized, no shares issued and outstanding	–	–
Series D 8% Cumulative Convertible Voting Preferred Stock, 600 shares authorized, stated value $10,000 per share, aggregate liquidation value $1,884, issued and outstanding 157 and 265 shares at December 31, 2004 and 2003, respectively	747	1,261
Series E Convertible Voting Preferred Stock, 2,000 shares authorized, stated value $10,000 per share, aggregate liquidation value $3,492, issued and outstanding, 291 and 1,315 shares at December 31, 2004 and 2003, respectively	1,795	8,110
Common stock, par value $0.001 per share, 50,000,000 shares authorized; 14,825,558 and 8,097,927 shares issued and outstanding at December 31, 2004 and 2003, respectively	15	8
Additional paid-in capital	201,218	168,590
Deferred stock-based compensation	(97)	(192)
Accumulated other comprehensive income, unrealized gain on available for sale securities	–	6
Accumulated deficit	(165,788)	(153,502)
Total stockholders' equity	37,890	24,281
Total liabilities and stockholders' equity	$ 40,758	$ 27,389

The accompanying notes are an integral part of the financial statements.

Spectrum Pharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Operations

	Years Ended December 31,		
	2004	2003	2002
	(In thousands, except share and per share data)		
Revenues:			
Licensing fees	$ 73	$ 1,000	$ 2,371
Product sales	185	–	–
Total revenues	258	1,000	2,371
Operating expenses:			
Cost of product sold	123	–	–
Research and development	6,954	3,683	11,706
General and administrative including related party consulting costs	5,096	5,049	3,691
Stock-based charges	885	2,573	1,431
Restructuring expenses	–	163	3,050
Total operating expenses	13,058	11,468	19,878
Loss from operations	(12,800)	(10,468)	(17,507)
Other income (expense):			
Interest income	519	83	161
Interest expense	(3)	(17)	(123)
Other income (expense)	2	12	(165)
Total other income (expense)	518	78	(127)
Net loss before minority interest in consolidated subsidiary	(12,282)	(10,390)	(17,634)
Minority interest in net income of consolidated subsidiary	(4)	–	–
Net loss	$ (12,286)	$ (10,390)	$ (17,634)
Basic and diluted loss per share	$ (0.98)	$ (4.83)	$ (12.34)
Basic and diluted weighted average common shares outstanding	12,674,506	4,169,374	1,429,380
Supplemental Information:			
Stock-based charges – components:			
Research and development	$ 634	$ 1,000	$ 1,020
General and administrative	251	1,573	411
Total stock-based charges	$ 885	$ 2,573	$ 1,431

The accompanying notes are an integral part of the financial statements.

Spectrum Pharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Stockholders' Equity and Comprehensive Income (Loss)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Deferred Compensation	Notes Receivable from Directors	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount						
					(In thousands, except share data)					
Balance at December 31, 2001	–	$ –	951,086	$ 1	$134,683	$(1,890)	$(616)	$ 87	$(125,478)	$ 6,787
Net loss	–	–	–	–	–	–	–	–	(17,634)	(17,634)
Unrealized loss on available-for-sale securities, net	–	–	–	–	–	–	–	(81)	–	(81)
Total comprehensive loss								(81)	(17,634)	(17,715)
Issuance of common stock for cash, net of issuance costs	–	–	1,407,607	1	9,920	–	–	–	–	9,921
Repurchase of common stock and warrants	–	–	(16,000)	–	(143)	–	–	–	–	(143)
Issuance of common stock to vendors for services in settlement of accounts payable based on the fair value of the stock	–	–	383,326	1	775	–	–	–	–	776
Issuance of warrants to a vendor based on the fair value of the services	–	–	–	–	244	–	–	–	–	244
Expiration of stock options granted	–	–	–	–	(1,423)	1,423	–	–	–	–
Amortization of deferred compensation and services	–	–	–	–	–	411	–	–	–	411
Repayment of notes receivable from directors and officers	–	–	–	–	–	–	391	–	–	391
Termination of notes receivable from directors and officers	–	–	–	–	(225)	–	225	–	–	–
Balance at December 31, 2002	–	$ –	2,726,019	$ 3	$143,831	$ (56)	$ –	$ 6	$(143,112)	$ 672
Net loss								–	(10,390)	(10,390)
Total comprehensive loss								–	(10,390)	(10,390)
Issuance of Series D Preferred Stock and common stock warrants, net	600	2,856	–	–	2,300	–	–	–	–	5,156
Issuance of Series E Preferred Stock and common stock warrants, net	2,000	11,269	–	–	6,919	–	–	–	–	18,188
Conversion of Series D Preferred Stock into common stock	(335)	(1,595)	1,425,532	2	1,593	–	–	–	–	–
Conversion of Series E Preferred Stock into common stock	(685)	(4,224)	1,370,000	1	4,223	–	–	–	–	–
Issuance of common stock and warrants for cash, net of issuance costs	–	–	1,211,578	1	4,536	–	–	–	–	4,537
Issuance of common stock upon exercise of warrants	–	–	1,169,070	1	3,303	–	–	–	–	3,304
Issuance of common stock to employees as compensation	–	–	105,700	–	547	–	–	–	–	547
Issuance of common stock upon exercise of employee stock options	–	–	61,550	–	173	–	–	–	–	173
Intrinsic value of stock options granted to employees	–	–	–	–	1,749	–	–	–	–	1,749
Fair value of warrants and options issued to consultants	–	–	–	–	516	(240)	–	–	–	276
Amortization of deferred compensation and services	–	–	–	–	–	104	–	–	–	104
Recognition of beneficial conversion feature on preferred stock	–	(8,447)	–	–	8,447	–	–	–	–	–
Preferred dividends:										
Deemed dividend related to beneficial conversion features on preferred stock	–	8,447	–	–	(8,447)	–	–	–	–	–
Deemed dividend related to issuance costs	–	1,065	–	–	(1,065)	–	–	–	–	–
Series D Preferred Stock dividend paid with common stock	–	–	28,478	–	–	–	–	–	–	–
Series D Preferred Stock dividends paid in cash	–	–	–	–	(35)	–	–	–	–	(35)
Balance at December 31, 2003	1,580	$ 9,371	8,097,927	$ 8	$168,590	$ (192)	$ –	$ 6	$(153,502)	$ 24,281
Net loss	–	–	–	–	–	–	–	–	(12,286)	(12,286)
Realized loss on available-for-sale securities	–	–	–	–	–	–	–	(6)	–	(6)
Total comprehensive loss, net								(6)	(12,286)	(12,292)
Conversion of Series D Preferred Stock into common stock	(108)	(514)	459,574	1	513	–	–	–	–	–
Conversion of Series E Preferred Stock into common stock	(1,024)	(6,315)	2,048,000	2	6,313	–	–	–	–	–
Issuance of common stock for cash, net of issuance costs	–	–	3,220,005	3	22,576	–	–	–	–	22,579
Fair value of common stock issued in connection with drug license	–	–	251,896	–	634	–	–	–	–	634
Issuance of common stock upon exercise of warrants	–	–	516,994	1	2,020	–	–	–	–	2,021
Issuance of common stock upon exercise of employee stock options	–	–	199,150	–	415	–	–	–	–	415
Fair value of warrants issued to consultants	–	–	–	–	157	(157)	–	–	–	–
Amortization of deferred compensation and services	–	–	–	–	–	252	–	–	–	252
Series D Preferred Stock dividends paid with common stock	–	–	32,012	–	–	–	–	–	–	–
Balance at December 31, 2004	448	$ 2,542	14,825,558	$15	$201,218	$ (97)	$ –	$ –	$(165,788)	$ 37,890

The accompanying notes are an integral part of the financial statements.

