
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): August 2, 2018

CTI BIOPHARMA CORP.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-12465
(Commission
File Number)

91-1533912
(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:

- 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 or Rule 12b-2 of the Securities Exchange Act of 1934.
 - 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 2.02. Results of Operations and Financial Condition.

On August 2, 2018, CTI BioPharma Corp. issued a press release announcing its financial results for the quarter ended June 30, 2018 and certain other information. The full text of the press release is set forth in Exhibit 99.1 hereto. The information in this Current Report on Form 8-K and the attached exhibit are furnished to, but not filed with, the Securities and Exchange Commission.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Pursuant to the rules and regulations of the Securities and Exchange Commission, the attached exhibit is deemed to have been furnished to, but not filed with, the Securities and Exchange Commission:

<u>Exhibit No.</u>	<u>Description</u>	<u>Location</u>
99.1	Press Release of CTI BioPharma Corp., dated August 2, 2018.	Furnished herewith.

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: August 2, 2018

By: _____
/s/ David H. Kirske
David H. Kirske
Chief Financial Officer



CTI BioPharma Reports Second Quarter 2018 Financial Results

-Management to Host Conference Call/ Webcast Today at 4:30 p.m. Eastern Time-

SEATTLE, August 2, 2018 - CTI BioPharma Corp. (NASDAQ:CTIC) today reported financial results for the second quarter and six months ended June 30, 2018.

In July 2018, CTI BioPharma announced the continuation without modification of the PAC203 Phase 2 study following a planned interim review by an Independent Data Monitoring Committee. The Company also announced a pacritinib program update following a Type B meeting with the U.S. Food and Drug Administration (FDA) and announced a plan to conduct a new, randomized, Phase 3 study of pacritinib in patients with myelofibrosis. The Company has recently received the Day 180 List of Outstanding Issues from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) regarding the marketing authorization application (MAA) for pacritinib. Following the recently reported results from the PIX306 study, the Company is conducting a review of the clinical study data to assess the next steps for the PIXUVRI® program.

Upcoming Milestones

- In the third quarter of 2018, a second interim analysis of the PAC203 study of pacritinib in patients with myelofibrosis will be conducted by an Independent Data Monitoring Committee. PAC203 is expected to complete enrollment in the fourth quarter of 2018. Full top-line data from the study is expected in the second quarter of 2019.
- The Company has been granted a two month extension for submitting the responses to the Day 180 List of Outstanding Issues. The extension will allow CTI to submit clinical data from PAC203 for review by the EMA. Given this extension, the CHMP opinion on the MAA is now expected in the fourth quarter of 2018.

“We believe we have now re-established a collaborative relationship with the FDA and have received greater clarity on the development path for pacritinib in the U.S.,” commented Adam R. Craig, M.D., Ph.D., President and Chief Executive Officer of CTI BioPharma. “We plan to request a meeting with the FDA following the second interim analysis of PAC203 data with a meeting expected in the fourth quarter of 2018. The purpose of the meeting will be to discuss the interim data and to review the design of a registrational Phase 3 trial. We expect that this trial will begin in 2019, once the optimal dose of pacritinib has been confirmed using all pharmacokinetic, efficacy and safety data from the PAC203 study.”

“In Europe, we continue to make progress with our marketing authorization application (MAA) and have now received the Day 180 List of Outstanding Issues report. The EMA has expressed interest in the emerging data from the PAC203 study, so the two month extension granted by CHMP will allow us to submit additional PAC203 data for review as part of our Day 180 responses.”

Second Quarter Financial Results

Total revenues for the second quarter and six months ended June 30, 2018 were \$0.6 million and \$11.1 million, respectively, compared to \$22.2 million and \$23.0 million for the respective periods in 2017. The decrease in total revenues for the second quarter in 2018 compared to the same period in 2017 is primarily due to license and contract revenue that included the recognition of payments received from the expansion of the license and collaboration agreement for PIXUVRI® with Servier in 2017 as well as the receipt of a payment from Teva Pharmaceutical Industries Ltd. related to the achievement of a sales milestone for TRISENOX® (arsenic trioxide) in 2017. The decrease in total revenues for the six months ended June 30, 2018, compared to the same period in 2017 is primarily due to license and contract revenue that included the recognition of payments received from the expansion of the license and collaboration agreement for PIXUVRI® with Servier in 2017.

