



# SPECTRUM

PHARMACEUTICALS



2006 Annual Report

**SPPI**  
**NASDAQ**  
LISTED

## ONCOLOGY

Satraplatin	Hormone Refractory Prostate Cancer	NDA
ISO-Vorin™	Osteogenic Sarcoma	NDA
EOquin®	Non-Invasive Bladder Cancer	Phase 3
Ozarelix	Hormone Dependent Prostate Cancer	Phase 2
Elsamitrucin	Solid Tumors	Phase 1/2
Lucanthone	Brain Tumors	Phase 1/2
SPI-1620	Chemotherapy Enhancer	Preclinical
SPI-205	Chemo-Induced Neuropathy	Preclinical

## UROLOGY

Satraplatin	Hormone Refractory Prostate Cancer	NDA
EOquin®	Non-Invasive Bladder Cancer	Phase 3
Ozarelix	Benign Prostatic Hypertrophy	Phase 2b

## OTHERS

Sumatriptan Injection	Migraine	Launch 2008
Ozarelix	Endometriosis	Preclinical
RenaZorb™	Hyperphosphatemia	Preclinical

## RECENT ACCOMPLISHMENTS

### Satraplatin

- Positive data from the Phase 3 clinical trial for the treatment of hormone-refractory prostate cancer in patients who have failed prior chemotherapy
- Completion of the rolling new drug application filing with the FDA
- Acceptance of the new drug application by the FDA with priority review, resulting in \$4 million of revenue to Spectrum

### EOquin®

- Completion of U.S. pilot safety study enrollment in non-invasive bladder cancer
- Reached agreement on a Special Protocol Assessment (SPA) with the FDA for Phase 3 trial in non-invasive bladder cancer
- Initiation of Phase 3 clinical trial for the treatment of non-invasive bladder cancer

### Ozarelix

- Positive data from the European Phase 2 clinical trial of ozarelix in benign prostate hypertrophy
- Acceptance of an Investigational New Drug application by the FDA
- Completed rapid patient enrollment of Phase 2b clinical trial in approximately 3 months for BPH

### Other

- Acquisition of ISO-Vorin™ for North America
- Settlement of the Paragraph IV litigation with GlaxoSmithKline for sumatriptan injection\* resulting in exclusive distribution rights to authorized generic versions of certain sumatriptan injection products
- Received \$5 million milestone payment from Par Pharmaceutical Companies, our marketing partner for sumatriptan injection
- Hiring of key individuals to advance the Company's clinical, marketing and sales programs
- Maintained tight control over the Company's cash: only \$13.5 million net cash used in 2006 operations
- Enhancement of the Company's public profile, resulting in an expansion of the investor base and increased analyst coverage

*Trademarked products mentioned in this report are trademarks of their respective companies.*

*\*Sumatriptan Injection is the generic version of GlaxoSmithKline's Imitrex® injection.*

Dear Shareholders:

The year 2006 and the months since then have been our most important period to date. Three of our late stage drugs, satraplatin, EOquin® and ozarelix, for treating prostate cancer, bladder cancer and Benign Prostate Hypertrophy (BPH) respectively, have all made significant progress.

- We announced highly statistically significant Phase 3 clinical trial results for satraplatin, which led to the completion of filing of a New Drug Application and priority review by the FDA.
- We reached an agreement with the FDA on a Special Protocol Assessment (SPA) for EOquin®, and initiated a Phase 3 trial at 55 centers.
- We reported highly statistically significant results with ozarelix and initiated a Phase 2b trial in the U.S.
- We received tentative approval from the FDA for our Abbreviated New Drug Application for sumatriptan injection, a drug for treating migraine and settled litigation with GlaxoSmithKline on favorable terms for Spectrum.
- We received a \$5 million milestone payment, as non-dilutive funding, from Par Pharmaceutical Companies, our marketing partner for sumatriptan injection, which allowed us to end the year with more than \$50 million in cash.
- Earlier this year we raised some capital and as of May 24th, we had approximately \$75 million in cash, giving us the resources to continue to develop both our late stage and early stage drugs.



Envisioning, planning and executing our successful progress to date required tireless dedication and unwavering commitment by everyone at Spectrum. I am proud of what our team accomplished in 2006. We expect to do much more in the coming years. We believe we have laid a solid foundation on which we can build Spectrum into one of the world's leading biopharmaceutical companies.

### **Risk-Reduced Business Model**

In contrast to many small biopharmaceutical companies, the pillars of our business model include building a diversified portfolio of late stage drugs in the fields of oncology, urology and other unmet medical needs by acquisition and partnerships rather than through in-house drug discovery. We make strategic alliances with successful companies to leverage their strengths, mitigate risk inherent in the drug development process, accelerate drug development timelines, and generate cash through milestones, royalties and ultimately from direct sales.