Spectrum Pharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

	Years Ended December 31,		
	2004	2003	2002
	(In thousands, except share and per share data)		
Cash flows from operating activities:			
Net loss	$(12,286)	$(10,390)	$(17,634)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash items included in net loss:			
Depreciation and amortization	173	242	917
Amortization of deferred stock-based compensation	252	104	411
Fair value of common stock issued in connection with drug license	634	–	–
Minority interest in net income of consolidated subsidiary	4	–	–
Fair value of common shares and warrants issued to employees and consultants	–	823	1,020
Intrinsic value of stock options granted to employees	–	1,749	–
Impairment on property and equipment	–	130	2,288
Forgiveness of notes to officers and directors	–	–	391
Impairment on investment in marketable security	–	–	51
Changes in operating assets and liabilities:			
Increase in accounts receivable	(199)	–	–
Increase in inventory	(224)	–	–
(Increase) decrease in other current assets	(59)	76	486
(Increase) decrease in other assets	(5)	–	39
Increase (decrease) in accounts payable and accrued expenses	79	(89)	(2,172)
Increase (decrease) in accrued compensation	(376)	836	(34)
Increase (decrease) in other non-current liabilities	178	(101)	(260)
Net cash used in operating activities	(11,829)	(6,620)	(14,497)
Cash flows from investing activities:			
Purchases of marketable securities	(44,515)	(1,704)	–
Proceeds from redemption of marketable securities	10,314	–	6,209
Purchases of property and equipment	(200)	–	(59)
Proceeds from sale of equipment	–	390	122
Net cash provided by (used in) investing activities	(34,401)	(1,314)	6,272

Spectrum Pharmaceuticals, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

	Years Ended December 31,		
	2004	2003	2002
	(In thousands, except share and per share data)		
Cash flows from financing activities:			
Proceeds from issuance of common stock and warrants, net of related offering costs and expenses	$ 22,579	$ 4,537	$9,921
Proceeds from sale of preferred stock, net of issuance costs	–	23,344	–
Proceeds from the exercise of warrants	2,021	3,304	–
Proceeds from exercise of stock options	415	173	–
Payments made on capital lease and loan obligations	(145)	(320)	(653)
Minority investment in subsidiary	20	–	–
Cash dividends paid on preferred stock	–	(35)	–
Repurchase of common stock and warrants	–	–	(143)
Repayment of notes payable to related parties	–	–	(136)
Net cash provided by financing activities	24,890	31,003	8,989
Net increase (decrease) in cash and cash equivalents	(21,340)	23,069	764
Cash and cash equivalents, beginning of period	24,581	1,512	748
Cash and cash equivalents, end of period	$ 3,241	$24,581	$1,512
Supplemental Cash Flow Information:			
Interest paid	$ 3	$ 17	$ 130
Income taxes paid	$ 1	$ 1	$ 1
Schedule of Noncash Investing and Financing Activities:			
Fair value of common stock issued in connection with drug license	$ 634	–	–
Fair value of warrants issued to placement agents	$ 542	$ 1,764	–
Preferred stock dividends paid with issuance of common stock	$ 162	$ 206	–
Fair value of warrants issued to consultants for services	$ 157	$ 240	–
Reclass of equipment previously held-for-sale to fixed assets	$ 100	–	–
Deemed dividends on beneficial conversion features on preferred stock	–	$ 8,447	–
Conversion of preferred stock and convertible debentures into shares of common stock	–	$ 5,819	–
Deemed dividends related to preferred stock related to issuance costs	–	$ 1,065	–
Retirement of stock options granted to employees below fair market value	–	–	$1,423
Unrealized loss on marketable securities	–	–	$ 81

The accompanying notes are an integral part of the financial statements.

1. Nature of Business

Overview

Spectrum Pharmaceuticals, Inc. (the "Company") is a specialty pharmaceutical company engaged in the business of acquiring, developing and commercializing prescription drug products for various indications. While we own patent rights to certain product candidates, the drug products we are currently developing, which are focused on the treatment of cancer and other unmet medical needs, are in-licensed from third parties whereby we acquired exclusive development and commercialization rights from the patent holders of those compounds. We are also actively engaged in seeking FDA approval for marketing generic versions of branded drugs whose patent protection is scheduled to expire in the near-term, or has already expired. In September 2004, the FDA granted us approval to market ciprofloxacin, the generic version of the anti-bacterial drug, Cipro®, and we recorded a sale of this product in the fourth quarter of 2004.

2. Summary of Significant Accounting Policies and Estimates

Principles of Consolidation and Basis of Presentation

The consolidated financial statements include the accounts of the Company and of our wholly owned and majority owned subsidiaries. As of December 31, 2004, we had three subsidiaries: NeoJB LLC (NeoJB), 80% owned, organized in Delaware in April 2002; Spectrum Pharmaceuticals GmbH, wholly owned, incorporated in Switzerland in April 1997; and NeoGene Technologies, Inc. (NeoGene), an inactive subsidiary, 88.4% owned, incorporated in California in October 1999. We have eliminated all significant intercompany accounts and transactions.

Since the adoption of our current strategy in August 2002, we have operated in one business segment, that of acquiring, developing and commercializing prescription drug products. The business has not matured to the point that disaggregated segment information would be meaningful. Accordingly the accompanying financial statements are reported in the aggregate including all our activities in one segment.

In September 2002, stockholders approved a reverse split of our outstanding common stock on the basis of 1 share for each 25 shares of the then outstanding common stock. All share and per share information presented in these financial statements has been restated to reflect the 25-for-1 reverse split.

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

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and disclosure of contingent obligations in the financial statements and accompanying notes. Our most significant assumptions are employed in estimates used in determining values of financial instruments and accrued obligations, as well as in estimates used in applying the revenue recognition policy and estimating stock-based charges. The estimation process requires assumptions to be made about future events and conditions, and as such, is inherently subjective and uncertain. Actual results could differ materially from our estimates.

Fair Value of Financial Instruments

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

Cash, Cash Equivalents and Marketable Securities

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

Concentrations of Credit Risk, Supplier and Customer

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

As of December 31, 2004, we had a bank account with a balance that exceeded the amount insured by the Federal Deposit Insurance Corporation by $533,000. We believe this concentration risk is mitigated by the financial strength of the bank that maintains the account.

During 2004, after FDA approval, we commenced sales of our first marketed product, ciprofloxacin. Pursuant to our strategic alliance agreements, described in Note 3, this product can only be sourced from J.B. Chemicals & Pharmaceuticals Ltd., and can only be distributed by Lannett Company. Our marketing rights to ciprofloxacin are limited to sales in the United States of America.

Inventory

Inventory is stated at the lower of cost (first-in, first-out method) or market. As of December 31, 2004, inventory consisted of raw materials acquired for the purpose of manufacturing finished drug product for our drug product candidate carboplatin.

Property and Equipment

We carry property and equipment at historical cost. Equipment is depreciated on a straight-line basis over its estimated useful life (generally 5 to 7 years). Leasehold improvements are amortized over the shorter of the estimated useful life or lease term. Maintenance and repairs are expensed as incurred. Major renewals and betterments that extend the life of the property are capitalized.

We review long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. If impairment is indicated, we reduce the carrying value of the asset to fair value. During the year ended December 31, 2002, we recorded a fixed asset impairment charge of $1,669,000, included in the restructuring charge of $3,050,000 recorded in connection with the termination of all research efforts related to neurology and functional genomics research and development.

Patents and Licenses

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

Revenue Recognition

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

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

Research and Development

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

Minority Interest in Consolidated Subsidiary

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

Basic and Diluted Net Loss Per Share

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

We incurred net losses in each of the periods presented, and as such, did not include the effect of potentially dilutive common stock equivalents in the diluted net loss per share calculation, as their effect would be anti-dilutive for all periods. Potentially dilutive common stock equivalents would include the common stock issuable upon conversion of preferred stock and the exercise of warrants and stock options that have conversion or exercise prices below the market value of our common stock at the measurement date. As of December 31, 2004, 2003 and 2002, such potentially dilutive common stock equivalents amounted to approximately 10 million, 11 million and 1 million shares, respectively.

The following data show the amounts used in computing basic loss per share for each of the three years in the period ended December 31, 2004.

