SPECTRUM PHARMACEUTICALS INC
Form 8-K
July 03, 2014

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): July 3, 2014

SPECTRUM PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-35006**	**93-0979187**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

11500 S. Eastern Ave., Ste. 240, Henderson, NV 89052

(Address of principal executive offices, including zip code)

Registrant s telephone number, including area code: (702) 835-6300

Not Applicable

(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 (see General Instruction A.2. below):

¨ 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 7.01 Regulation FD Disclosure.

On July 3, 2014, Spectrum Pharmaceuticals, Inc. (the Company) received notification from the U.S. Food and Drug Administration (FDA) of their early action granting accelerated approval of the Company s New Drug Application (NDA) for Beleodaq (belinostat) for Injection for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL). This indication was approved by FDA under accelerated approval based on tumor response rate and duration of response. An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trial. Important Beleodaq safety information is included in the attachment hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 2.04. Triggering Events That Accelerate or Increase a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement.

As previously announced, in 2010 the Company licensed the oncology drug asset Beleodaq (belinostat) for Injection from TopoTarget A/S (TopoTarget) through a License and Collaboration Agreement (the Agreement) for all uses in North America and India, with an option for China (as is defined in the Agreement). In connection with the transaction, TopoTarget remained eligible to receive contingent consideration upon the achievement of certain regulatory and sales milestones. As a result of the satisfaction of a NDA approval milestone, described above, pursuant to the Agreement, the Company becomes obligated to pay TopoTarget $25 million in cash.

Item 8.01 Other Events.

On July 3, 2014, the Company received further notifications from the FDA regarding the post marketing requirements (PMRs) for each of Beleodaq and Folotyn®. With respect to Folotyn, the two previous Folotyn PMRs for the Phase 3 PTCL trial and the Phase 3 cutaneous T-cell lymphoma (CTCL) trial have been released by FDA. The new PMRs for Beleodaq and Folotyn include a main study that evaluates the comparative efficacy and safety of Folotyn when used in combination with the treatment regimen cyclophosphamide/ vincristine/doxorubicin/prednisone (CHOP) or the combination of Beleodaq plus CHOP, versus CHOP alone for the initial therapy of patients with PTCL. Important safety information for Beleodaq and Folotyn is included in the attachment hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Important Safety Information for BELEODAQ (belinostat) for Injection and FOLOTYN (pralatrexate injection)

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.

Date: July 3, 2014

SPECTRUM PHARMACEUTICALS, INC.

By: /s/ Kurt A. Gustafson
Kurt A. Gustafson
Executive Vice President and Chief Financial Officer

EXHIBIT INDEX

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