At the core of our business model is a team with significant experience in oncology and urology drug development. We endeavor to leverage the talents of our team and add people who have "done it before." Members of our team have been responsible for the development of drugs such as adriamycin, cisplatin, carboplatin, paclitaxel, doxorubicin, etoposide, buspirone, nefazodone, Stadol® and Cialis®, among others. As the drugs in our pipeline mature and come closer to regulatory approval, we have also begun building expertise in marketing and sales.



*Management Team: (L-R) George Uy, PhD, VP, Marketing, Rajesh Shrotriya, MD, Chairman of the Board, President & CEO, Russell Skibsted, Sr. VP, Business Development, William Pedranti, Esq. VP General Counsel, Shyam Kumaria, VP Finance, Ashok Gore, PhD, Sr. VP, Pharm Op & Reg Compliance, Gino Lenaz, MD, Chief Scientific Officer*

## 2006: A Transformational Year

Some of the most exciting news of the year for Spectrum came from our lead drug candidate, satraplatin. In September, we announced that in a pivotal Phase 3 trial, satraplatin was shown to be highly statistically significant in progression free survival as a second-line chemotherapy for patients suffering from hormone refractory prostate cancer. The data from this trial supported a New Drug Application filing with the FDA that was completed at the beginning of 2007. We also announced in 2006 the initiations of two combination studies with satraplatin: a Phase 1 trial with Xeloda® in advanced solid tumors and a Phase 2 trial of satraplatin in combination with Tarceva® in patients with inoperable, advanced non-small-cell lung cancer.

Our second lead proprietary drug, EOquin®, being studied for the treatment of non-invasive bladder cancer, also advanced in 2006. After completing Phase 2 studies in Europe, we conducted a 20-patient pilot study in the U.S. and subsequently used data from these trials to negotiate a SPA with the FDA. We initiated a pivotal Phase 3 trial of EOquin® in early 2007.

We also saw favorable results with ozarelix. In October, we announced that in a placebo-controlled, 144 patient, multi-center, Phase 2 clinical trial, ozarelix was found to be highly statistically significant versus placebo in reducing the symptoms associated with BPH. Since then, we have initiated a 75-patient Phase 2b study of ozarelix in BPH and we anticipate initiating a Phase 3 trial before the end of 2007 or soon thereafter.

We received tentative approval of our Abbreviated New Drug Application for sumatriptan injection from the FDA in October. We settled our patent litigation related to sumatriptan injection with GlaxoSmithKline in November, which provides that we may exclusively distribute authorized generic versions of certain sumatriptan injection products in the second half of 2008. We also received a \$5 million milestone payment from our marketing partner for the drug, Par Pharmaceutical Companies.

## 2007: Looking Ahead

Spectrum's value lies in the depth and breadth of its product pipeline. In 2007, we plan to continue to advance this pipeline that consists of 10 promising and diverse opportunities.

We believe that one of the significant value drivers in Spectrum's pipeline in 2007 will be the potential approval and launch of satraplatin in the U.S. Perhaps more importantly, the approval and launch of satraplatin will provide clear validation of our team's ability to take a drug that has been shelved by big pharma and get it into the hands of doctors for the benefit of patients.

We also expect the filing for marketing approval of satraplatin in Europe by mid 2007. Upon filing, acceptance and approval of the EU application and approval of the NDA for satraplatin, Spectrum will receive milestone payments, as well as royalties on worldwide sales of satraplatin. We may also co-promote the drug in the U.S.

EOquin® brings promise to the thousands of non-invasive bladder cancer patients that have seen no new treatments approved for their disease in more than 20 years. Based on the SPA we have agreed upon with the FDA, we initiated the Phase 3 trials of EOquin® in non-invasive bladder cancer patients. We plan to seek a partner for development and commercialization of EOquin® outside the U.S.

In 2007, we will continue to focus on the swift development of ozarelix. We expect to initiate multi-center, registrational Phase 3 trials before the end of 2007 or soon thereafter.

Spectrum's early-stage programs are also poised for progress in 2007. Our most exciting preclinical compound, SPI-1620, is being developed as an adjunct to chemotherapy. We are preparing an investigational new drug, or IND, application for SPI-1620, which we plan to file later this year. Upon IND acceptance, we will initiate a Phase 1 clinical trial in solid tumors in 2007. We plan to advance our other early stage compounds while our late stage drugs move toward commercialization.

Finally, we expect to complete the filing of the NDA for ISO-Vorin™, the pure active isomer of Leucovorin (folinic acid), in mid 2007.

A diversified, broad and deep pipeline that we hope will one day help the lives of millions of people with cancer and other debilitating diseases, while creating value for our shareholders, is at the core of our excitement and pride of being part of the Spectrum team. Over the next year, we anticipate building on the successes of 2006 and continuing to employ the pillars that represent our risk-reduced business model as we begin to recognize revenues from our products, initiate additional late-stage clinical trials, and advance our earlier stage programs.

