Spectrum Pharmaceuticals Announces Fourth Quarter and Fiscal Year 2009 Corporate Update

- ***Form 10-K For Fiscal Year Ended December 31, 2009 Submitted to the SEC on April 2, 2010***
- ***FY09 Revenues Approximately $38.0M***
- ***ZEVALIN(R) FY09 and Q4 Revenues Approximately $15.7M and $5.1M, respectively***
- ***Strong Cash Position With Approximately $125M In Cash and Investments as of December 31, 2009***
- ***Major Development Programs on Track***
- ***Delay In Filing of Form 10-K Related To Accounting Restatement To Reclassify Common Stock Warrants From Equity To Liability***
  - ***$19.8M Income In FY09 and $6.6M Common Stock Warrant Liability At December 31, 2009, Result From Accounting Entries, With No Cash Impact***
  - ***No Impact On Financial Statement Amounts Previously Reported For Assets, Revenues, Operating Costs And Expenses, Or Net Cash Flows***
  - ***No Effect On Performance Of Core Business Operations***

IRVINE, Calif., Apr 05, 2010 (BUSINESS WIRE) -- Spectrum Pharmaceuticals, Inc. (NasdaqGM: SPPI), a commercial-stage biotechnology company with a primary focus in oncology, today reported financial results for the fourth quarter and fiscal year ended December 31, 2009.

Company Operations and Performance

"The year 2009 was filled with notable accomplishments for Spectrum that have laid the groundwork for continued and significant growth in 2010 and beyond," said Rajesh C. Shrotriya, MD, Chairman and Chief Executive Officer of Spectrum Pharmaceuticals, Inc. "The stabilization of the ZEVALIN(R) brand in 2009 and the signing of two partnerships for the Asian territories for apaziquone (EOquin(R)) provided us with the resources to acquire Belinostat, a novel HDAC inhibitor in pivotal trials for peripheral T-Cell lymphoma (PTCL). As of today, we have two FDA-approved and marketed anti-cancer drugs ZEVALIN and FUSILEV, that in 2009 generated approximately $28.2M in product revenue. In addition, we have two novel anti-cancer drugs in late stage pivotal trials being conducted under a Special Protocol Assessment (SPA) from the FDA. These are Belinostat for PTCL and apaziquone for bladder cancer. In 2009 we completed enrollment of over 1,600 patients in clinical trials with apaziquone. We currently expect to file the New Drug Applications for Belinostat and apaziquone in 2011 and 2012, respectively. We have been successful in growing Spectrum through strict fiscal discipline, portfolio management, and an opportunistic approach to drug acquisitions."

Fourth Quarter Results[1] Ended December 31, 2009

Consolidated revenue of $8.6 million was comprised of product sales of $5.2 million - $5.1 million from ZEVALIN, an increase of 8.5% over third quarter 2009, and $0.1 million from FUSILEV - $1.5 million attributable to the milestone payment upon full enrollment of the apaziquone Phase 3 trials, and $1.9 million attributable to the amortization of the Allergan licensing fee. This compares to $8.0 million in revenue in the same period in 2008. The Company recorded a net profit of $10.2 million, or $0.21 (basic earnings) and $0.20 (diluted earnings) per share, compared to a net loss of $8.9 million, or ($0.28) basic and diluted loss per share, in the fourth quarter of 2008, after reporting $19.8 million of income resulting from the reclassification of common stock warrants from equity to liability. Total research and development expenses were $3.5 million, as compared to $7.6 million in the same period of 2008, a $4.1 million, or 54% decrease, mainly due to sharing by our partner, Allergan, Inc., of apaziquone-related development costs, and a reduction in development costs related to other pipeline products. Selling, general and administrative expenses were $11.1 million compared to the $6.2 million in the same period in 2008. The $4.9 million increase was attributable to the direct cost of commercialization activities related to ZEVALIN and FUSILEV and related payroll costs.

