

CTI BIOPHARMA CORP
Form 8-K
November 26, 2018

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 26, 2018

CTI BIOPHARMA CORP.

(Exact name of registrant as specified in its charter)

Delaware 000-28386 91-1533912
(State or other jurisdiction (Commission (I.R.S. Employer
of incorporation or organization) File Number) Identification Number)
3101 Western Avenue, Suite 800
Seattle, Washington 98121
(Address of principal executive offices)
Registrant's telephone number, including area code: (206) 282-7100
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 8.01 Other Events.

As disclosed in its periodic filings, CTI BioPharma Corp. (the “Company”) previously submitted to the European Medicines Agency (“EMA”) a marketing authorization application (“MAA”) for its primary development candidate, pacritinib. The Company received a second round of questions relating to the Day 180 List of Outstanding Issues for the MAA and the Company plans to submit responses to the EMA, which will include data from the ongoing open label PAC203 trial, by the end of the year. In addition, the Company is preparing for an Oral Explanation meeting before the Committee for Medicinal Products for Human Use (“CHMP”). A decision by CHMP on the MAA is expected in the first quarter of 2019.

On November 26, 2018, the Company issued a press release regarding these matters. A copy of the press release is attached as Exhibit 99.1 to this current report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Description

99.1 Press Release dated November 26, 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.

CTI BIOPHARMA CORP.

Date: November 26, 2018 By: /s/ David H. Kirske
David H. Kirske
Chief Financial Officer