	Years Ended December 31,		
	2004	2003	2002
	(In thousands, except share and per share data)		
Net loss	$ (12,286)	$ (10,390)	$ (17,634)
Less:			
Preferred dividends paid in cash or stock	(162)	(241)	–
Loss attributable to stockholders before deemed dividend	(12,448)	(10,631)	(17,634)
Deemed dividend related to beneficial conversion feature on preferred stock	–	(8,447)	–
Deemed dividends related to issuance costs	–	(1,065)	–
Loss available to common stockholders after consideration of the deemed dividend used in computing basic loss per share	$ (12,448)	$ (20,143)	$ (17,634)
Weighted average shares	12,674,506	4,169,374	1,429,380
Basic and diluted net loss per share	$ (0.98)	$ (4.83)	$ (12.34)

Accounting for Stock-Based Employee Compensation

At December 31, 2004, we had three stock-based employee compensation plans, which are described more fully in Note 9. As permitted by FASB Statement No. 123, *Accounting for Stock-Based Compensation*, we account for grants pursuant to those plans under the intrinsic value method described in Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations. Under the intrinsic value method, no stock-based employee compensation cost is recorded when the exercise price is equal to, or higher than, the market value of the underlying common stock on the date of grant. We recognize stock-based compensation expense for all grants to consultants and for those grants to employees where the exercise prices are below the market price of the underlying stock at the measurement date of the grant.

The following table illustrates the effect on net loss and loss per share if we had applied the fair value recognition provisions of FASB Statement No. 123, *Accounting for Stock-Based Compensation*, to stock-based employee compensation, using the straight-line method, for each of the three years ended December 31, 2004.

	Years Ended December 31,		
	2004	2003	2002
	(In thousands, except share and per share data)		
Net loss, as reported	$(12,286)	$(10,390)	$(17,634)
Add: stock-based employee compensation included in the reported net loss	–	2,296	–
Less: total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effect	(2,571)	(5,077)	(6,094)
Pro forma net loss	$(14,857)	$(13,171)	$(23,728)
Loss per share:			
Basic and diluted – as reported	$ (0.98)	$ (4.83)	$ (12.34)
Basic and diluted – pro forma	$ (1.18)	$ (5.50)	$ (16.60)

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. However, we have recorded a valuation allowance to fully offset the net deferred tax assets as of December 31, 2004 and 2003, because realization of such assets is uncertain.

Comprehensive Loss

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

New Accounting Pronouncements

In November 2004, the FASB issued Statement No. 151, *Inventory Costs-an Amendment of ARB No. 43, Chapter 4*. Statement No. 151 requires the current expensing of abnormal production costs, and requires that allocation of fixed production overheads to the costs of conversion of inventory be based on the normal capacity of the production facilities. The adoption of Statement No. 151 is not expected to have any impact on our financial statements.

In December 2004, the FASB issued Statement No. 123(R), *Share-Based Payment*. This Statement eliminates the use of the intrinsic value method described in Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and requires an entity to measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost will be recognized over the period during which an employee is required to provide service in exchange for the award. We expect to adopt the provisions of Statement No. 123(R) when it becomes a mandatory requirement, currently expected to be July 1, 2005. The adoption of this statement is expected to result in significantly higher reported operating expenses in our future financial statements. Had we adopted the provisions of Statement No. 123(R) as of January 1, 2004, our reported loss for the year-ended December 31, 2004 would have been approximately $2,571,000 higher, or $14,857,000, as disclosed above in Note 2, *Accounting for Stock-Based Employee Compensation.*

In December 2004, the FASB issued Statement No. 153, *Exchanges of Nonmonetary Assets – an Amendment of APB Opinion No. 29.* Statement No. 153 eliminates certain exceptions from the principle that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. The adoption of Statement No. 153 is not expected to have any impact on our financial statements.

3. Products and Strategic Alliances

As of December 31, 2004, we had four proprietary drug product candidates under development: satraplatin, EOquin™, elsamitrucin, and SPI-153; and through that date had filed seven Abbreviated New Drug Applications (ANDAs) with the FDA, including that for ciprofloxacin, which was approved in September 2004. We are developing our proprietary drug product candidates for the treatment of a variety of cancers. We are also active in filing ANDAs with the FDA seeking approval for marketing generic versions of branded prescription drugs whose patent protection is scheduled to expire in the near-term, or has already expired. In addition, we have a few neurology compounds that we may out-license these compounds to third parties for further development.

In general, we direct and pay for all aspects of the drug development process, and consequently incur the risks and rewards of drug development, which is an inherently uncertain process. To mitigate such risks we enter into alliances where we believe that our partners can provide strategic advantage in the development, manufacturing or distribution of our drugs. In such situations, the alliance partners may share in the risks and rewards of the drug development and commercialization. As of December 31, 2004, we had entered into the following strategic alliances:

Product Development and Manufacturing

- *GPC Biotech AG (GPC):* In 2002, in exchange for an upfront license fee, and future milestones and royalties, we entered into a Co-Development and License Agreement with GPC for further development and commercialization of satraplatin. Under the terms of this agreement, GPC agreed to fully fund the development expenses for satraplatin. A development committee with members from both GPC and Spectrum establishes the development plans for satraplatin. GPC, however, represents a majority of the committee and the final procedures are effectively decided and implemented by GPC. We have the ability to perform additional studies, if so desired, at our expense. Licensing fees, including upfront fees and milestone payments, received in 2004, 2003, and 2002 amounted to $73,000, $1,000,000 and $2,000,000, respectively. In addition, during 2003, pursuant to the license agreement, GPC made an equity investment of $1,000,000 in 128,370 shares of our common stock at fair value. We are entitled to additional revenues upon achievement of specified milestones, which are generally based on developmental or regulatory events; and royalties, if any, on worldwide sales of the product.

- *J.B. Chemicals & Pharmaceuticals Ltd. (JBCPL):* In 2002, we formed a subsidiary, NeoJB, with JBCPL, an India based pharmaceutical manufacturer, which has a minority interest in NeoJB. This subsidiary expects to utilize the existing manufacturing capabilities of JBCPL to produce selected oral prescription drug products for marketing in the United States. Through December 31, 2004, we filed three ANDAs on behalf of NeoJB. In September 2004, the FDA approved for marketing ciprofloxacin manufactured by JBCPL. NeoJB purchases product from JBCPL based on market prices prevailing at the time of purchase, and at this time does not have long-term volume or price commitments.

- *FDC Limited (FDC):* In 2003, we entered into an agreement with FDC, an India based pharmaceutical manufacturer, with a view to marketing in the United States certain ophthalmic drugs manufactured by FDC. Through December 31, 2004, we have filed two ANDAs pursuant to this alliance. We do not have long-term volume or price commitments.

- *Shantha Biotechnics Pvt. Ltd. (Shantha):* In 2004, we entered into an alliance with Shantha, a leading Indian biopharmaceutical company engaged in the development, manufacture and commercialization of human healthcare products produced by recombinant technology for the detection and treatment of cancer and infectious diseases. We are responsible for all regulatory, marketing and distribution matters in the United States for certain products currently marketed by Shantha elsewhere in the world and certain other products under development by Shantha. As of December 31, 2004, the product candidates under consideration for development of ANDAs include certain oncology biologics and cancer diagnostics, as well as certain vaccines. However, there are no current U.S. regulatory guidelines that allow for generic equivalents to branded biologics to be filed with the FDA using an abbreviated application and review process. The FDA is working with the pharmaceutical industry at-large to better understand the position of the biotech and biopharmaceutical companies regarding the issue of equivalence of biogenerics to the branded products and the equivalence of the processes used to manufacture the active biological ingredient. Until such time that the FDA adopts clear guidelines covering biogenerics and/or Congress creates new laws and regulations that would allow for an abbreviated application, review and approval process for such biogenerics, we will not be in a position to move forward in the United States on a number of product candidates covered under this agreement.
- *Zentaris GmbH (Zentaris):* In 2004, we entered into a license agreement with Zentaris, whereby we acquired an exclusive license to develop and commercialize SPI-153 in North America (including Canada and Mexico) and India. In addition, we have a financial interest in any income Zentaris derives from SPI-153 in Japan. With certain exceptions, we are required to purchase all finished drug product from Zentaris for the clinical development of SPI-153 at a set price. The parties will discuss entering into a joint supply agreement for commercial supplies of finished drug product.
- *Others:* In connection with two ANDAs for sumatriptan and for carboplatin filed with the FDA through December 31, 2004, we are negotiating commercial supply and service arrangements with active pharmaceutical ingredient sources and developmental laboratories with the capacity to manufacture drug products on a commercial scale, after FDA approval is received.