GAAP operating loss was \$14.0 million and \$18.3 million for the second quarter and six months ended June 30, 2018, respectively, compared to GAAP operating income of \$5.3 million and GAAP operating loss of \$14.0 million for the respective periods in 2017. Non-GAAP operating loss, which excludes non-cash share-based compensation expense, for the second quarter and six months ended June 30, 2018 was \$13.0 million and \$16.0 million, respectively, compared to non-GAAP operating income of \$6.4 million and non-GAAP operating loss of \$11.1 million for the respective periods in 2017. Non-cash share-based compensation expense for the second quarter and six months ended June 30, 2018, was \$1.0 million and \$2.4 million, respectively, compared to \$1.1 million and \$2.9 million for the respective periods in 2017. Operating loss in the second quarter of 2018 as compared to an operating income for the same period in 2017 resulted primarily from the decrease in license and contract revenue as mentioned above and a decrease in selling, general and administrative expenses. Operating loss for the six months ended June 30, 2018, compared to the same period in 2017 resulted primarily from the decrease in license and contract revenue as mentioned above and a decrease in selling, general and administrative expenses. For information on CTI BioPharma’s use of non-GAAP operating loss and a reconciliation of such measure to GAAP operating loss, see the section below titled “Non-GAAP Financial Measures.”

Net loss for the second quarter of 2018 was \$11.3 million, or \$(0.20) per share, compared to a net income of \$1.0 million, or \$0.03 per share, for the same period in 2017. Net loss for six months ended June 30, 2018, was \$15.4 million, or \$(0.29) per share, compared to a net loss of \$18.8 million, or \$(0.63) per share, for the same period in 2017.

As of June 30, 2018, cash, cash equivalents and short-term investments totaled \$92.8 million, compared to \$43.2 million as of December 31, 2017.

Conference Call Information

CTI BioPharma management will host a conference call to review its second quarter 2018 financial results and provide an update on business activities. The event will be held today at 1:30 p.m. PT / 4:30 p.m. ET. Participants can access the call at 877-260-1479 (domestic) or +1 334-323-0522 (international). To access the live audio webcast or the subsequent archived recording, visit www.ctibiopharma.com. Webcast and telephone replays of the conference call will be available approximately two hours after completion of the call. Callers can access the replay by dialing 1-888-203-1112 (domestic) or +1 719-457-0820 (international). The access code for the replay is 3255708. The telephone replay will be available until August 9, 2018.

About CTI BioPharma Corp.

CTI BioPharma Corp. is a biopharmaceutical company focused on the acquisition, development and commercialization of novel targeted therapies covering a spectrum of blood-related cancers that offer a unique benefit to patients and healthcare providers. The CTI BioPharma lead product candidate, pacritinib, is being developed for the treatment of patients with myelofibrosis. CTI BioPharma is headquartered in Seattle, Washington.

Non-GAAP Financial Measures

CTI BioPharma has provided in this press release the historical non-GAAP financial measure of operating loss, excluding non-cash share-based compensation expense, for the second quarter and six months ended June 30, 2018 and 2017. Due to varying available valuation methodologies, subjective assumptions and the different GAAP accounting treatment of different award types that companies can use under ASC Topic 718, CTI BioPharma's management believes that providing a non-GAAP financial measure that excludes non-cash share-based compensation expense can enhance management's and investors' comparison of CTI BioPharma's operating results over different periods of time as compared to the operating results of other companies.