Fiscal Year End Results[1] Ended December 31, 2009

Consolidated revenue of $38.0 million was comprised of product sales of $28.2 million - of which $15.7 million derived from ZEVALIN and $12.5 million from FUSILEV - $1.5 million attributable to the milestone payment upon full enrollment of the apaziquone Phase 3 trials, and $8.3 million attributable to the amortization of the Allergan licensing fee. This consolidated revenue compares to $28.7 million for the same period in 2008, which was comprised of approximately $7.7 million and $0.3 million derived from FUSILEV and ZEVALIN sales. After the recording of $8.1 million income resulting from the reclassification of common stock warrant from equity to liability, the Company recorded a net loss of $19.0 million, or ($0.48) basic and diluted loss per share, compared to a net loss of $14.2 million, or ($0.45) basic and diluted loss per share, in the same period of 2008. Research and development expenses were $21.1 million, as compared to $26.7 million in the same period of 2008, a $5.6 million, or 21% decrease, mainly due to sharing by our partner, Allergan Inc., of apaziquone-related development costs, and a reduction in development costs related to other pipeline products. Selling, general and administrative expenses were $33.6 million, compared to the $15.2 million in the same period in 2008, attributable to the direct cost of commercialization activities related to ZEVALIN and FUSILEV and related payroll costs.

Net cash used in operations in the fiscal year ended December 31, 2009 was $17.6 million compared to approximately $8.0 million during 2008, stated after revenues of approximately $20.7 million from the sale of interests in certain non-core assets. The 2009 operating cash outflows are reflective of higher selling, general, and administrative expenses due, in a large part, to the marketing efforts associated with ZEVALIN, substantially mitigated by revenues from ZEVALIN and FUSILEV and the participation by Allergan Inc. in apaziquone-related development expenses.

As of December 31, 2009, the Company had cash and total investments of approximately $125 million, compared to approximately $78 million as of December 31, 2008. Currently there are approximately 49 million shares of common stock outstanding.

Restatement of Financial Statements

As more fully described in the Company's Annual Report on Form 10K for the fiscal year ended December 31, 2009, the common stock warrants issued in connection with registered common stock offerings during 2005 and 2009, were previously classified as equity. In connection with the audit for the fiscal year 2009, the Company, in consultation with its independent registered public accounting firm, Ernst & Young LLP, reassessed the "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock", a highly complex area of accounting under US Generally Accepted Accounting Principles. In view of an interpretation that these common stock warrants could, under highly remote theoretical circumstances require net-cash-settlement, the Company's audit committee determined that recordation of common stock warrants as liabilities was required under US GAAP. Accordingly, the Company made accounting adjustments restating previously issued consolidated financial statements, including the quarterly condensed consolidated financial statements for the periods ended March 31, 2008 through September 30, 2009.

"The restatement does not have any impact on the financial statement amounts previously reported for the Company's cash balances, assets, revenues, operating costs and expenses, or reported net cash flows for any of the restated years, or any quarterly period in those years," said Shyam Kumaria, Vice President of Finance.

In our Form 10-K for the fiscal year ended December 31, 2009, we have reflected the necessary adjustments to previously filed financial statements. We have not amended such previously filed Annual Reports on Form 10-K for the fiscal years ended December 31, 2005, 2006, 2007 and 2008, or the Quarterly Reports on Form 10-Q for the periods ended September 30, 2005 through September 30, 2009, which previously issued statements should thus no longer be relied upon. For further information regarding the restatement, please read our Annual Report on Form 10-K for the fiscal year ended December 31, 2009.

Upcoming Company Milestones

ZEVALIN

- Continue to grow the ZEVALIN brand, currently approved for:
  - Treatment of patients with previously untreated follicular non-Hodgkin's lymphoma, who achieve a partial or complete response to first-line chemotherapy; and
  - Treatment of patients with relapsed or refractory, low-grade or follicular B-cell non-Hodgkin's lymphoma.
- Pursue removal of the bioscan requirement prior to ZEVALIN administration;
- Pursue consistent reimbursement for ZEVALIN in the community setting.

FUSILEV

- Submit requested FUSILEV data in colorectal cancer to the FDA in the second half of 2010.

Belinostat

- Peripheral T-Cell Lymphoma
  - File NDA in 2011, with a potential approval in late 2011 or early 2012.
- Carcinoma of Unknown Primary
  - Target complete enrollment by year-end in the ongoing Phase 2 trial that is being conducted and 100% funded by TopoTarget.
- Other tumor types
  - Explore additional trials in additional indications.