Sales, Marketing and Distribution

- *The Lannett Company (Lannett):* In 2003, we entered into a sales and distribution agreement with Lannett, a Philadelphia based pharmaceutical company engaged in the marketing and distribution of prescription drugs. Under the agreement Lannett is our exclusive distributor for ciprofloxacin tablets in the United States, and we are obligated to distribute ciprofloxacin tablets only through Lannett. During the 4th quarter of 2004, after receipt of FDA approval, we sold ciprofloxacin tablets to Lannett. We sell product to Lannett based on market prices prevailing at the time of sale, and do not have any long-term volume or price commitments.
- We anticipate entering into additional sales, marketing and distribution alliances during 2005.

The following is a brief outline of the products under development as of December 31, 2004:

Satraplatin: Satraplatin is an orally-administered chemotherapeutic agent that has an initial indication of efficacy in treating hormone refractory prostate cancer. As of December 31, 2004, a Phase 3 clinical trial was proceeding in accordance with plans. In 2001, we in-licensed satraplatin from Johnson Matthey PLC. We paid an up-front fee, and are obligated to pay additional amounts based upon achievement of milestones and royalties based on any future sales. In 2002, we out-licensed satraplatin to GPC, as discussed above. Each of our contingent future cash payment milestone obligations to Johnson Matthey is generally matched by a corresponding, greater milestone receivable from GPC Biotech. We did not have to make any cash payments to Johnson Matthey for the upfront fees, milestone payments and equity investments we have received so far from GPC.

EOquin™: EOquin (EO-9), a synthetic prodrug (an inactive drug compound) which is activated by certain enzymes present in higher amounts in cancer cells than in normal tissues, is currently being developed for its initial indication, refractory superficial bladder cancer. As of December 31, 2004, a Phase 2 clinical trial was proceeding in accordance with plans. In addition, EO-9 is being evaluated as a radiation sensitizer. In 2001, we in-licensed exclusive worldwide rights to EOquin from the New Drug Development Office in the Netherlands. We paid an up-front fee, and are contingently obligated to pay additional amounts based upon achievement of specified milestones and royalties based on any future net sales.

Elsamitrucin: Elsamitrucin, an anti-tumor antibiotic that acts as a dual inhibitor of two key enzymes involved in DNA replication, topoisomerase I and II, is currently being developed for its initial indication, refractory non-Hodgkin's lymphoma. As of December 31, 2004, a Phase 2 clinical trial was proceeding in accordance with plans. In 2001, we in-licensed exclusive worldwide rights to elsamitrucin from Bristol-Myers Squibb. We paid an up-front fee, and are contingently obligated to pay additional amounts based upon achievement of milestones and a royalty based on any future net sales.

SPI-153: SPI-153, a fourth generation LHRH (Luteinizing Hormone Releasing Hormone, also known as GnRH or Gonadotropin Releasing Hormone) antagonist is under evaluation for its initial indications, hormone-dependent prostate cancer, and benign prostatic hypertrophy. As of December 31, 2004, we were evaluating results from clinical research, done by Zentaris, with a view to continuing that research into Phase 2. We paid an up-front fee, and are contingently obligated to pay additional amounts based upon achievement of milestones and a royalty based on any future net sales.

4. Marketable Securities

A summary of marketable securities and short-term investments at December 31, 2004 and 2003 is as follows:

	2004	2003
	(Amounts in thousands)	
Type of investment:		
"Held-to-maturity" – bank certificates of deposits	$ 1,015	–
"Available-for-sale" – corporate and municipal bonds	34,950	$1,770
Total marketable securities	$35,965	$1,770

"Held-to-maturity" marketable securities are carried at cost, which approximates fair value because of their short-term maturities and insignificant interest rate risk. "Available-for-sale" marketable securities are carried at fair value, with any unrealized gains and losses included as a component of accumulated other comprehensive income (loss) in stockholders' equity.

Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities, as well as interest income and dividends on investments, are included in other income and expense. Unrealized and realized gains or losses were not significant as of December 31, 2004 and 2003, or for the three years in the period ended December 31, 2004.

As of December 31, 2004 and 2003, the maturities of our "available for sale securities", primarily 28-day auction rate notes, was in excess of 10 years. These securities are classified as current assets based on our intent and ability to use any and all of these securities as necessary to satisfy our cash needs as they arise, by redeeming them at par within a 28-day period.

5. Property and Equipment

As of December 31, 2004 and 2003, property and equipment consisted of:

	December 31,	
	2004	2003
	(Amounts in thousands)	
Equipment	$ 1,411	$ 1,177
Leasehold improvements	575	509
Total property and equipment	1,986	1,686
Less: accumulated depreciation and amortization	(1,299)	(1,126)
Property and equipment, net	$ 687	$ 560

During the year ended December 31, 2002, in connection with the termination of all research efforts related to neurology and functional genomics research and development, we classified certain equipment as held for sale. During 2002 and 2003 we sold the majority of the equipment. During 2004 we redeployed the unsold "held for-sale" equipment to productive use. Accordingly, during 2004, we reclassified to property and equipment the $100,000 that, as of December 31, 2003, was classified as held for sale.

For the years ended December 31, 2004, 2003, and 2002, the Company recorded depreciation expense of $173,000, $242,000, and $917,000, respectively.

6. Income Taxes

Significant components of the income tax expense are as follows:

	For the Years Ended December 31,		
	2004	2003	2002
	(Amounts in thousands)		
Current:			
Federal	–	–	–
State	$4	$4	$3
Foreign	–	–	–
	4	4	3
Deferred:			
Federal	–	–	–
State	–	–	–
Foreign	–	–	–
	$4	$4	$3

The following is a reconciliation from the statutory federal income tax rate to our effective tax rate for income taxes:

	2004	2003	2002
	(Amounts in thousands)		
Computed at statutory tax rate	$(5,208)	$(4,091)	$(6,172)
Non-utilization of net operating losses	5,208	4,091	6,172
Tax expense at the effective tax rate	$ –	$ –	$ –

Significant components of our deferred tax assets and liabilities as of December 31, 2004 and 2003 are shown below. A valuation allowance has been recognized to fully offset the net deferred tax assets as of December 31, 2004 and 2003 as realization of such assets is uncertain.

	2004	2003
	(Amounts in thousands)	
Deferred tax assets:		
Net operating loss and business credit carryforwards	$ 51,214	$ 47,201
Depreciation and amortization differences	255	275
Total deferred tax assets	51,469	47,476
Deferred tax liabilities:		
Depreciation and amortization differences	–	–
Net deferred tax assets	51,469	47,476
Valuation allowance for deferred tax assets	(51,469)	(47,476)
Total deferred tax assets	$ –	$ –

At December 31, 2004 we had federal and California income tax loss carryforwards of approximately $101 million and $57 million, respectively. The federal and California tax loss carryforwards will begin to expire in 2009 and 2005, respectively. At December 31, 2004 we had research and development credit carryforwards of approximately $5 million. The research and development credit carryforwards will begin to expire in 2007. The Tax Reform Act of 1986 limits the use of net operating loss and research and development credit carryforwards in the case of an "ownership change" of a corporation. We believe an "ownership change" may have occurred due to our issuances of equity securities over the past several years. Any ownership changes, as defined by the tax code, may severely restrict utilization of our carryforwards to the point that they may never be utilized. As of December 31, 2004, we had foreign loss carryforwards of approximately $41 million.

7. Commitments and Contingencies

Facility and Equipment Leases

As of December 31, 2004 we were obligated under a facility lease and operating equipment leases. During 2004 we renewed our facility lease for five years through June 2009, at which time we will have the option to renew for one additional five-year term. During 2004, we subleased a portion of our leased facility for a three year term through September 2007, with a renewal option through the remaining term of our underlying lease.

