



CTI BioPharma Reports Third Quarter 2018 Financial Results

November 1, 2018

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

SEATTLE, Nov. 1, 2018 /PRNewswire/ -- CTI BioPharma Corp. (NASDAQ:CTIC) today reported financial results for the third quarter and nine months ended September 30, 2018.

In October 2018, CTI BioPharma announced the continuation of the PAC203 Phase 2 study without modification, following a planned second interim review by an Independent Data Monitoring Committee (IDMC). The IDMC did not identify significant drug- or dose-related safety concerns and specifically did not identify any concerns around hemorrhagic or cardiac toxicity. A complete dataset from the full enrollment of 150 patients (including efficacy, safety, pharmacokinetic and pharmacodynamic data) will now be used to determine the optimal dose of pacritinib for further clinical development. The PAC203 study is expected to complete enrollment by the end of 2018, with the next planned interim safety review to be conducted in the first quarter of 2019. Top-line data from the study are expected in the second quarter of 2019. The Company has scheduled a Type C meeting with the U.S. Food and Drug Administration (FDA) to take place before the end of the year to discuss the design of a new registrational Phase 3 study of pacritinib in myelofibrosis patients with severe thrombocytopenia (platelet counts of less than 50,000 per microliter). Following the identification of the optimal dose from the PAC203 study, the Company expects to begin Phase 3 patient recruitment mid-year in 2019.

In the third quarter of 2018, the Company submitted comprehensive responses to the Day 180 List of Outstanding Issues from the European Medicines Agency (EMA) regarding the marketing authorization application (MAA) for pacritinib. These responses include new data from the PAC203 trial. The Company expects an opinion from the EMA Committee for Medicinal Products for Human Use (CHMP) on the MAA for pacritinib by the end of 2018.

"We continue to progress with pacritinib development and look forward to our meeting with the FDA to discuss the design of a registrational Phase 3 trial expected to address the needs of myelofibrosis patients with severe thrombocytopenia," commented Adam R. Craig, M.D., Ph.D., President and Chief Executive Officer of CTI BioPharma. "Regarding PAC203, we expect to determine the optimal dose of pacritinib in the first half of 2019 and initiate patient recruitment for the Phase 3 trial in mid-2019, adapting the PAC203 study from a Phase 2 to a Phase 3."

Third Quarter Financial Results

Total revenues for the third quarter and nine months ended September 30, 2018, were \$0.7 million and \$11.8 million, respectively, compared to \$1.7 million and \$24.7 million for the respective periods in 2017. The decrease in total revenues for the third quarter in 2018 compared to the same period in 2017 is primarily due to the recognition of license and contract revenue in 2017 related to the achievement of a regulatory milestone under the license and collaboration agreement for PIXUVRI[®] with Servier. The decrease in total revenues for the nine months ended September 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 \$14.8 million and \$33.1 million for the third quarter and nine months ended September 30, 2018, respectively, compared to GAAP operating loss of \$11.8 million and \$25.8 million for the respective periods in 2017. Non-GAAP operating loss, which excludes non-cash share-based compensation expense, for the third quarter and nine months ended September 30, 2018, was \$12.2 million and \$28.2 million, respectively, compared to non-GAAP operating loss of \$10.4 million and \$21.5 million for the respective periods in 2017. Non-cash share-based compensation expense for the third quarter and nine months ended September 30, 2018, was \$2.5 million and \$4.9 million, respectively, compared to \$1.4 million and \$4.3 million for the respective periods in 2017. Operating loss in the third quarter of 2018 as 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. Operating loss for the nine months ended September 30, 2018, as compared to the same period in 2017 resulted primarily from the decrease in license and contract revenue as mentioned above and an increase in research and development 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 attributable to common stockholders for the third quarter of 2018 was \$14.8 million, or \$(0.26) per share, compared to \$12.0 million, or \$(0.28) per share, for the same period in 2017. Net loss attributable to common stockholders for the nine months ended September 30, 2018, was \$30.2 million, or \$(0.55) per share, compared to a net loss of \$30.8 million, or \$(0.90) per share, for the same period in 2017.

As of September 30, 2018, cash, cash equivalents and short-term investments totaled \$80.9 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 third 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 4559931. The telephone replay will be available until November 8, 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 third quarter and nine months ended September 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 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 and our interactions with regulators, the efficacy of, and potential changes to, our clinical trial designs and anticipated enrollment, including timing thereof, 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 the development of pacritinib 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.

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Revenues:				
Product sales, net	\$ —	\$ —	\$ —	\$ 853
License and contract revenue	723	1,705	11,813	23,831
Total revenues	<u>723</u>	<u>1,705</u>	<u>11,813</u>	<u>24,684</u>
Operating costs and expenses:				
Cost of product sold	114	69	792	280
Research and development	9,730	7,601	28,539	25,768
Selling, general and administrative	5,649	5,802	15,923	24,452
Other operating income	—	—	(334)	—
Total operating costs and expenses, net	<u>15,493</u>	<u>13,472</u>	<u>44,920</u>	<u>50,500</u>
Loss from operations	(14,770)	(11,767)	(33,107)	(25,816)
Non-operating income (expense):				
Interest income	436	—	800	—
Interest expense	(308)	(457)	(893)	(1,479)

Amortization of debt discount and issuance costs	(130)	(38)	(394)	(113)
Foreign exchange (loss) gain	(46)	161	(898)	775
Other non-operating income	—	102	4,295	72
Total non-operating (expense) income, net	(48)	(232)	2,910	(745)
Net loss before noncontrolling interest	(14,818)	(11,999)	(30,197)	(26,561)
Noncontrolling interest	9	25	31	157
Net loss	(14,809)	(11,974)	(30,166)	(26,404)
Deemed dividends on preferred stock	—	—	(80)	(4,350)
Net loss attributable to common stockholders	\$ (14,809)	\$ (11,974)	\$ (30,246)	\$ (30,754)
Basic and diluted net loss per common share	\$ (0.26)	\$ (0.28)	\$ (0.55)	\$ (0.90)
Shares used in calculation of basic and diluted net loss per common share	57,964	42,878	55,434	34,270

Balance Sheet Data (unaudited):

	(amounts in thousands)	
	September 30, 2018	December 31, 2017
Cash, cash equivalents and restricted cash	\$ 52,911	\$ 43,218
Short-term investments	28,005	—
Working capital	59,303	27,666
Total assets	89,629	54,886
Current portion of long-term debt	3,923	444
Long-term debt, less current portion	10,470	13,575
Total stockholders' equity	51,362	16,090

Non-GAAP Reconciliations
(In thousands)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
As reported - loss from operations (GAAP)	\$ (14,770)	\$ (11,767)	\$ (33,107)	\$ (25,816)
As reported - share-based compensation expense (GAAP)	2,528	1,355	4,904	4,303
As adjusted - loss from operations (Non-GAAP)	\$ (12,242)	\$ (10,412)	\$ (28,203)	\$ (21,513)



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