UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): December 14, 2018

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)	(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:

☐ 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On December 19, 2018, Spectrum Pharmaceuticals, Inc. issued a press release announcing that, based on a subset of data from MD Anderson's ongoing Phase 2 study, the U.S. Food and Drug Administration (FDA) did not grant Breakthrough Therapy Designation (BTD) to poziotinib for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have EGFR exon 20 mutations. A copy of such 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 No.	Description
99.1	Press Release dated December 19, 2018

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: December 19, 2018

By: /s/ Kurt A. Gustafson

Kurt A. Gustafson
Executive Vice President and Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated December 19, 2018

COMPANY CONTACT
Shiv Kapoor
Vice President, Strategic Planning & Investor Relations
702-835-6300
InvestorRelations@sppirx.com

Spectrum Pharmaceuticals Provides Poziotinib Update

- Spectrum will host a live webcast today at 4:30 p.m. EST/1:30 p.m. PST

HENDERSON, Nev.—December 19, 2018-- Spectrum Pharmaceuticals, Inc. (NasdaqGS: SPPI), today announced that based on a subset of data from MD Anderson's ongoing Phase 2 study, the U.S. Food and Drug Administration (FDA) did not grant Breakthrough Therapy Designation (BTD) to poziotinib for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have EGFR exon 20 mutations. The company's overall development plan and timeline for a New Drug Application (NDA) filing based on the first cohort of the ZENITH20 trial remains unchanged.

Breakthrough Therapy Designation is one of several FDA programs designed to expedite the review of drugs to treat serious or life threatening conditions. Spectrum's BTD application included data from 30 patients from the MD Anderson Phase 2 study who had failed platinum-based chemotherapy. The data demonstrated a confirmed objective response rate of 40% and median duration of response of 6.6 months. The safety profile in this subset was consistent with historical data published on poziotinib and other tyrosine kinase inhibitors. The historical objective response rates for mutation specific NSCLC patients range between 0% and 8% with tyrosine kinase inhibitors and for non-mutation specific NSCLC patients range between 0.8% and 22.9% with other treatments.

"Our enthusiasm for poziotinib, our commitment to the program, and our overall development plan remain unchanged," said Joe Turgeon, President and Chief Executive Officer of Spectrum Pharmaceuticals. "We will continue to work with the FDA to achieve the fastest route to approval of poziotinib based on our ZENITH20 study."

ZENITH20 is a Spectrum-sponsored, open-label, single-arm, multi-center, global Phase 2 study evaluating more than 300 NSCLC patients with EGFR or HER2 exon 20 insertion mutations. The study consists of four cohorts, each of which is independently powered for a pre-specified statistical hypothesis.

"Poziotinib's overall development program is robust, and the clinical profile remains very attractive in an area of high unmet need," said Francois Lebel, M.D., F.R.C.P.C, Chief Medical Officer of Spectrum Pharmaceuticals. "Data required for the NDA filing for previously treated NSCLC patients with EGFR exon 20 insertion mutations is expected to come from an 87-patient cohort in our ZENITH20 study. We expect to complete enrollment in this cohort in the first quarter of 2019, and announce topline data in the second half of 2019."

Conference Call Details:

Wednesday, December 19, 2018 at 4:30 p.m. Eastern/1:30 p.m. Pacific

Domestic: (877) 837-3910, Conference ID# 1577888
International: (973) 796-5077, Conference ID# 1577888

The conference call will also be webcast live. To access the webcast, please visit the Investor Relations page of the Spectrum Pharmaceuticals website at http://investor.sppirx.com/events-and-presentations.

For interested individuals unable to join the call, a replay will be available from December 19, 2018 @ 7:30 p.m. ET/4:30 p.m. PT through December 26, 2018, until 7:30 p.m. ET/4:30 p.m. PT.

