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): November 1, 2018

Constellation Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-38584**	**26-1741721**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

215 First Street, Suite 200 **Cambridge, Massachusetts**	**02142**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 714-0555

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))

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 7.01. Regulation FD Disclosure.

On November 1, 2018, Constellation Pharmaceuticals, Inc. issued a press release entitled "Constellation Pharmaceuticals Receives FDA Fast Track Designation for CPI-0610 in Treatment of Myelofibrosis" announcing its receipt of fast track designation based on preliminary results in its Phase 2 trial of CPI-0610. A copy of the press release is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 7.01, including Exhibit 99.1 attached hereto, is furnished under Item 7.01 of Form 8-K, and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release dated November 1, 2018 (furnished herewith)

SIGNATURES

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

CONSTELLATION PHARMACEUTICALS, INC.

Date: November 1, 2018

By: /s/ Jigar Raythatha
Name: Jigar Raythatha
Title: Chief Executive Officer

Exhibit 99.1

Constellation Pharmaceuticals Receives FDA Fast Track Designation for CPI-0610 in Treatment of Myelofibrosis

- *Recently Expanded and Enhanced MANIFEST Phase 2 Trial Ongoing with Proof of Concept Data Expected Mid-2019*

CAMBRIDGE, Massachusetts, November 1, 2018 – Constellation Pharmaceuticals, Inc., a clinical-stage biopharmaceutical company using its expertise in epigenetics to discover and develop novel therapeutics, today announced that it has received Fast Track designation from the United States Food and Drug Administration (FDA) for CPI-0610 in treatment of myelofibrosis (MF) based on preliminary results from the Company's Phase 2 study, MANIFEST.

Constellation is developing CPI-0610 with the goal of providing a new treatment option for patients with MF who have progressed after treatment with Jakafi (ruxolitinib), the only approved therapy for MF. Enrollment is ongoing in the Phase 2 portion of the open-label Phase 1/2 MANIFEST clinical trial, which is exploring CPI-0610's potential both as a monotherapy and as a combination therapy with Jakafi. As previously reported, preliminary data demonstrated clinical activity, such as spleen volume reduction, symptom improvement, increase in hemoglobin levels, and conversion to transfusion independent status in a patient who was transfusion dependent. Constellation recently expanded the MANIFEST study to include a third cohort, designed to evaluate CPI-0610 as a first-line therapy in combination with ruxolitinib in JAK 1/2-inhibitor-naïve MF patients.

"We believe there is an opportunity to improve the standard of care for MF patients with agents that modify the underlying disease," said Adrian Senderowicz, Senior Vice President and Chief Medical Officer of Constellation Pharmaceuticals. "This Fast Track designation highlights CPI-0610's potential to address a significant unmet need. Based on promising early data and our progress with site initiation and patient enrollment, we continue to expect to determine proof of concept in mid-2019."

The FDA grants Fast Track designation to facilitate the development and expedite the review of drugs to treat serious or life-threatening diseases and fill unmet medical needs. A drug that receives Fast Track designation is

eligible for more frequent meetings with the FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval, more frequent written communication about the design of the proposed clinical trials and use of biomarkers, eligibility for accelerated approval and priority review, and rolling review.

About Myelofibrosis

MF is part of a collection of progressive blood cancers known as myeloproliferative neoplasms and is associated with significantly reduced quality of life and shortened survival. As the disease progresses, the bone marrow produces fewer red blood cells. Within one year of diagnosis, the incidence of thrombocytopenia (a condition characterized by low platelet counts in the blood) and severe anemia (a condition characterized by low red blood cell counts) and the need for red blood cell transfusion increase significantly. Among other complications, most patients with MF have enlarged spleens, as well as many other physical symptoms, including abdominal discomfort, bone pain, and extreme fatigue.

About CPI-0610

CPI-0610 is a potent and selective small molecule designed to promote anti-tumor activity by selectively inhibiting the function of BET proteins to decrease the expression of abnormally expressed genes in cancer. Constellation's epigenetics platform includes a deep understanding of the biological contexts in which BET proteins operate, including cancer pathways that are highly sensitive to CPI-0610. The results from preclinical studies, as well as translational insights from the successful first-in-human study of CPI-0610, led to prioritizing the clinical development of CPI-0610 in myelofibrosis (MF). Enrollment is ongoing in the Phase 2 portion of the open-label Phase 1/2 MANIFEST clinical trial of CPI-0610, either as a monotherapy or in combination with ruxolitinib, in patients with MF who are refractory or intolerant or have relapsed or lost response to the standard of care. MANIFEST also includes a third cohort designed to evaluate treatment with CPI-0610 in combination with ruxolitinib as a first-line therapy in JAK 1/2-inhibitor-naïve MF patients. The company expects to determine proof of concept for CPI-0610 in MF in mid-2019.

About Constellation Pharmaceuticals

Constellation Pharmaceuticals is a clinical-stage biopharmaceutical company developing novel therapeutics that selectively modulate gene expression to

address serious unmet medical needs in patients with cancer. The Company has a deep understanding of how epigenetic and chromatin modifications in cancer cells and in the tumor and immune microenvironment play a fundamental role in driving disease progression and drug resistance. Constellation is driving development of the EZH2 inhibitors CPI-1205 and CPI-0209 for the treatment of metastatic castration-resistant prostate cancer and other cancers as well as the BET inhibitor CPI-0610 for the treatment of myelofibrosis. The Company is also applying its broad research and development capabilities to explore other novel targets that directly and indirectly impact gene expression to fuel a sustainable pipeline of innovative small-molecule product candidates.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties, including statements regarding the development status of the Company's product candidates, the anticipated benefits of the changes to its clinical trial protocols and its anticipated achievement of milestones, including determination of proof of concept. All statements, other than statements of historical facts, contained in this press release, including statements regarding the Company's strategy, future operations, future financial position, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in, or implied by, such forward-looking statements. These risks and uncertainties include, but are not limited to, risks associated with Constellation's ability to: obtain and maintain necessary approvals from the FDA and other regulatory authorities; continue to advance its product candidates in clinical trials; replicate in later clinical trials positive results found in preclinical studies and early-stage clinical trials of CPI-1205, CPI-0610 and its other product candidates; advance the development of its product candidates under the timelines it anticipates, or at all, in current and future clinical trials; obtain, maintain or protect intellectual property rights related to its product candidates; manage expenses; and raise

the substantial additional capital needed to achieve its business objectives. For a discussion of other risks and uncertainties, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, see the "Risk Factors" section, as well as discussions of potential risks, uncertainties, and other important factors, in the Company's most recent filings with the Securities and Exchange Commission. In addition, the forward- looking statements included in this press release represent the Company's views as of the date hereof and should not be relied upon as representing the Company's views as of any date subsequent to the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. CPI-1205, CPI-0610, CPI-0209, and other product candidates are investigational in nature and have not yet been approved by the FDA or other regulatory authorities.

Jakafi® is a registered trademark of Incyte Corporation.

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