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Oggetto : CTI BIOPHARMA REPORTS FOURTH  
QUARTER AND FULL YEAR 2014  
FINANCIAL RESULTS

*Testo del comunicato*

Vedi allegato.



## CTI BIOPHARMA REPORTS FOURTH QUARTER AND FULL YEAR 2014 FINANCIAL RESULTS

- Positive Top-Line Results from PERSIST-1 Phase 3 Study of Pacritinib in Patients with Myelofibrosis -

- PIXUVRI Receives Reimbursement in Spain -

- Total Revenues for Full Year 2014 Reach \$60.1 Million -

- Conference Call Scheduled for Today at 4:30 p.m. Eastern Time -

**SEATTLE, Wash., March 12, 2015**—CTI BioPharma Corp. (NASDAQ and MTA: CTIC) today reported financial results for the fourth quarter and full year ended December 31, 2014.

*“In 2014, we successfully accomplished various key company objectives, from achieving reimbursement in England/Wales and securing a development and commercialization collaboration for PIXUVRI<sup>®</sup>, to pacritinib receiving Fast Track designation by the U.S. FDA and reporting on data highlighting pacritinib’s potential therapeutic utility in blood-related cancer indications beyond myelofibrosis,” said James A. Bianco, M.D., CTI BioPharma’s President and CEO. “Now, with positive top-line pacritinib data in hand, we look forward to building on this momentum as we set our sights on completing the second pacritinib Phase 3 trial and potentially starting a regulatory submission as early as late in 2015. We are committed to bringing this new treatment option to patients with myelofibrosis as soon as possible.”*

### Recent Highlights

#### Pacritinib:

- In March 2015, reported top-line results for the primary endpoint from the PERSIST-1 Phase 3 clinical trial of pacritinib for the treatment of patients with myelofibrosis. The trial met its primary endpoint in the intent-to-treat population with statistically significant activity observed in patients irrespective of their initial platelet count, including patients with very low platelet counts at study entry. The primary endpoint of the trial was the proportion of patients achieving a 35 percent or greater reduction in spleen volume from baseline to Week 24 as measured by magnetic resonance imaging (MRI) or computerized tomography (CT) when compared with physician-specified best available therapy (BAT), excluding treatment with JAK2 inhibitors.
- In December 2014, announced presentation of pacritinib data at the American Society of Hematology Annual Meeting. A pre-clinical study demonstrated a unique kinome profile for pacritinib among agents in development for myelofibrosis and suggests potential therapeutic benefit across a spectrum of blood-related cancers such as acute myeloid leukemia (AML), myelodysplastic syndromes (MDS), chronic myelomonocytic leukemia (CMML) and chronic lymphocytic leukemia (CLL). A separate pre-clinical study presented showed that pacritinib overrides stromal mediated resistance in FLT3-ITD positive AML cells, which is believed to be an important mechanism of resistance to other FLT3 antagonists in treating AML.

#### PIXUVRI:

- In February 2015, The Spanish Directorate General of Pharmacy and Health Products, part of the Spanish Ministry of Health, approved the reimbursement of PIXUVRI (pixantrone) for the treatment of patients with aggressive B-cell non-Hodgkin lymphoma (NHL). PIXUVRI will be included in the national list of available reimbursed products commencing March 1, 2015. CTI BioPharma’s partner, Servier, holds the commercialization

rights to PIXUVRI and will be responsible for the launch of the drug in Spain. As a result of such reimbursement approval in Spain, CTI BioPharma received a €1.5 million milestone payment from Servier.

Corporate:

- In January 2015, appointed Alan K. Burnett, M.D., to serve as the strategic leader for myeloid development. Dr. Burnett most recently served as Professor and Head of the Department of Haematology in the Institute of Cancer and Genetics at Cardiff University and is highly regarded internationally for his work in the treatment of AML and MDS.

