

SPECTRUM PHARMACEUTICALS INC
Form 8-K
October 09, 2009

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): October 9, 2009

SPECTRUM PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

| | | |
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| Delaware (State or other Jurisdiction of Incorporation) | 000-28782 (Commission File Number) | 93-0979187 (IRS Employer Identification No.) |
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|---|----------------------------|
| 157 Technology Drive, Irvine, CA (Address of Principal Executive Offices) | 92618 (Zip Code) |
|---|----------------------------|

Registrant's telephone number, including area code: **(949) 788-6000**

(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:

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

Item 8.01 Other Events.

On October 9, 2009, Spectrum Pharmaceuticals, Inc. issued a press release announcing that it received a Complete Response letter from the U.S. Food and Drug Administration (FDA) regarding its supplemental New Drug Application (sNDA) for FUSILEV® (levoleucovorin) for injection for treatment of patients with advanced metastatic colorectal cancer. The FDA stated in the Complete Response letter that the submission did not demonstrate that FUSILEV is non-inferior to leucovorin; and recommended that the Company meet with them to discuss options for continuing to seek approval of FUSILEV in advanced metastatic colorectal cancer. The Company plans to promptly request such meeting to discuss options for FUSILEV in this indication. The FDA did not request any changes to the currently approved indications and package insert. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number Description

99.1 Press Release dated October 9, 2009.

Signatures

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.

October 9, 2009

By: /s/ Shyam Kumaria
Shyam Kumaria
Vice President, Finance

EXHIBIT INDEX

| <i>Exhibit Number</i> | <i>Description</i> |
|-----------------------|--------------------------------------|
| 99.1 | Press Release dated October 9, 2009. |