Apaziquone (EOquin)

- Phase 3 data expected in first quarter 2012; and
- Initiate a multiple-instillation trial in non-muscle invasive bladder cancer by year-end 2010.

Conference Call

Tuesday, April 6, 2010 @ 11:30a.m. Eastern/8:30a.m. Pacific
Domestic: 877-837-3910 passcode 57165403
International: 973-796-5077 passcode 57165403

Webcast and replays: www.sppirx.com

Audio replays will be available through April 17, 2010.
Domestic: (800) 642-1687, passcode 57165403
International: (706) 645-9291, passcode 57165403

About ZEVALIN(R) and the ZEVALIN Therapeutic Regimen

ZEVALIN (ibritumomab tiuxetan) is indicated for the treatment of patients with previously untreated follicular non-Hodgkin's Lymphoma (NHL), who achieve a partial or complete response to first-line chemotherapy. ZEVALIN is also indicated for the treatment of patients with relapsed or refractory, low-grade or follicular B-cell non-Hodgkin's lymphoma.

ZEVALIN is a CD20-directed radiotherapeutic antibody administered as part of the ZEVALIN therapeutic regimen. The ZEVALIN therapeutic regimen consists of three components: rituximab, Indium-111 (In-111) radiolabeled ZEVALIN for imaging, and Yttrium-90 (Y-90) radiolabeled ZEVALIN for therapy. The ZEVALIN therapeutic regimen is a form of cancer therapy called radioimmunotherapy. Radioimmunotherapy (RIT) is an innovative form of cancer treatment with a mechanism of action that is different from traditional chemotherapy. RIT builds on the combined effect of a targeted biologic monoclonal antibody augmented with the therapeutic effects of a beta-emitting radioisotope.

Full prescribing information can be found at www.ZEVALIN.com.

About FUSILEV(R) (levoleucovorin) for Injection

FUSILEV, a novel folate analog, is available in 50-mg vials of freeze-dried powder. FUSILEV rescue is indicated after high-dose methotrexate therapy in osteosarcoma. FUSILEV is also indicated to diminish the toxicity and counteract the effects of impaired methotrexate elimination and of inadvertent overdosage of folic acid antagonists. FUSILEV (levoleucovorin or (6S)-leucovorin) is the only commercially available formulation containing only the pharmacologically active isomer of leucovorin.

Full prescribing information can be found at www.FUSILEV.com.

About Spectrum Pharmaceuticals

Spectrum Pharmaceuticals is a commercial-stage biotechnology company with a focus in oncology. The Company's strategy is comprised of acquiring, developing and commercializing a broad and diverse pipeline of late-stage clinical and commercial products. In addition to building an efficient in-house clinical research organization with regulatory and data management capabilities, the Company has established a commercial infrastructure for its drug portfolio. The Company markets two oncology drugs, FUSILEV and ZEVALIN and has two drugs in late stage development, apaziquone and belinostat, along with a diverse pipeline. The Company also leverages the expertise of its worldwide partners to assist in the execution of its strategy. For more information, please visit the Company's website at www.sppirx.com.

Forward-looking statement - This press release may contain forward-looking statements regarding future events and the future performance of Spectrum Pharmaceuticals that involve risks and uncertainties that could cause actual results to differ materially. These statements include but are not limited to statements that relate to the restatement of our consolidated financial statements, our business and its future, Spectrum's ability to identify, acquire, develop and commercialize a broad and diverse pipeline of late-stage clinical and commercial products, establishing a commercial organization for our approved drugs, continuing to build our team, leveraging the expertise of partners around the world to assist us in the execution of our strategy, continued and significant growth in 2010 and beyond, that we expect to file the New Drug Applications for Belinostat and Apaziquone as early as 2011 and 2012, respectively, the safety and efficacy of ZEVALIN and FUSILEV, continue to grow the ZEVALIN brand, pursue removal of the bioscan requirement prior to ZEVALIN administration, pursue consistent reimbursement for ZEVALIN in the community setting, submit requested FUSILEV data in colorectal cancer to the FDA by the end of the third quarter 2010; in ongoing belinostat PTCL pivotal trial; file an NDA in 2011, with a potential approval in late 2011 or early 2012, target complete enrollment for Belinostat by year-end in the ongoing Phase 2 CUP trial, explore additional trials in additional indications for Belinostat, that Apaziquone Phase 3 data is expected in first quarter 2012; initiate a multiple-instillation trial in non-muscle invasive bladder cancer by year-end 2010 for Apaziquone and any statements that relate to the intent, belief, plans or expectations of Spectrum or its management, or that are not a statement of historical fact. Risks that could cause actual results to differ include the possibility that our existing and new drug candidates, may not prove safe or effective, the possibility that our existing and new drug candidates may not receive approval from the FDA, and other regulatory agencies in a timely manner or at all, the possibility that our existing and new drug candidates, if approved, may not be more effective, safer or more cost efficient than competing drugs, the possibility that our efforts to acquire or in-license and develop additional drug candidates may fail, our lack of revenues, our limited marketing experience, our dependence on third parties for clinical trials, manufacturing, distribution and quality control and other risks that are described in further detail in the Company's reports filed with the Securities and Exchange Commission. We do not plan to update any such forward-looking statements and expressly disclaim any duty to update the information contained in this press release except as required by law.