## 2015 Key Objectives

### Pacritinib

- **Report PERSIST-1 top-line results.** As discussed above, CTI BioPharma achieved its previously stated objective of reporting top-line results from the PERSIST-1 pivotal Phase 3 trial of pacritinib for patients with myelofibrosis.
- **Commence regulatory submission.** CTI BioPharma plans to possibly commence a regulatory submission to the U.S. Food and Drug Administration (FDA) and/or European Medicines Agency (EMA) as early as late in 2015.
- **Initiate trial in second indication.** CTI BioPharma intends to advance a pacritinib development program in other hematologic malignancies in collaboration with Baxter International, Inc. (Baxter) by year-end 2015.

### PIXUVRI (pixantrone)

- **Complete enrollment in PIX306.** CTI BioPharma expects to complete enrollment in the PIX306 post-marketing commitment Phase 3 study of PIXUVRI in the fourth quarter of 2015. If the results from this trial are positive, CTI BioPharma expects to seek conversion of the existing conditional marketing authorization to full marketing authorization in the E.U. and pursue a potential extension of label to second-line combination therapy.
- **Initiate additional studies.** CTI BioPharma and Servier plan to collaborate to support the initiation of investigator-sponsored combination trials in other indications.

### Tosedostat

- **Report on Phase 2 trial.** CTI BioPharma anticipates reporting an update from an investigator-sponsored randomized Phase 2 trial of tosedostat in combination with low-dose cytarabine in older patients with AML or high-risk MDS.
- **Define registrational path.** Depending upon the clinical data for tosedostat in AML and MDS, CTI BioPharma plans to consult with the FDA and the European Medicines Agency regarding a registrational strategy for this product candidate. If positive, these discussions could enable the initiation of a pivotal program in AML in early 2016.

## Fourth Quarter and Full Year Financial Results

Total revenues for the fourth quarter and the full year ended December 31, 2014, were \$17.8 million and \$60.1 million, respectively, compared to \$32.9 million and \$34.7 million for the same periods in 2013. For the fourth quarter and full year 2014, net product revenues of PIXUVRI were \$2.5 million and \$6.9 million, respectively, compared to \$0.5 million and \$2.3 million for the same periods in 2013. Total revenues for the full year 2014 included license and contract revenue of \$53.2 million, which was primarily attributed to the following: \$20.0 million development milestone payment received from Baxter for completion of enrollment in the PERSIST-1 Phase 3 clinical trial of pacritinib, recognition of \$17.3 million from an upfront payment under the PIXUVRI collaboration agreement with Servier and \$15.0 million in sales milestones related to TRISENOX<sup>®</sup> (arsenic trioxide) from Teva Pharmaceutical Industries Ltd. The decrease in fourth quarter 2014 license and contract revenues compared to the same period in 2013 relates to an upfront payment from Baxter upon entering into a license and collaboration agreement for pacritinib in 2013.

The non-GAAP operating loss, which excludes non-cash share-based compensation expense, for the fourth quarter of 2014 was \$36.2 million, compared to non-GAAP operating income of \$13.1 million for the same period in 2013. The GAAP operating loss for the fourth quarter of 2014 was \$39.4 million, compared to a GAAP operating income of \$10.3 million for the same period in 2013. The increase in operating loss for the fourth quarter 2014 compared to the same period in 2013 was primarily due to the acquired in process research and development associated with the acquisition of

certain assets related to tosedostat from Chroma in 2014 in addition to the upfront payment received from BAXTER in 2013. For the full year ended December 31, 2014, the non-GAAP operating loss was \$66.0 million, compared to \$32.5 million for the same period in 2013. For the full year ended December 31, 2014, the GAAP operating loss was \$86.2 million, compared to \$41.5 million for the same period in 2013. Non-cash share-based compensation expense for the fourth quarter and full year 2014 was \$3.2 million and \$20.2 million, respectively, compared to \$2.7 million and \$9.1 million for the same periods in 2013. For information on CTI BioPharma's use of the aforementioned non-GAAP measure and a reconciliation of such measure to GAAP operating loss, see the section below entitled "Non-GAAP Financial Measures."

Net loss for the fourth quarter 2014 was \$44.2 million, or \$0.27 per share, compared to a net income of \$10.2 million, or \$0.08 per share, for the same period in 2013. Net loss for the full year 2014 was \$96.0 million, or \$0.65 per share, compared to \$49.6 million, or \$0.43 per share, for the same period in 2013.

