CTI BIOPHARMA CORP
Form 8-K
January 25, 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): January 25, 2018

CTI BIOPHARMA CORP.
(Exact name of registrant as specified in its charter)

Delaware	001-12465	91-1533912
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer 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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 o
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. o

Item 8.01. Other Events.

On January 25, 2018, CTI BioPharma Corp. (the "Company") announced that the Company was granted a three month extension for submitting its response to the Day 120 List of Questions (D120 LoQ) from the Committee for Medicinal Products for Human Use (CHMP) of the EMA, with regard to the Marketing Authorization Application (MAA) for pacritinib. As a result of the extension, the Company anticipates submitting its response to the D120 LoQ by May 2018. The Company primarily requested the extension in order to provide the EMA with new pharmacokinetic analyses that include data from the ongoing phase 2 PAC203 study. The MAA was originally submitted to the EMA in June 2017 based on data from the PERSIST-2 phase 3 study. The Day 120 LoQ were received by the Company in November 2017 and included Major Objections in areas including efficacy, safety (including hematological, cardiovascular and infectious toxicities) and other concerns including the size of the data set and the pharmacokinetic analyses of the two dosing regimens studied in PERSIST-2. The extension request was submitted following a clarification meeting with the rapporteur and co-rapporteur and members of the EMA.

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: January 25, 2018 By: /s/ David H. Kirske
David H. Kirske
Chief Financial Officer