I would like to thank our stockholders, employees, board members and strategic partners for their continued support and look forward to updating you on our progress in the near future.

Sincerely,



Rajesh C. Shrotriya, M.D.

Chairman, President, and Chief Executive Officer

Spectrum Pharmaceuticals, Inc.

June 8, 2007

# Upcoming Key Milestones

## Satraplatin

- Oncology Drug Advisory Committee (ODAC) Meeting
- U.S. Approval - (Triggers Milestone payment to Spectrum)
- U.S. Launch
- EU Filing - (Triggers Milestone payment to Spectrum)
- EU Acceptance - (Triggers Milestone payment to Spectrum)
- EU Approval - (Triggers Milestone payment to Spectrum)
- Receipt of Royalty Payments on Worldwide Sales

## EOquin®

- Initiate Second Phase 3 Trial
- Strategic Alliance for Rights Outside U.S.

## Ozarelix

- Completion of U.S. Phase 2b Trial in BPH
- Initiation of Phase 3 Trial in BPH
- Initiation of Phase 1 Trial in Endometriosis

## SPI-1620

- File IND
- Initiate Phase 1 trial

## ISO-Vorin™

- Completion of NDA
- Approval of NDA

## SPI-205

- IND Filing

## Sumatriptan Injection

- Launch (2008)



**Bela Denes, M.D., FACS**

*Senior Director, Clinical Research  
Spectrum Pharmaceuticals, Inc.*

**Ozarelx Project Leader**

Dr. Denes brings more than 30 years of experience in the field of urology to Spectrum Pharmaceuticals.

Dr. Denes has served as the Director of Clinical Research with Lilly/ICOS and was involved with the clinical development and launch of Cialis® (tadalafil).

He has broad experience in diseases of the prostate including BPH, prostate cancer, bladder cancer, overactive bladder and erectile dysfunction.

Dr. Denes is Senior Director for Clinical Research, and the Medical Monitor and Project Leader for ozarelx.

**Claus G. Roehrborn, M.D.**

*Professor and Chairman  
University of Texas, Southwestern*

**Ozarelx Lead Investigator**

Claus G. Roehrborn, M.D., is one of the most well known experts in his field. His research interests are in the areas of benign and malignant prostate diseases, including medical and minimally invasive therapies for BPH and markers for prostate cancer.

His basic, translational and clinical research has yielded over 250 peer-reviewed publications, over 30 book chapters and numerous other contributions to literature. He has chaired committees at the WHO-sponsored Consensus Conferences on BPH from 1994-2000 and is co-chairman of the AUA BPH Guidelines Committee.

Dr. Roehrborn is the Lead Investigator of the ozarelx trials in BPH.

# CLINICAL EXPERTISE

**Shanta Chawla, M.D.**

*Senior Director, Clinical Research  
Spectrum Pharmaceuticals, Inc.*

**EOquin® Project Leader**

Dr. Chawla is Board Certified in Internal Medicine. She has participated as a researcher in numerous clinical trials.

Since Dr. Chawla joined the Company, she has coordinated many of the clinical trials with record enrollment.

Currently, Dr. Chawla is Senior Director, Clinical Research and is also the Medical Monitor and Project Leader for EOquin® clinical trials.

**Mark Soloway, M.D., FACS**

*Professor and Chairman  
University of Miami School of Medicine*

**EOquin® Principal Investigator**

Dr. Soloway, a leading expert in his field, has authored over 300 articles on prostate, bladder and kidney cancer.

Some of Dr. Soloway's major contributions include the role of periprostatic nerve block for prostate biopsy, technical modifications in prostatectomy for prostate cancer, rationale for intravesical chemotherapy for bladder cancer and a grading scale for bone scans in prostate cancer. Dr. Soloway was one of the first to identify the efficacy of cisplatin for urothelial cancer and for the additive effect of cisplatin with radiation.

Dr. Soloway is the Principal Investigator for EOquin® clinical trials in non-invasive bladder cancer.





### **Board of Directors**

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

Richard D. Fulmer, M.B.A.  
*Former Vice President, Licensing and Development and Vice President of Marketing, Pfizer, Inc.*

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

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

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

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

### **Management Team**

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

Luigi G. Lenaz, M.D.  
*Chief Scientific Officer*

Shyam K. Kumaria  
*Vice President, Finance*

Russell L. Skibsted  
*Senior Vice President, Chief Business Officer*

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

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

George C. Uy  
*Vice President, Marketing*

### **Independent Auditors**

Kelly & Company  
*Costa Mesa, CA*

### **Outside Counsel**

Gibson, Dunn & Crutcher LLP  
*Irvine, 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*

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### **Website**

[www.spectrumpharm.com](http://www.spectrumpharm.com)

### **Market for Common Stock**

Nasdaq Global 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. Risks that could cause results to differ include risks described in the enclosed Annual Report on Form 10-K and other risks described in further detail in the Company's other reports filed with the Securities and Exchange Commission.*