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

Year Ending December 31:	Lease Commitments	Sub-Lease Commitments
	Amounts in thousands	
2005	$ 368	$216
2006	440	225
2007	457	171
2008	478	–
2009	237	–
	$1,980	$612

Rent expense for the years ended December 31, 2004, 2003, and 2002 amounted to approximately $435,000, $1,058,000 and $1,382,000, respectively, and was net of sub-lease rent income of $100,000, $64,000 and $0, respectively.

Licensing Agreements

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

The potential contingent milestone obligations, aggregating approximately $25 million as of December 31, 2004, under all our licensing agreements are generally tied to progress through the FDA approval process, which approval significantly depends on positive clinical trial results. The following list is typical of milestone events: commencement of Phase 3 clinical trials, filing of new drug applications in the United States, Europe and Japan, and the approvals from those regulatory agencies.

Given the unpredictability of the drug development process, it is not possible to predict the probability of achieving successful results from the currently on-going clinical trials. We are, therefore, unable to predict the likelihood of any of the milestones occurring in the foreseeable future and, accordingly, the milestone payments represent contingent obligations, which will be recorded as expense when the milestone occurs.

If we reach a milestone, it will likely occur prior to revenues being generated from the related compound. However, in connection with the milestone obligations related to one of our drug product candidates, satraplatin, each of our contingent future payment obligations is generally matched by a corresponding, greater payment milestone obligation of GPC Biotech to us. In addition, upon successful achievement of one of the development milestones for RenaZorb™ under our licensing agreement with Altair Nanotechnologies, which is anticipated to occur in 2005, we will be obligated to issue Altair 100,000 shares of our restricted common stock.

Service Agreements

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

Employment Agreements

We have entered into employment agreements with two of our Executive Officers, Dr. Shrotriya, Chief Executive Officer, and Dr. Lenaz, Chief Scientific Officer, expiring December 31, 2005 and July 1, 2005, respectively. The employment agreements automatically renew for a one-year term unless either party gives

written notice at least 90 days prior to the commencement of the next year of such party's intent not to renew the agreement. The agreements require each executive to devote his full working time and effort to the business and affairs of the Company during the term of the agreement. The agreements provide for an annual base salary with annual increases, periodic bonuses and option grants as determined by the Compensation Committee of our Board of Directors.

Each officer's employment may be terminated by us with or without cause as defined in the agreement. The agreements provide for certain guaranteed severance payments and benefits if the officer's employment is terminated without cause, if the officer's employment is terminated due to a change in control or is adversely affected due to a change in control and the officer resigns or if the officer decides to terminate his employment due to a disposition of a significant amount of assets or business units. The guaranteed severance payment includes a payment equal to twice the officer's then current annual base salary. In addition, all options held by the officer shall immediately vest and will be exercisable for one year from the date of termination; provided, however, if the Board determines that the officer's employment is being terminated for the reason that the shared expectations of the officer and the Board are not being met, in the Board's judgment, then the options currently held by the officer will vest in accordance with their terms for up to one year after the date of termination, with the right to exercise those options, when they vest, for approximately thirteen (13) months after the date of termination. The agreements also provide that, upon his retirement, all options held by the officer will become fully vested.

8. Stockholders' Equity

Preferred Stock

The following table describes the preferred stock transactions by series issuance for each of the three years in the period ended December 31, 2004:

	Series D Convertible Preferred Stock		Series E Convertible Preferred Stock		
	Shares	Amount	Shares	Amount	Total
	(Amounts in thousands, except share data)				
Balance, December 31, 2001	–	–	–	–	–
No activity	–	–	–	–	–
Balance, December 31, 2002	–	–	–	–	–
Issuance of preferred stock and common stock warrants, for cash	600	$2,856	2,000	$11,269	$14,125
Conversion of preferred stock into common stock	(335)	(1,595)	(685)	(4,224)	(5,819)
Recognition of beneficial conversion features on preferred stock	–	(2,247)	–	(6,200)	(8,447)
Deemed dividend related to beneficial conversion features	–	2,247	–	6,200	8,447
Deemed dividend related to issuance costs	–	–	–	1,065	1,065
Balance, December 31, 2003	265	1,261	1,315	8,110	9,371
Conversion of preferred stock into common stock	(108)	(514)	(1,024)	(6,315)	(6,829)
Balance, December 31, 2004	157	$ 747	291	$ 1,795	$ 2,542

In December 2000, we adopted a Stockholder Rights Plan and declared a dividend of one right to purchase shares of our Series B Junior Participating Preferred Stock ("Series B Preferred Stock") for each outstanding share of common stock, which became 25 rights per share of common stock following our 25 for one reverse stock split completed in September 2002. In addition, each share of common stock issued by us following the adoption of the Stockholders Rights Plan is accompanied by 25 rights (as adjusted for the reverse stock split). A right may be exercised under certain circumstances to purchase one one-hundredth of a share of Series B Preferred Stock at an exercise price of $75.00 per right, subject to certain anti-dilution adjustments. The rights become exercisable if and when a person (or group of affiliated or associated persons) acquires 20% or more of our outstanding common stock, or announces an offer that would result in such person acquiring 20% or more of our outstanding common stock. Five days after the rights become exercisable, each right, other than rights held by the person or group of affiliated persons whose acquisition of more than 20% of our outstanding common stock caused the rights to become exercisable, will entitle its holder to buy, in lieu of shares of Series B Preferred Stock, a number of shares of our common stock having a market value of twice the exercise price of the rights. After the rights become exercisable, if we are a party to certain merger or business combination transactions or transfers 50% or more of our assets or earnings power (as defined), each right will entitle its holder to buy a number of shares of common stock of the acquiring or surviving entity having a market value of twice the exercise price of the right. The rights expire on December 13, 2010 and may be redeemed by us at one tenth of one cent per right at any time up to ten days after a person has announced that they have acquired 20% or more of our outstanding common stock. Amendments to this plan have been made to exclude shares issued pursuant to the Series D and Series E Preferred Stock offerings in the determination of an Acquiring Group.

In May 2003, we received gross cash proceeds of $6,000,000 in exchange for the issuance of 600 shares of our Series D 8% Cumulative Convertible Voting Preferred Stock (Series D Preferred Stock), convertible into 2,553,191 shares of common stock, and Series D Warrants, exercisable for five years, to purchase up to a total of 1,276,595 shares of our common stock at an exercise price of $3.00 per share and up to a total of 1,276,595 shares of our common stock at an exercise price of $3.50 per share. Dividends on the Series D Preferred Stock are payable quarterly at an annual rate of 8 percent either in cash or shares of our common stock at our discretion. In addition to cash fees we issued, to placement agents, five-year warrants to purchase up to a total of 255,319 shares of our common stock at an exercise price of $3.00 per share. Offering costs of this transaction were $1,240,000, including cash and equity commissions paid to placement agents. The fair value of the placement agent warrants, $396,000, was computed using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%; expected volatility of 92.2%; risk free interest rate of 2.9%; and an expected life of five years.

In September 2003, we received gross cash proceeds of $20,000,000 in exchange for the issuance of 2,000 shares of our Series E Convertible Voting Preferred Stock (Series E Preferred Stock), convertible into 4,000,000 shares of common stock, and Series E Warrants, exercisable for five years, to purchase up to a total of 2,800,000 shares of our common stock at an exercise price of $6.50 per share. No dividends are payable on the Series E Preferred Stock. In addition to cash fees we issued, to placement agents, five-year warrants to purchase up to a total of 400,000 shares of our common stock at an exercise price of $6.50 per share. Offering costs of this transaction were $3,180,000, including cash and equity commissions paid to placement agents. The fair value of the placement agent warrants was estimated to be $1,368,000 using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%; expected volatility of 95.64%; risk free interest rate of 3.2%; and an expected life of five years. Certain provisions of the Certificate of Designation, Rights and Preferences of the Series E Preferred Stock provided, at the option of the holder, a right to redeem up to one half of the Series E Preferred Stock on or before January 27, 2004. No stockholder exercised the redemption right prior to its expiration. Pursuant to certain provisions of the Certificate of Designation, Rights and Preferences of the Series E Preferred Stock, we have the option to redeem all of the unconverted Series E

Preferred Stock outstanding at the end of a 20-day trading period if, among other things, in that period the common stock of the Company trades above $12.00 per share.

