SPECTRUM PHARMACEUTICALS INC

FORM 8-K
(Current report filing)

Filed 10/18/17 for the Period Ending 10/17/17

Address	11500 S. EASTERN AVE., SUITE 240 HENDERSON, NV, 89052
Telephone	702-835-6300
CIK	0000831547
Symbol	SPPI
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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): October 17, 2017

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 October 17, 2017, Spectrum Pharmaceuticals, Inc. (the "Company") announced the oral presentation of interim data from a Phase 2 clinical study evaluating poziotinib in EGFR Exon 20 Mutant Non-Small-Cell Lung Cancer (NSCLC) by scientists from the MD Anderson Cancer Center which was presented in Yokohama, Japan, October 15-18, 2017. A copy of this press release announcing the interim data is being filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 8.01 by reference.

Item 7.01 Regulation FD Disclosure

On October 18, 2017, the Company held a conference call at 8:30 a.m. Eastern Time to further discuss the poziotinib study results. Interested parties may access a replay of the webcast, including presentation materials, on the investor relations page of the Company's website: http://investor.sppirx.com/events.cfm .

The information contained in Item 7.01 of this Current Report on Form 8-K, including without limitation any information contained on the Company's website, 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.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated October 17, 2017, issued by Spectrum Pharmaceuticals, Inc.

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: October 18, 2017

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 October 17, 2017, issued by Spectrum Pharmaceuticals, Inc.

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

Spectrum Pharmaceuticals Highlights Poziotinib Data in Non-Small-Cell Lung Cancer (NSCLC) Presented at the 18th IASLC World Conference on Lung Cancer in Japan

- Poziotinib demonstrates evidence of significant antitumor activity in NSCLC patients with EGFR exon 20 insertion mutations, with interim data showing an Objective Response Rate of 73%.
- Evidence of central nervous system (CNS) activity in a patient with CNS metastasis and another with leptomeningeal disease (LMD).
- On October 18th at 8:30 a.m. EST/5:30 a.m. PST, the Company will hold a conference call with Dr. John Heymach, from The University of Texas MD Anderson Cancer Center to discuss the study results.

HENDERSON, Nev.—October 17, 2017- - Spectrum Pharmaceuticals, Inc. (NasdaqGS: SPPI), a biotechnology company with fully integrated commercial and drug development operations with a primary focus in Hematology and Oncology, announced the oral presentation of interim data from a Phase 2 clinical study evaluating poziotinib in EGFR Exon 20 Mutant Non-Small Cell Lung Cancer (NSCLC) by scientists from the MD Anderson Cancer Center which was presented in Yokohama, Japan, October 15-18, 2017. The Company will hold a conference call tomorrow, October 18 th at 8:30 a.m. EST/5:30 a.m. PST with Dr. John Heymach, M.D., Ph.D., Chairman, Professor, and David Bruton Junior Chair in Cancer Research, Department of Thoracic/Head and Neck Medical Oncology, The University of Texas MD Anderson Cancer Center to discuss his study results.

“These data are remarkable for NSCLC patients with exon 20 insertion mutations,” said John Heymach, M.D., Ph.D., The University of Texas MD Anderson Cancer Center. “These patients currently have a poor prognosis, single-digit response rate on first generation tyrosine kinase inhibitors (TKI’s), and a PFS of about two months. What is truly noteworthy is that all 11 study patients who received poziotinib at a 16mg daily dose and have reached their first scan, have seen some level of tumor shrinkage. Interestingly, we have also seen evidence of CNS activity. Toxicities have included rash, diarrhea, paronychia, and mucositis consistent with those previously described for poziotinib and other TKI’s, which led to dose reduction in 55% of the patients. We believe that poziotinib specifically inhibits EGFR with exon 20 insertion mutations because it overcomes steric hindrance caused by exon 20 insertions, due to its smaller size and flexibility. To date poziotinib has shown promising results in patients with exon 20 insertion mutations and we are fortunate to be leading the efforts in the continuing development of this product.”

"We are greatly encouraged with the clinical data emerging from poziotinib and plan to pursue its clinical development expeditiously and aggressively," said Rajesh C. Shrotriya, MD, Chairman and Chief Executive Officer of Spectrum Pharmaceuticals. "In the near future, we plan to discuss the regulatory pathway for poziotinib with the FDA. At the same time, we are embarking upon an overall strategy for global clinical development and regulatory filings. With three promising drugs in late-stage development, Spectrum's pipeline has never been as exciting and our prospects never as bright."

Conference Call

Wednesday, October 18, 2017 @ 8:30 a.m. Eastern/5:30 a.m. Pacific

Domestic: (877) 837-3910, Conference ID# 86093351

International: (973) 796-5077, Conference ID# 86093351

For interested individuals unable to join the call, a replay will be available from October 18, 2017 @ 11:30 a.m. ET/8:30 a.m. PT through October 28, 2017 until 11:30 a.m. ET/8:30 a.m. PT.

Domestic Replay Dial-In #: (855) 859-2056, Conference ID# 86093351

International Replay Dial-In #: (404) 537-3406, Conference ID# 86093351

This conference call will also be webcast. Listeners may access the webcast, which will be available on the investor relations page of Spectrum Pharmaceuticals' website: www.sppirx.com on October 18, 2017 at 8:30 a.m. Eastern/5:30 a.m. Pacific.

About Poziotinib

Poziotinib is a novel, oral pan-HER inhibitor that irreversibly blocks signaling through the Epidermal Growth Factor Receptor (EGFR, HER) Family of tyrosine-kinase receptors, including HER1 (erbB1; EGFR), HER2 (erbB2), and HER4 (erbB4), and importantly, also HER receptor mutations; this, in turn, 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 to develop, manufacture and commercialize worldwide excluding Korea and China from Hanmi Pharmaceuticals. Poziotinib is currently being investigated by Spectrum and Hanmi in several mid-stage trials in multiple solid tumor indications.

About the WCLC

The World Conference on Lung Cancer (WCLC) is the world's largest meeting dedicated to lung cancer and other thoracic malignancies, attracting over 6,000 researchers, physicians and specialists from more than 100 countries. The goal is to disseminate the latest scientific achievements; increase awareness, collaboration and understanding of lung cancer; and to help participants implement the latest developments across the globe. Organized under the theme of "Synergy to Conquer Lung Cancer," the conference covers a wide range of

disciplines and unveil several research studies and clinical trial results. For more information, visit http://wclc2017.iaslc.org/.

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 six 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 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 are based on management's current beliefs and expectations. These statements include, but are not limited to, statements that relate to Spectrum's business and its future, including certain company milestones, Spectrum's ability to identify, acquire, develop and commercialize a broad and diverse pipeline of late-stage clinical and commercial products, the timing and results of FDA decisions, 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 Spectrum's existing and new drug candidates may not prove safe or effective, the possibility that our 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 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 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. The Company does not plan to update any such forward-looking statements and expressly disclaims any duty to update the information contained in this press release except as required by law.