SPECTRUM PHARMACEUTICALS INC

Form 8-K September 28, 2010

UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 28, 2010

SPECTRUM PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware 000-28782 93-0979187

(State or other Jurisdiction of (Commission File Number) (IRS Employer Identification No.)

Incorporation)

157 Technology Drive, Irvine, CA 92618

(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (949) 788-6700

N/A

(Former name or former address if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01 Regulation FD Disclosure

Spectrum Pharmaceuticals, Inc. ("the Company") rang the Nasdaq Stock Market opening bell today. In his remarks and in interviews, Rajesh C. Shrotriya, MD, Chairman of the Board, Chief Executive Officer, and President of the Company announced, among other things, that the Company expects product revenues to exceed \$10 million during the third quarter of 2010.

Dr. Shrotriya's full statement is below:

"Ladies and gentlemen, shareholders, Nasdaq representatives, and fellow employees, it is with a great deal of pride that we come here today to ring the opening bell for Nasdaq trading.

Spectrum Pharmaceuticals has had an incredible journey over nearly a decade. We have had the good fortune of acquiring, developing, and commercializing drugs with life saving potential over this period. Moreover, we have generated millions in shareholder value and created a platform to build an enduring, successful biopharmaceutical firm.

Today we have 2 FDA-approved anticancer drugs on the market helping thousands of patients and generating revenue for the Company. These drugs are:

- ZEVALIN, a best in class treatment for progression free survival of Non-Hodgkins lymphoma with significant life saving capability. Zevalin is so unique that often a single dose treatment is sufficient for the majority of patients.
- FUSILEV, a novel drug being developed for the treatment of colorectal cancer.

For the first time in the history of our company, we expect to do over \$30 million in product revenue this year, underscoring the success of our growth strategy. Moreover, I am pleased to announce today that we expect to achieve over \$10 million in product revenue for the third quarter of this year, for the first time in our history – of course this is subject to the usual caveats about forward looking statements.

We also plan to submit to the FDA, by the end of this year, data supporting FUSILEV's use in treating colorectal cancer, a significantly larger indication than available today. According to the American Cancer Society, more than 150 thousand men and women are diagnosed every year with colorectal cancer, resulting in nearly 50 thousand deaths every year.

We also have 2 late stage drugs in development, with blockbuster potential:

- Belinostat, a novel HDAC inhibitor with potentially best in class profile for treatment of various cancers; this drug is in final stages of testing and we plan to file a new drug application next year; Finally
- Apaziquone, a novel drug for the treatment of bladder cancer in the last 25 years no new drugs have been approved and marketed, underscoring the importance and promise of this treatment.

We expect to file a New Drug Application for Apaziquone in 2012.

In addition, we are unique among our peers for having a broad and deep pipeline with several other drugs in various phases of development.

So let me quickly summarize again where we are in 2010. We are a company with:

- 2 FDA approved and marketed drugs that we expect to generate over \$30 million in revenue in 2010, including \$10 million in Q3 for the first time ever <u>- a major corporate milestone</u>
- 2 Expected NDA filings in 2011 and 2012, respectively,
- Behind these 4 drugs, we have a broad and deep pipeline of promising drug candidates,
- Strong cash position
- About 150 employees working every day to bring these new treatments to cancer patients. As a reflection of our growth, we now have strategically expanded our operations from Irvine, California, to include Henderson, Nevada, Montreal, Canada, and Mumbai, India.

I am grateful to our shareholders, our board of directors, our employees, and of course Nasdaq for giving us the opportunity to be here today.

Thank you very much. I would now like to open the day for trading."

Forward-looking statement — This Form 8-K contains 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 our business and its future financial results, Spectrum's ability to identify, acquire, develop and commercialize a broad and diverse pipeline of late-stage clinical and commercial products, leveraging the expertise of partners and employees around the world to assist us in the execution of our strategy, the safety and efficacy of ZEVALIN, FUSILEV, apaziquone, and belinostat, 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 Form 8-K except as required by law.

The information in this Current Report on Form 8-K is furnished pursuant to Item 7.01 and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

SIGNATURE

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

Spectrum Pharmaceuticals, Inc.

Date: September 28, 2010 By: /s/ SHYAM KUMARIA

Name: Shyam Kumaria

Title: Senior Vice President, Finance

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