As of December 31, 2014, cash and cash equivalents totaled \$70.9 million, compared to \$71.6 million as of December 31, 2013.

## **2015 Financial Outlook**

CTI BioPharma expects that total revenues for 2015 will be approximately \$50 million to \$55 million. CTI BioPharma expects that non-GAAP operating loss for 2015 will be approximately \$75 million to \$85 million, which excludes non-cash share-based compensation expense. These financial projections are primarily based upon current expectations regarding the following:

- Net product sales from PIXUVRI commercial operations;
- License and contract revenues under the agreements with Baxter, Servier and Teva;
- Research and Development expenses, including those relating to the advancement of PIXUVRI, ongoing and planned Phase 3 clinical trials involving pacritinib and investigator-sponsored trials involving PIXUVRI, pacritinib and tosedostat; and
- Selling, General and Administrative expenses, including programs for the hematologist/oncologist community to support the ongoing commercialization of PIXUVRI in the E.U.

Actual financial results for 2015 will vary based upon many factors, including the degree of market acceptance, reimbursement rates and sales of PIXUVRI in the applicable countries, the rate of patient enrollment and results of ongoing clinical trials, achievement of potential license and contract revenue under agreements with Baxter, Servier and Teva and other factors described in CTI BioPharma's filings with the Securities and Exchange Commission (SEC).

## **Information required by CONSOB pursuant to section 114, paragraph 5, of the Italian Legislative Decree no. 58/98**

### ***Report on possible failure to comply with covenants***

To the knowledge of CTI BioPharma's management, CTI BioPharma and its subsidiaries are in compliance with all covenants, negative pledges and other provisions concerning long-term debt.

### ***Business and financial plan***

CTI BioPharma's strategy is to become a leader in the acquisition, development and commercialization of novel therapeutics for the treatment of blood-related cancers. The key elements of CTI BioPharma's strategy to achieve this goal are to:

- **Successfully Commercialize PIXUVRI.** Together with Servier, CTI BioPharma intends to continue its efforts to build a successful PIXUVRI franchise in Europe as well as other markets. CTI BioPharma is currently focused on educating physicians on the unmet medical need and building brand awareness for PIXUVRI among physicians in the countries where PIXUVRI is available.
- **Develop Pacritinib in Myelofibrosis and Additional Indications.** Together with Baxter, CTI BioPharma intends to develop and commercialize pacritinib for adult patients with myelofibrosis. CTI BioPharma also intends to continue evaluation of pacritinib in other blood-related cancers, including AML and MDS, through ongoing and planned ISTs.
- **Continue to Develop Other Pipeline Programs.** CTI BioPharma believes that it is important to maintain a diverse pipeline to sustain its future growth. To accomplish this, CTI BioPharma intends to continue to advance the development of its other pipeline candidates through cooperative group sponsored trials and ISTs. CTI BioPharma believes that sponsoring such trials provides a more economical approach for further developing investigational products.
- **Evaluate Strategic Product Collaborations to Accelerate Development and Commercialization.** Where CTI BioPharma believes it may be beneficial, it intends to evaluate additional collaborations to broaden and accelerate clinical trial development and potential commercialization of product candidates. Collaborations have the potential to generate non-equity based operating capital, supplement internal expertise and provide access to the marketing, sales and distribution capabilities of its collaborators in specific territories.
- **Identify and Acquire Additional Pipeline Opportunities.** CTI BioPharma's current pipeline is the result of licensing and acquiring assets that it believes were initially undervalued opportunities. CTI BioPharma plans to continue to seek out additional product candidates in an opportunistic manner.

### Conference Call Information

CTI BioPharma management will host a conference call to review its fourth quarter and full year 2014 financial results and provide an update on business activities. The event will be held today at 1:30 p.m. PDT / 4:30 p.m. EDT / 9:30 p.m. CET. Participants can access the call at 1-888-572-7025 (domestic) or +1 719-325-2463 (international). To access the live audio webcast or the subsequent archived recording, visit CTI BioPharma's website, [www.ctibiopharma.com](http://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 3193570. The telephone replay will be available until Thursday, March 19, 2015.