Domestic Replay Dial-In: (855) 859-2056, Conference ID# 1577888
International Replay Dial-In: (404) 537-3406, Conference ID# 1577888

About Poziotinib

Poziotinib is a novel, oral Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor (EGFR TKI) that inhibits the tyrosine kinase activity of EGFR as well as HER2 and HER4. Importantly this leads to the inhibition of the proliferation of tumor cells that overexpress these receptors. Mutations or overexpression/amplification of EGFR family receptors have been associated with a number of different cancers, including non-small cell lung cancer (NSCLC), breast cancer, and gastric cancer. Spectrum received exclusive license from Hanmi Pharmaceuticals to develop, manufacture, and commercialize poziotinib worldwide, excluding Korea and China. Poziotinib is currently being investigated by Spectrum and Hanmi in several mid-stage trials in multiple solid tumors.

About ZENITH20

The ZENITH20 study is Spectrum-sponsored, Phase 2, open-label, single-arm, multi-center, global study for patients with EGFR or HER2 exon 20 insertion mutations in NSCLC. It consists of four cohorts, each of which is an independent study with pre-specified statistical hypotheses and statistical power. There are two cohorts in the previously-treated setting and two in the first-line setting. The full poziotinib targeted therapy clinical program is focused on four development areas for EGFR and HER2 mutations, including previously treated NSCLC, first-line NSCLC, treatment of other solid tumors and combination therapy.

About Spectrum Pharmaceuticals, Inc.

Spectrum Pharmaceuticals is a leading biotechnology company focused on acquiring, developing, and commercializing drug products, with a primary focus in hematology and oncology. Spectrum currently markets seven hematology/oncology drugs, and has an advanced stage pipeline that has the potential to transform the company. Spectrum's strong track record for in-licensing and acquiring differentiated drugs, and expertise in clinical development have generated a robust, diversified, and growing pipeline of product candidates in advanced-stage Phase 2 and Phase 3 studies. More information on Spectrum is available at www.sppirx.com.

Forward-Looking Statements

Certain statements in this press release may constitute "forward-looking statements" within the meaning of the United States Private Securities Litigation Reform Act of 1995, as amended to date. These forward-looking statements relate to a variety of matters, including, without limitation, statements that relate to Spectrum's business and its future, including the role of poziotinib in treating NSCLC patients with EGFR and HER2 exon 20 mutations and the advancement in treatment of such patients, the treatment potential of poziotinib to consistently deliver high response and disease control rates for NSCLC patients with EGFR and HER2 exon 20 mutations, the likelihood and timing of obtaining BTD for poziotinib, the timeline for filing a NDA for poziotinib, the timing of enrollment of the poziotinib EGFR, previously treated cohort in the ZENITH20 trial, the ability of Spectrum to release data from the ZENITH20 study in the second half of 2019, the future potential of Spectrum's existing drug pipeline, and any other statements that are not purely statements of historical fact. These forward-looking statements are based on management's current beliefs, expectations and assumptions and are subject to significant risks and uncertainties. Investors are cautioned not to place undue reliance on any such forward-looking statements. All such forward-looking statements speak only as of the date they are made, and Spectrum undertakes no obligation to update or revise these statements, whether as a result of new information, future events or otherwise. Although Spectrum believes that the expectations reflected in these forward-looking statements are reasonable, these statements involve many risks and uncertainties that may cause actual results to differ materially from what may be expressed or implied in these forward-looking statements, including, without limitation, the uncertainties inherent in new product development, including clinical trial results and additional analysis of existing clinical data, the possibility that Spectrum's existing and new drug candidates, including poziotinib and ROLONTIS® , may not ultimately prove to be safe or effective, the possibility that Spectrum's existing and new applications to the FDA and other regulatory agencies may not receive approval in a timely manner or at all, the possibility that Spectrum's existing and new drug candidates, if approved, may not be more effective, safer or more cost efficient than competing drugs, and Spectrum's dependence on third parties for clinical trials, manufacturing, distribution and quality control. For a further discussion of risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of Spectrum in general, see the risk disclosures in the Annual Report on Form 10-K of Spectrum for March 7, 2018, as amended, and in subsequent reports on Forms 10-Q and 8-K and other filings made with the SEC by Spectrum.

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