During the year ended December 31, 2003, a deemed dividend of $8,447,000 was recorded. Such amount, which is a non-cash transaction impacting equity, represents the beneficial conversion feature of convertible preferred stock issued with warrants during the 2003 fiscal year and was computed in accordance with requirements of Emerging Issues Task Force Issue No. 00-27, *Application of Issue No. 98-5 to Certain Convertible Instruments.*

During the year ended December 31, 2003, the Company recorded a charge to additional paid-in capital related to the issuance expenses for preferred stock with redemption features of $1,065,000. This amount has been treated as a preferred dividend for the earnings per share calculation.

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation, before any distribution of assets of the Corporation shall be made to the common stockholders, the holders of the Series D and Series E Preferred Stock shall be entitled to receive a liquidation preference in an amount equal to 120% of the stated value per share plus any declared and unpaid dividends thereon.

Common Stock Issuances for Cash

During the three years ended December 31, 2004, we issued common stock and warrants for cash as follows:

	2004	2003	2002
	(Amounts in thousands except share data)		
Shares of common stock	3,220,005	1,211,578	1,407,607
Weighted average price per share	$ 7.75	$ 3.94	$ 7.46
Amount of financing	24,955	4,771	10,502
Less: Cash offering costs	2,376	234	581
Proceeds from common stock and warrants issued for cash	$ 22,579	$ 4,537	$ 9,921
Range of issuance prices on common stock sold	$ 7.75	$1.99 to $7.79	$2.00 to $50.00
Warrants issued	1,252,005	463,379	237,641
Average exercise price per share on warrants	$ 10.03	$ 4.57	$ 12.55

In order to comply with certain Nasdaq rules, during the year ended December 31, 2002 we repurchased 16,000 shares of common stock and 16,000 warrants for $143,000.

In April 2004, we sold 3,220,005 shares of our common stock at a purchase price of $7.75 per share and five-year warrants to purchase up to a total of 1,127,005 shares of our common stock at an exercise price of $10.00 per share, for gross proceeds of approximately $24,955,000, before offering costs of approximately $2,918,000, which includes cash commissions to placement agents, the fair value of placement agent warrants to purchase up to a total of 125,000 shares of our common stock at an exercise price of $10.00 per share, and the printing and legal costs of the offering. The fair value of the placement agent warrants, $542,000 charged to the costs of the offering was estimated using the Black-Scholes option pricing model with the following assumptions: dividend yield of 0%; expected volatility of 97.8%; risk free interest rate of 3.6%; and an expected life of five years.

Other Equity Transactions

In August 2004, in connection with the license agreement with Zentaris GmbH, we issued 251,896 shares of common stock, restricted from resale until December 31, 2005, as partial payment for the upfront license fee. The fair value of the common stock, $634,000, was charged as a research and development component of stock-based charges. The fair value was based on the quoted price of our common stock on the date of the transaction, less a discount for the restrictions on the marketability of the stock, which discount (48%) was estimated using the Black-Scholes option-pricing model with the following assumptions: dividend yield of 0%; expected volatility of 97.8%; risk free interest rate of 1.4%; and a 17-month period of restriction.

During the year ended December 31, 2002, we issued 383,326 shares of common stock and warrants to purchase up to 161,460 shares of our common stock at an exercise price of $0.25 per share, in settlement of $1,020,000 payable to vendors. The warrant was exercised in 2003.

Common Stock Reserved for Future Issuance

As of December 31, 2004, 10,299,123 shares of common stock were issuable upon conversion or exercise of rights granted under prior financing arrangements and stock options and warrants, as follows:

Conversion of Series D preferred shares	665,691
Conversion of Series E preferred shares	582,000
Exercise of outstanding stock options	2,370,026
Exercise of outstanding warrants	6,561,789
Investment by an entity affiliated with JBCPL (see below)	119,617
Total shares of common stock reserved for future issuances	10,299,123

In 2002, 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. Also, during the year ended December 31, 2003, an entity affiliated with JBCPL agreed to invest $1,000,000 in Spectrum. The first $250,000 was invested in 2003, in exchange for 125,565 shares of our common stock, following acceptance by the FDA of our ANDA filing for ciprofloxacin. Investment of the remaining $750,000, which was scheduled for investment in September 2004, upon receipt of the FDA approval of the ciprofloxacin ANDA, had been delayed due to the investor's compliance with Indian Exchange Control provisions. In February 2005, we received the $750,000 and issued 119,617 shares of common stock, based on the closing price of our common stock on the day prior to the FDA approval.

Warrants Activity

Warrants are typically issued by us to investors as part of a financing transaction, or in connection with services rendered by placement agents and outside consultants and expire at varying dates through April 2009. A summary of our warrant activity follows:

Warrants Activity, Primarily in Connection with Financing Transactions

Warrants are typically issued by the Company to investors as part of a financing transaction, or in connection with services rendered by placement agents and outside consultants and expire at varying dates through April 2009. A summary of warrant activity follows:

	2004		2003		2002	
	Common Stock Warrants	Weighted Average Exercise Price	Common Stock Warrants	Weighted Average Exercise Price	Common Stock Warrants	Weighted Average Exercise Price
Outstanding at beginning of year	5,918,926	$10.10	490,060	$65.83	103,890	$322.75
Granted	1,252,005	10.03	6,601,888	4.94	408,601	8.92
Exercised	(516,994)	4.35	(1,169,070)	2.83	–	–
Forfeited	(69,140)	3.00	–	–	–	–
Expired	(23,008)	308.03	(3,952)	450.12	(22,431)	19.57
Outstanding, at end of year	6,561,789	$ 9.71	5,918,926	$10.10	490,060	$ 65.83
Exercisable at the end of year	5,309,784	$ 9.64	5,845,780	$10.24	490,060	$ 65.83

The following table summarizes information about warrants outstanding at December 31, 2004:

Range of Exercise Price	Warrants Outstanding 12/31/04	Weighted Average Remaining Life	Weighted Average Exercise Price	Warrants Exercisable 12/31/04	Weighted Average Exercise Price
$ 3.00 to $ 5.00	2,154,614	3.43	$ 3.62	2,154,614	$ 3.62
$ 5.01 to $ 10.00	4,254,165	3.96	$ 7.53	3,027,160	$ 6.53
$10.01 to $525.00	153,010	0.92	$156.29	128,010	$184.56
	6,561,789			5,309,784	

9. Stock-Based Compensation

Stock Incentive Plans

We have three stock incentive plans: the 1991 Stock Incentive Plan (1991 Plan), the 1997 Stock Incentive Plan (1997 Plan) and the 2003 Amended and Restated Incentive Award Plan (2003 Plan), (collectively, the Plans). As of December 31, 2004 we are not granting any more options pursuant the 1991 and 1997 Plans.

The 2003 Plan, authorizes the grant, in conjunction with all of our other plans, of incentive awards, including stock options, for the purchase of up to a total of 30% of our issued and outstanding stock at the time of grant. As of December 31, 2004, approximately 2 million incentive awards were available for grant under the 2003 Plan.

Except as described below, all of the options granted under the Plans have been made at fair market values on the dates originally authorized by the Board of Directors, or the Compensation committee.

A summary of activity, for all Plans, for each of the three years in the period ended December 31, 2004, is as follows:

	2004		2003		2002	
	Common Stock Options	Weighted Average Exercise Price	Common Stock Options	Weighted Average Exercise Price	Common Stock Options	Weighted Average Exercise Price
Outstanding at beginning of year	1,401,694	$ 10.83	601,799	$37.27	116,679	$168.50
Granted	1,179,000	$ 6.15	1,093,200	$ 3.48(1)	500,390	$ 9.48
Exercised	(199,150)	$ 2.08	(167,250)	$ 2.57(1)	–	–
Forfeited	(1,630)	$ 13.12	(20,884)	$81.06	(9,147)	$116.51
Expired	(9,888)	$312.71	(105,171)	$96.58	(6,123)	$148.75
Outstanding, at end of year	2,370,026	$ 7.97	1,401,694	$10.83	601,799	$ 37.27
Exercisable at end of year	1,282,923	$ 9.07	808,509	$14.60	192,733	$101.80

(1) Calculations exclude an award of 105,700 shares of common stock to employees in 2003.