### About CTI BioPharma Corp.

CTI BioPharma Corp. (NASDAQ and MTA: CTIC) 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. CTI BioPharma has a commercial presence in Europe and a late-stage development pipeline, including pacritinib, CTI BioPharma's lead product candidate, which is currently being studied in a Phase 3 program for the treatment of patients with myelofibrosis. CTI BioPharma is headquartered in Seattle, Washington, with offices in London and Milan under the name CTI Life Sciences Limited. For additional information and to sign up for email alerts and get RSS feeds, please visit [www.ctibiopharma.com](http://www.ctibiopharma.com).

### Non-GAAP Financial Measures

CTI BioPharma has provided in this press release the historical financial measure of loss from operations, excluding non-cash share-based compensation expense, which is a non-GAAP measure, for the fourth quarter and year ended December 31, 2014, and the financial projection of loss from operations, excluding non-cash share-based compensation expense, which is a non-GAAP measure, for the 2015 fiscal year. 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 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 loss from operations results in the exclusion of a recurring expense, since 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 loss from operations, 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 loss from operations or similarly titled measures and accordingly 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 their most directly comparable GAAP measures has been provided in the financial statement tables included below in this press release.

CTI BioPharma has not included a reconciliation of its projected non-GAAP loss from operations to a projected GAAP loss from operations because the calculation of the excluded share-based compensation would require information that is presently uncertain, such as the future level of additional equity awards that will be granted to meet CTI BioPharma's compensation philosophy and objectives after taking into account the economic climate at the time of grant. In addition, the calculation is largely based on the price of CTI BioPharma's stock at the time of the specific grants (as required under ASC Topic 718), which price is variable and therefore unknowable until the grant is made. Because of the contingent nature of such factors, CTI BioPharma believes that the specific adjustment for future share-based compensation cannot be forecast with accuracy.

PIXUVRI is a registered trademark of CTI BioPharma Corp.

Source: CTI BioPharma Corp.

### **Forward-Looking Statements**

This press release includes forward-looking statements within the meaning of the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995. Such statements are subject to a number of risks and uncertainties, the outcome of which could materially and/or adversely affect actual future results and the trading price of CTI BioPharma's securities. Such statements include, but are not limited to, statements regarding CTI BioPharma's expectations with respect to the development of CTI BioPharma and its product and product candidate portfolio, pacritinib's potential therapeutic utility in blood-related cancer indications beyond myelofibrosis, the anticipated completion of enrollment in PERSIST-2, potentially starting a regulatory submission for pacritinib as early as late in 2015, the advancement of a pacritinib development program in other hematologic malignancies in the second half of 2015, enrollment projections and expected outcome of the PIX306 post-marketing commitment study, intent to seek conversion of existing conditional marketing authorization to full marketing authorization for PIXUVRI, intent to pursue potential label extensions and initiate additional studies in other indications in PIXUVRI, the anticipated reporting of an update from a Phase 2 trial of tosedostat and the development of a registrational strategy and development program for tosedostat, CTI BioPharma's ability to achieve its articulated 2015 business and financial plan, goals, objectives and projections, CTI BioPharma's projected revenues and non-GAAP operating loss and the expectations and assumption on which they are based and the ability to successfully commercialize PIXUVRI in the manner projected. In particular, this release addresses top line results regarding primary endpoints of the PERSIST-1 study, and should be evaluated together with secondary endpoints, safety and additional data once such data has been more fully analyzed and is made publicly available. The statements are based on assumptions about many important factors and information currently available to us to the extent we have thus far had an opportunity to fully and carefully evaluate such information in light of all surrounding facts, circumstances, recommendations and analyses. Risks that contribute to the uncertain nature of the forward-looking statements include, among others, risks associated with the biopharmaceutical industry in general and with CTI BioPharma and its product and product candidate portfolio in particular including, among others, risks associated with the following: that CTI BioPharma cannot predict or guarantee the pace or geography of enrollment of its clinical trials, that CTI BioPharma