[1] All numbers are approximates

SPECTRUM PHARMACEUTICALS, INC. AND SUBSIDIARIES
(In thousands, except share and per share data)
Summary Condensed Consolidated Statement of Operations

	Quarter Ended December 31, (Unaudited)		Year Ended December 31,	
	2009	Restated 2008	2009	Restated 2008
Total revenues	$ 8,620	$ 8,049	$ 38,025	$ 28,725
Operating expenses:				
Cost of product sales (excludes amortization of purchased intangibles shown below)	2,446	1,193	8,148	1,193
Selling, general and administrative	11,069	6,209	33,607	15,156
Research and development	3,525	7,594	21,058	26,683
Amortization of purchased intangibles	870	158	3,720	158
Acquired in-process research and development	-	4,700	-	4,700
Total operating expenses	17,910	19,854	66,533	47,890
Loss from operations	(9,290)	(11,805)	(28,508)	(19,165)
Change in fair value of common stock warrant liability	19,834	(210)	8,075	1,271
Other income, net	61	609	662	1,165
Pre-tax net income (loss)	10,605	(11,406)	(19,771)	(16,729)
Income tax expense	(421)	(5)	(421)	(5)
Net loss of attributable to non-controlling interest	-	2,538	1,146	2,538
Net income (loss) - attributable to Spectrum Pharmaceuticals, Inc. stockholders	$ 10,184	$ (8,873)	$ (19,046)	$ (14,196)
Net loss per share - attributable to Spectrum Pharmaceuticals, Inc. stockholders				

Basic	$ 0.21	$ (0.28)	$ (0.48)	$ (0.45)
Diluted	$ 0.20	$ (0.28)	$ (0.48)	$ (0.45)
Basic weighted average common shares outstanding	48,425,486	31,928,778	39,273,905	31,551,152
Diluted weighted average common shares outstanding	49,704,126	31,928,778	39,273,905	31,551,152

Summary Condensed Consolidated Balance Sheets

	December 31, 2009	December 31, 2008 Restated
ASSETS		
Current Assets:		
Cash, cash equivalents and marketable securities	$ 113,341	$ 75,938
Accounts receivable, net	8,658	9,776
Inventories	3,230	1,841
Prepaid expenses and other current assets	1,028	693
Total Current Assets	126,257	88,248
Bank certificates of deposit & treasuries	11,438	2,148
Property and equipment, net	1,928	1,782
Zevalin related intangible assets, net	33,325	37,042
Other assets	185	289
Total assets	$ 173,133	$ 129,509
LIABILITIES AND EQUITY		
Total current liabilities (excluding common stock warrant liability)	$ 32,864	$ 32,806
Common stock warrant liability	6,635	765
Total current liabilities	39,499	33,571
Total noncurrent liabilities and deferred revenues	25,310	42,822
Total liabilities	64,809	76,393
Total equity (including non-controlling interest)	108,324	53,116
Total liabilities and equity	$ 173,133	$ 129,509

SOURCE: Spectrum Pharmaceuticals, Inc.

Spectrum Pharmaceuticals, Inc.
Paul Arndt
Senior Manager, Investor Relations
949-788-6700x216