CTI BioPharma's use of a non-GAAP financial measure has limitations and should not be considered in isolation from, or as a substitute for, financial information prepared in accordance with GAAP. One limitation is that CTI BioPharma's reported non-GAAP operating loss in 2018 results in the exclusion of a recurring expense, since CTI BioPharma expects that share-based compensation will continue to be a significant recurring expense in CTI BioPharma's business. A second limitation is that CTI BioPharma's methodology for calculating non-GAAP operating loss, which only excludes the component of share-based compensation, may differ from the methodology CTI BioPharma's peer companies utilize to the extent they report non-GAAP operating income or similarly titled measures. Accordingly, CTI BioPharma's non-GAAP operating loss may not necessarily be comparable to similarly titled measures of other companies. Investors are urged to review the reconciliation of these non-GAAP measures to their most directly comparable GAAP financial measures. A reconciliation of CTI BioPharma's non-GAAP financial measures to the most directly comparable GAAP measures has been provided in the financial statement tables included below in this press release.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These forward-looking statements include statements regarding our expectations regarding, the timing of and results from clinical trials and pre-clinical development activities related to pacritinib, the potential efficacy, safety profile, future development plans, addressable market, regulatory success and commercial potential of pacritinib, the anticipated timing of regulatory submissions, the efficacy of, and potential changes to, our clinical trial designs and anticipated enrollment, our ability to successfully develop and achieve milestones in the development of pacritinib, and the anticipated benefits of pacritinib. These forward-looking statements are based on current assumptions that involve risks, uncertainties and other factors that may cause the actual results, events or developments to be materially different from those expressed or implied by such forward-looking statements. These risks and uncertainties, many of which are beyond our control, include, but are not limited to: clinical trials may not demonstrate safety and efficacy of any of our or our collaborators' product candidates; our assumptions regarding our planned expenditures and sufficiency of our cash to fund operations may be incorrect; our efforts to advance our pipeline may not be successful; any of our or our collaborators' product candidates may fail in development, may not receive required regulatory approvals, or may be delayed to a point where they are not commercially viable; we may not achieve additional milestones in our proprietary or partnered programs; the impact of competition; the impact of expanded product development and clinical activities on operating expenses; adverse conditions in the general domestic and global economic markets; as well as the other risks identified in our filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof and we assume no obligation to update these forward-looking statements, and readers are cautioned not to place undue reliance on such forward-looking statements.

“CTI BioPharma” and the CTI BioPharma logo are registered trademarks or trademarks of CTI BioPharma Corp. in various jurisdictions. All other trademarks belong to their respective owner.

###

CTI BioPharma Investor Contacts:

Julia Balanova (investors)

+1 646 378 2936

jbalanova@troutgroup.com

Rich Allan (media)

+1 646-378-2958

rallan@troutgroup.com

CTI BioPharma Corp.
Condensed Consolidated Statements of Operations
(In thousands, except per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenues:				
Product sales, net	\$ —	\$ 211	\$ —	\$ 837
License and contract revenue	613	22,014	11,090	22,142
Total revenues	613	22,225	11,090	22,979
Operating costs and expenses:				
Cost of product sold	588	78	678	211
Research and development	9,124	8,914	18,809	18,167
Selling, general and administrative	4,865	7,962	10,274	18,650
Other operating expense (income)	37	—	(334)	—
Total operating costs and expenses, net	14,614	16,954	29,427	37,028
(Loss) income from operations	(14,001)	5,271	(18,337)	(14,049)
Non-operating (expense) income:				
Interest expense	(297)	(488)	(585)	(1,022)
Amortization of debt discount and issuance costs	(130)	(37)	(264)	(75)
Foreign exchange (loss) gain	(1,575)	657	(852)	614
Other non-operating income (expense)	4,659	(30)	4,659	(30)
Total non-operating income (expense), net	2,657	102	2,958	(513)
Net (loss) income before noncontrolling interest	(11,344)	5,373	(15,379)	(14,562)
Noncontrolling interest	8	25	22	132
Net (loss) income	(11,336)	5,398	(15,357)	(14,430)
Deemed dividends on preferred stock	—	(4,350)	(80)	(4,350)
Net (loss) income attributable to common stockholders	\$ (11,336)	\$ 1,048	\$ (15,437)	\$ (18,780)
Net (loss) income per common share:				
Basic	\$ (0.20)	\$ 0.03	\$ (0.29)	\$ (0.63)
Diluted	\$ (0.20)	\$ 0.03	\$ (0.29)	\$ (0.63)
Shares used in calculation of (loss) income per common share:				
Basic	57,941	31,725	54,148	29,895
Diluted	57,941	31,901	54,148	29,895

Balance Sheet Data (unaudited):

	(amounts in thousands)	
	June 30, 2018	December 31, 2017
Cash, cash equivalents and restricted cash	\$ 65,374	\$ 43,218
Short-term investments	27,450	—
Working capital	72,818	27,666
Total assets	102,586	54,886
Current portion of long-term debt	2,590	444
Long-term debt, less current portion	11,673	13,575
Total stockholders' equity	63,648	16,090

Non-GAAP Reconciliations
(In thousands)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
As reported - (loss) income from operations (GAAP)	\$ (14,001)	\$ 5,271	\$ (18,337)	\$ (14,049)
As reported - share-based compensation expense (GAAP)	1,040	1,149	2,376	2,948
As adjusted - loss from operations (Non-GAAP)	\$ (12,961)	\$ 6,420	\$ (15,961)	\$ (11,101)