The following table summarizes information about stock options outstanding under all plans at December 31, 2004:

Range of Exercise Price	Options Outstanding 12/31/04	Weighted Average Remaining Life	Weighted Average Exercise Price	Options Exercisable 12/31/04	Weighted Average Exercise Price
$ 1.00 - $ 2.50	621,250	8.30	$ 1.57	621,250	$ 1.57
$ 2.51 - $ 5.00	446,900	8.60	$ 4.67	426,067	$ 4.69
$ 5.01 - $ 10.00	1,240,780	9.48	$ 6.16	179,280	$ 6.37
$10.01 - $325.00	61,096	5.43	$134.03	56,326	$133.55
	2,370,026			1,282,923	

During the year ended December 31, 2003, we recorded a non-cash stock-based employee compensation expense of $2,296,000, primarily because certain grants made in 2003 had later measurement dates than originally contemplated by the Board, as described below.

On March 28, 2003 our Board of Directors determined it was in the best interest of the Company to grant options to certain of its executives, employees and consultants at $1.99 per share, the closing sale price of our common stock on March 28, 2003, in recognition of their services to the Company during our financial and strategic restructuring and as an incentive for the completion of the restructuring. Due to state securities law requirements, not all of these grants could be made on March 28, 2003. The Board was not able to obtain clearance to make the grants under state securities law until September 2003. During the period from March 2003 to September 2003, the fair market value of our stock rose substantially. The actual grants occurred as follows:

- Options to purchase an aggregate of 315,000 shares at an exercise price of $1.99 per share to certain executive officers on September 5, 2003. The difference between the exercise price of the 315,000 executive officer options granted on September 5, 2003, and the fair market value of our common stock

at that date, amounting to $1,005,000, was expensed during the year ended December 31, 2003, in accordance with APB Opinion No. 25.

- Certain employees received an aggregate of 105,700 shares of common stock in lieu of options. To accomplish this under state law, rights to purchase were issued that are similar to options. The employees did not have to pay money for the award and a charge to expense of $547,000 was recorded based on the fair market value of the common stock on the date of award.

In addition, during the year ended December 31, 2003, the Company recorded a non-cash stock-based employee compensation expense of $744,000 in connection with the grant of options to purchase 529,000 shares of the Company's common stock in September 2002, subject to stockholder approval.

We apply APB Opinion No. 25 and related interpretations in accounting for stock options granted to employees, and do not recognize compensation expense when the exercise price of the options equals or exceeds the fair market value of the underlying shares at the date of grant. Directors' stock options are treated in the same manner as employee stock options for accounting purposes. Under Statement No. 123, we are required to present certain pro forma earnings information determined as if employee stock options were accounted for under the fair value method of that statement and is disclosed in Note 1 to the Consolidated Financial Statements.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions used for grants in 2004, 2003, and 2002, respectively: risk-free interest rates of 3.59% (2004); 3.16% (2003); and 3.04% (2002), zero expected dividend yields; expected lives of 5 years; expected volatility of 93.4% (2004); 95.23% (2003); and 118.54% in (2002). The weighted average fair value of stock options, using the Black-Scholes option pricing model, that were granted in 2004, 2003, and 2002 was $4.48, $3.50, and $1.45, respectively.

Deferred Stock-based Compensation

During the years ended December 31, 2004 and 2003, we issued stock options and warrants to consultants, for services rendered, at exercise prices equal to or greater than the quoted price of our common stock on the grant dates. The fair values of these issuances, recorded as deferred compensation, was estimated at $157,000 (in 2004) and $516,000 (in 2003),using the Black-Scholes option pricing model, with the following assumptions: dividend yield of 0%; expected volatility of 96% (2004) and 95.64% (2003); risk free interest rate of 3.1% (2004) and 3.2% (2003); and an expected life of five years; and is being amortized to expense over the vesting period of the option.

During the year ended December 31, 2001, we issued stock options of NeoGene to our employees, with exercise prices less than the fair market value of NeoGene's common stock at the measurement date. The intrinsic value of these option grants amounting to $2,391,000 was recorded as deferred compensation and was being amortized to expense over the vesting period, in accordance with APB Opinion No. 25. During the year ended December 31, 2002, five of our executive officers that held NeoGene stock options voluntarily and without any consideration, agreed to cancel their NeoGene stock options. In addition, the remaining holders of the options were terminated in connection with the elimination of research activities at our functional genomics subsidiary. Therefore, as of December 31, 2002, there was no deferred compensation remaining related to the NeoGene.

As a result of the foregoing, we amortized deferred compensation for the years ended December 31, 2004, 2003 and 2002 by $252,000, $104,000, and $411,000, respectively.

10. Restructuring Expenses

The restructuring charge of $3,050,000 recorded in 2002 related to the termination of all research efforts related to neurology and functional genomics research and development, and consisted of:

- A fixed asset impairment charge of $1,669,000 resulting from the review of the carrying value of our laboratory equipment. An independent appraiser determined the fair market value of such laboratory equipment at $619,000 which amount was classified as Property and Equipment held for sale in the Company's balance sheet as of December 31, 2002. The majority of the laboratory equipment was sold during the year ended December 31, 2003. The remaining balance of $100,000 represents management's estimate of the liquidation value as of December 31, 2003. Adjustments to the carrying value of impaired assets are included in restructuring charges.
- Severance costs of $763,000 related to termination agreements with two senior executives, and 21 employees:
  - The former Chairman of our Board of Directors, Chief Executive Officer and Chief Scientific Officer resigned effective August 16, 2002. In connection with his retirement agreement, we recognized a charge of approximately $504,000 for contractually obligated severance benefits.
  - The former Senior Vice President Finance, Chief Financial Officer, Secretary, Treasurer and Director resigned effective August 21, 2002. In connection with his retirement agreement we recognized a charge of approximately $200,000 for contractually obligated severance benefits through December 31, 2002.
  - Severance charge of $59,000 related to termination agreements with twenty-one research and administrative employees.
  - A $312,000 loss on exchange of certain assets in connection with the settlement of certain payment obligations to the University of California, Irvine, in connection with the former functional genomics operations.
  - Other restructuring related administrative and legal expenses of $306,000.

The restructuring charge of $163,000 in 2003 is related to an adjustment of the realizable value of assets held for sale as of December 31, 2003.

11. Related Party Transactions

Outsource Arrangement

Between November 2002 and November 2003, we had outsourced the administration, accounting and human resources functions, and SEC report preparation to McManus Financial Consulting (MFC) for a monthly fee of $15,000; and all investor relations activities to McManus & Co. (M&C) for a monthly fee of $10,000 to $12,000 per month. Between January and June 2002, MFC also provided services to us at hourly rates, subject to a minimum annual retainer of $24,000. During the years ended December 31, 2004, 2003 and 2002, MFC and M&C received total fees and payments under severance arrangements amounting to $75,000, $539,000 and $106,000, respectively. MFC and M&C are co-owned by two of our former officers, John and Michael McManus, who are also brothers. John McManus received direct compensation from the Company as Vice President Finance and Strategic Planning and Assistant Corporate Secretary; however, Michael McManus received no direct compensation from us for his services as Controller. In November 2003, John and Michael McManus resigned their positions with the Company to return to their consulting business to pursue other opportunities. All payment obligations under these arrangements terminated in July 2004.

Director and Officer Notes for the Exercise of Equity Instruments

As of January 1, 2002, certain of our directors and officers owed us $616,000 previously loaned to them for the exercise of stock options or the purchase of stock. During 2002, we were repaid $391,000, which included all loans to officers. In February 2003, we agreed to forgive and terminate the remaining $225,000 and in return, the directors agreed to return the shares of common stock originally purchased under the loans. For accounting purposes, this arrangement was considered to be an uncompleted transaction and therefore, the common stock and related notes receivable were eliminated as of December 31, 2002.