cannot predict or guarantee the outcome of preclinical and clinical studies, that top-line results observed to date may differ from future results or that difference conclusions or considerations may qualify such results once existing data has been more fully evaluated, clinical trial results, that CTI BioPharma may not obtain favorable determinations by other regulatory, patent and administrative governmental authorities, that CTI BioPharma may experience delays in the commencement of preclinical and clinical studies, risks related to the costs of developing pacritinib and CTI BioPharma's other product candidates, and other risks, including, without limitation, competitive factors, technological developments, that CTI BioPharma may not be able to sustain its current cost controls or further reduce its operating expenses, that CTI BioPharma may not achieve previously announced goals, contractual milestones and objectives as or when projected, that CTI BioPharma's average net operating burn rate may increase, that CTI BioPharma will continue to need to raise capital to fund its operating expenses, but may not be able to raise sufficient amounts to fund its continued operation as well as other risks listed or described from time to time in CTI BioPharma's most recent filings with the SEC on Forms 10-K, 10-Q and 8-K. Except as required by law, CTI BioPharma does not intend to update any of the statements in this press release upon further developments.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2014	2013	2014	2013
<b>Revenues:</b>				
Product sales, net	\$ 2,472	\$ 520	\$ 6,909	\$ 2,314
License and contract revenue	15,317	32,364	53,168	32,364
Total revenues	17,789	32,884	60,077	34,678
<b>Operating costs and expenses:</b>				
Cost of product sold	296	33	895	137
Research and development	21,871	10,004	64,596	33,624
Selling, general and administrative	13,137	12,514	56,241	42,288
Acquired in-process research and development	21,859	—	21,859	—
Settlement expense	—	—	—	155
Other operating expense	—	—	2,719	—
Total operating costs and expenses	57,163	22,551	146,310	76,204
Income (loss) from operations	(39,374)	10,333	(86,233)	(41,526)
<b>Non-operating income (expense):</b>				
Interest expense	(544)	(346)	(1,947)	(1,026)
Amortization of debt discount and issuance costs	(182)	(164)	(729)	(513)
Foreign exchange gain (loss)	(1,814)	260	(4,435)	61
Other non-operating expense	—	(113)	(885)	(546)
Net income (loss) before noncontrolling interest	(41,914)	9,970	(94,229)	(43,550)
Noncontrolling interest	345	226	862	807
Net income (loss) attributable to CTI	(41,569)	10,196	(93,367)	(42,743)
Deemed dividends on preferred stock	(2,625)	—	(2,625)	(6,900)
Net income (loss) attributable to CTI common shareholders	\$ (44,194)	\$ 10,196	\$ (95,992)	\$ (49,643)
<b>Net income (loss) per common share:</b>				
Basic	\$ (0.27)	\$ 0.08	\$ (0.65)	\$ (0.43)
Diluted	\$ (0.27)	\$ 0.08	\$ (0.65)	\$ (0.43)
<b>Shares used in calculation of earnings (loss) per common share:</b>				
Basic	162,211	131,127	148,531	114,195
Diluted	162,211	132,711	148,531	114,195

Balance Sheet Data (unaudited):

	(amounts in thousands) December 31,	
	2014	2013
Cash and cash equivalents	\$ 70,933	\$ 71,639
Working capital	44,165	60,446
Total assets	92,287	93,723
Current portion of long-term debt	9,014	3,155
Long-term debt, less current portion	8,363	10,152
Total shareholders' equity	38,478	42,758



Non-GAAP Reconciliations  
(In thousands)  
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2014	2013	2014	2013
As reported - income (loss) from operations (GAAP)	\$ (39,374)	\$ 10,333	\$ (86,223)	\$ (41,526)
As reported - share-based compensation expense (GAAP)	3,174	2,742	20,196	9,066
As adjusted - income (loss) from operations (Non-GAAP)	<u>\$ (36,200)</u>	<u>\$ 13,075</u>	<u>\$ (66,027)</u>	<u>\$ (32,460)</u>

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