12. Quarterly Financial Information (Unaudited)

The following is a summary of the unaudited quarterly results of operations for each of the calendar quarters ended in the two-year period ended December 31, 2004 (in thousands, except per share data):

	March 31,	June 30,	September 30,	December 31,
	(Amounts in thousands except share and per share data)			
Fiscal 2004				
Revenues	$ –	$ 73	$ –	$ 185
Total operating expenses	$ 2,217	$ 2,732	$ 4,247	$ 3,862
Net loss	$ (2,168)	$ (2,572)	$ (4,069)	$ (3,477)
Basic and diluted loss per share	$ (0.24)	$ (0.20)	$ (0.29)	$ (0.24)
Shares used in calculation	9,304,000	12,767,000	14,063,000	14,528,000
Fiscal 2003				
Revenues	$ –	$ –	$ 1,000	$ –
Total operating expenses	$ 1,698	$ 1,612	$ 3,599	$ 4,559
Net loss	$ (1,697)	$ (1,647)	$ (2,720)	$ (4,326)
Basic and diluted loss per share	$ (0.58)	$ (1.27)	$ (2.27)	$ (0.82)
Shares used in calculation	2,909,000	3,117,000	3,975,000	6,637,000

13. Subsequent Events

On January 28, 2005, we entered into a license agreement with Altair Nanotechnologies, Inc., whereby we acquired an exclusive worldwide license to develop and commercialize RenaZorb™ (two second-generation lanthanum-based phosphate binding agents), which utilize Altair's proprietary lanthanum nano-material technology and have the potential to treat hyperphosphatemia, i.e., high phosphate levels in blood, in patients with end-stage renal disease (ESRD) and/or chronic kidney disease (CKD). We paid Altair an upfront payment of 100,000 shares of restricted Spectrum common stock and made an equity investment of $200,000 for 38,314 shares of Altair common stock, and will be obligated to make future payments contingent upon the successful achievement of certain development and regulatory milestones. In addition we will pay royalties on potential net sales, if any, after marketing approval is obtained from regulatory authorities.

On February 18, 2005, we entered into a license agreement with Chicago Labs, Inc., whereby we acquired an exclusive worldwide license to develop and commercialize endothelinB agonists (which we believe may selectively dilate tumor blood vessels and thereby selectively increase the delivery of anti-cancer drugs to cancer tissue) for all cancer related applications, including treatment of solid tumors. We paid Chicago Labs, Inc. an upfront fee of $100,000, and are obligated to make future payments contingent upon the successful achievement of certain development and regulatory milestones. In addition we will pay royalties and sales milestones on potential net sales, if any, after marketing approval is obtained from regulatory authorities.

On February 18, 2005, GlaxoSmithKline filed a lawsuit against us in the United States District Court for the District of Delaware, alleging infringement of the patent on Imitrex®. This lawsuit was filed as a result of an ANDA that we filed with the FDA in October 2004 for sumatriptan succinate injection 6mg/0.5mL, seeking approval to engage in the commercial manufacture, sale, and use of the sumatriptan succinate

injection product in the United States. Sumatriptan succinate is marketed by GlaxoSmithKline under the brand name Imitrex® and is used for the acute treatment of migraine attacks with or without aura and the acute treatment of cluster headache episodes in adults. Our ANDA includes a Paragraph IV certification that the existing patent associated with GlaxoSmithKline's Imitrex® injection, is invalid, unenforceable and/or will not be infringed by our generic product candidate. While it is not possible to determine with any degree of certainty the ultimate outcome of these legal proceedings, we believe that we have substantial and meritorious basis with respect to our Paragraph IV challenge of the GlaxoSmithKline patent for sumatriptan succinate injection 6mg/0.5mL.

Standing: **Thomas Speace,** *VP, Marketing and Sales,* **Ashok Gore,** *Senior VP, Pharmaceutical Operations and Regulatory Compliance,* **Rajesh Shrotriya,** *Chairman, CEO and President*
Seated: **Shyam Kumaria,** *VP, Finance,* **William Pedranti,** *VP, General Counsel,* **Luigi Lenaz,** *Chief Scientific Officer,* **Paul Vilk,** *VP, Regulatory Affairs*

corporate information

Executive Officers

Rajesh C. Shrotriya, M.D.
Chairman, CEO and President

Luigi Lenaz, M.D.
Chief Scientific Officer

Shyam K. Kumaria
Vice President, Finance

Management Team

Ashok Y. Gore, Ph.D.
Senior Vice President, Pharmaceutical Operations & Regulatory Compliance

William N. Pedranti, Esq.
Vice President, General Counsel

Thomas M. Speace
Vice President, Marketing, Business Development & Sales

Paul J. Vilk, R.Ph., RAC
Vice President, Regulatory Affairs

Board of Directors

Rajesh C. Shrotriya, M.D.
Chairman of the Board, Chief Executive Officer & President, Spectrum Pharmaceuticals, Inc.

Stuart M. Krassner, Ph.D.
Professor of Developmental and Cell Biology at the School of Biological Sciences, University of California at Irvine

Anthony E. Maida, III, M.A., M.B.A.
Chairman, BioConsul Drug Development Corporation and DendriTherapeutics, Inc., Consultant to various Venture Capital, Pharmaceutical and Investment Funds

Dilip J. Mehta, M.D., Ph.D.
Former Senior VP, U.S. Clinical Research, Pfizer Inc.

Julius A. Vida, Ph.D.
President, Vida International Pharmaceutical Consultants; Former VP, Business Development, Licensing & Strategic Planning, Bristol-Myers Squibb Company

Ann C. Kessler, Ph.D.

Armin M. Kessler

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Chairman, Cliphamed Consultants Pvt. Ltd., Mumbai India, Agarwala & Associates, Mumbai India, Board Member, JBCPL, Mumbai India

Hagop Kantarjian, M.D.
The MD Anderson Hospital and Tumor Institute, Houston, TX

Enrico Mihich, M.D.
Grace Cancer Drug Center Roswell Park Cancer Institute Buffalo, NY

Herbert M. Pinedo, M.D., Ph.D.
University Hospital Vrije Universiteit, Department of Oncology, Amsterdam, The Netherlands

Outside Counsel

Lathan & Watkins LLP
Costa Mesa, CA

Independent Auditors

Kelly & Company
Costa Mesa, CA

Transfer Agent

U.S. Stock Transfer Corporation
Glendale, CA

SEC Form 10-K

Please see the enclosed Annual Report on Form 10-K filed with the Securities and Exchange Commission for a more detailed description of the Company's business, financial and other information. **This Form 10-K Report is also available without charge upon written request to:**

Investor Relations
Spectrum Pharmaceuticals, Inc.
157 Technology Drive
Irvine, CA 92618

Website

www.spectrumpharm.com

Market for Common Stock

NASDAQ National Market Trading Symbol: SPPI

This report contains forward-looking statements regarding future events and the future performance of Spectrum Pharmaceuticals, Inc. that involve risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements. These statements include but are not limited to statements that relate to our business, strategy and future, the strategies of our generic and proprietary businesses, a strong and sustainable business with sustainable future growth, the fact that the Company is positioned for growth, building shareholder value, moving the Company's drugs as rapidly as possible through clinical testing and regulatory approval, the timing of regulatory filings and initiation of clinical trials for our various proprietary drugs, the acquisition and development of the next generation of novel drugs with better efficacy and safety than existing ones, our three key strengths in acquiring compounds, our strategy's ability to reduce the risks of drug development, the likelihood of obtaining expedited regulatory review of our drugs through the FDA's fast-track designation, moving quickly to take advantage of new opportunities including in the fields of generic drugs, creating a strong and sustainable presence in the generics market, revenue from our generics business and its ability to offset proprietary development expense, filing of additional ANDAs, approval of our ANDA for carboplatin in the near term, our team's ability to drive our vision, strategy and unique business model forward, keeping tight control over development costs and timelines and any statements that relate to the intent, belief, plans or expectations of the Company or its management, or that are not a statement of historical fact. Risks that could cause actual results to differ include risks described in the enclosed Annual Report on Form 10-K and other risks that are described in further detail in the Company's other reports filed with the Securities and Exchange Commission.

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SPECTRUM
Pharmaceuticals, Inc.

"Realizing the Possibilities"

157 Technology Drive, Irvine, CA 92618 Tel: 949.788.6700 Fax: 949.788.6706