| Informazione Regolamentata n. 0696-89-2015 | Data/Ora Ricezione 06 Agosto 2015 22:02:26 | MTA |
|---|---|---|

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|---|---|---|
| Societa' | : | CTI BIOPHARMA |
| Identificativo Informazione Regolamentata | : | 62023 |
| Nome utilizzatore | : | CELLN02 - Villa |
| Tipologia | : | IRAG 03 |
| Data/Ora Ricezione | : | 06 Agosto 2015 22:02:26 |
| Data/Ora Inizio Diffusione presunta | : | 06 Agosto 2015 22:17:27 |
| Oggetto | : | CTI BioPharma Corp.: CTI BIOPHARMA REPORTS SECOND QUARTER 2015 FINANCIAL RESULTS |

*Testo del comunicato*

Vedi allegato.

# CTI BIOPHARMA REPORTS SECOND QUARTER 2015 FINANCIAL RESULTS

*- Positive Phase 3 Results for Pacritinib Demonstrating Significant Clinical Benefit in Patients with Myelofibrosis Presented at ASCO and EHA -*
*- Conference Call Scheduled for Today at 4:30 p.m. Eastern Time -*

**SEATTLE, Wash., August 6, 2015**–CTI BioPharma Corp. (NASDAQ and MTA: CTIC) today reported financial results for the second quarter ended June 30, 2015.

*"The significant interest from the oncology community generated by the Phase 3 PERSIST-1 clinical data, presented at the ASCO and EHA conferences, supports our belief that there remains a significant unmet medical need for patients with myelofibrosis and that pacritinib may play an important role in addressing the current treatment gaps for this disease," said James A. Bianco, M.D., CTI BioPharma's President and CEO. "Armed with these positive data from the PERSIST-1 trial, our efforts are now directed toward exploring potential regulatory pathways in the U.S., while our partner Baxalta expects to submit a marketing application in Europe before the end of the year. Concurrently, we remain committed to completing the second pacritinib Phase 3 trial, PERSIST-2, and to continuing investigation into the potential for pacritinib in other blood-related cancers outside of myelofibrosis."*

**Second Quarter 2015 and Recent Highlights**

Clinical:

- In May, data from the PERSIST-1 Phase 3 clinical trial of pacritinib for the treatment of patients with myelofibrosis showed that, compared to best available therapy (exclusive of a JAK inhibitor), or BAT, pacritinib therapy resulted in a significantly higher proportion of patients with spleen volume reduction and control of disease-related symptoms. Treatment with pacritinib resulted in improvements in severe thrombocytopenia and severe anemia, eliminating the need for blood transfusions in a quarter of patients who were transfusion dependent at the time of enrollment. Gastrointestinal symptoms were the most common adverse events and typically lasted for approximately one week. A limited number of patients discontinued treatment due to side effects. There were no Grade 4 gastrointestinal events reported. These results were presented in a late-breaking oral session at the 51st Annual Meeting of the American Society of Clinical Oncology.
- In June, results from PERSIST-1 patient-reported outcome (PRO) and other quality of life measures presented at a late-breaking oral session at the 20th Congress of the European Hematology Association (EHA) showed significant improvements in symptom score with pacritinib therapy compared to BAT across the symptoms reported in the presentation.
- In June, data from an investigator-sponsored Phase 2 trial of tosedostat in elderly patients with either primary acute myeloid leukemia (AML), or AML that has evolved from myelodysplastic syndrome (MDS) showed that the combination of tosedostat with low-dose cytarabine/Ara-C (LDAC) resulted in an overall response rate of 54 percent in elderly patients with AML, with 45 percent of patients achieving durable complete responses. These findings were also presented at the EHA congress.

Corporate:

- In June, the following two potential milestone payments from Baxalta Incorporated, or Baxalta, to CTI BioPharma were accelerated in the amount of $32 million: a $12 million development milestone advance payable in connection with the potential regulatory submission to the European Medicines Agency with respect to pacritinib, which Baxalta anticipates submitting as early as late in 2015, and a $20 million development milestone advance payable for the first treatment dosing of the last patient enrolled in PERSIST-2 (the ongoing randomized Phase 3 trial evaluating pacritinib for patients with myelofibrosis whose platelet counts are less than or equal to 100,000 per microliter).
- In June, entered into an amendment to the loan agreement with Hercules Technology Growth Capital, Inc. under which we received $6.2 million in additional funding with the potential to borrow an additional $5 million subject to certain conditions.
- In July, Bruce J. Seeley was appointed as Executive Vice President and Chief Commercial Officer to lead all aspects of commercial operations.

**Second Quarter 2015 Financial Results**

Total revenues for the second quarter and the six months ended June 30, 2015 were $1.1 million and $3.8 million, respectively, compared to $1.3 million and $2.8 million for the same periods in 2014. Net product revenues of PIXUVRI for the second quarter 2015 were $0.8 million and $1.7 million, respectively, compared to $1.1 million and $2.4 million for the same periods in 2014.

The non-GAAP operating loss, which excludes non-cash share-based compensation expense, for the second quarter ended June 30, 2015 was $28.3 million, compared to non-GAAP operating loss of $21.3 million for the same period in 2014. The GAAP operating loss for the second quarter ended June 30, 2015 was $31.0 million, compared to a GAAP operating loss of $26.7 million for the same period in 2014. The increase in operating loss is predominantly associated with the Phase 3 development program for pacritinib and the PIX306 post-authorization Phase 3 trial for PIXUVRI. For the six months ended June 30, 2015, the non-GAAP operating loss was $51.4 million, compared to $41.1 million for the same period in 2014. For the six months ended June 30, 2015, the GAAP operating loss was $58.5 million, compared to $54.3 million for the same period in 2014. Non-cash share-based compensation expense for the second quarter and six months ended June 30, 2015 was $2.8 million and $7.1 million, respectively, compared to $5.4 million and $13.2 million for the same periods in 2014. 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 second quarter ended June 30, 2015 was $32.6 million, or $0.19 per share, compared to a net loss of $27.4 million, or $0.19 per share, for the same period in 2014. Net loss for the six months ended June 30, 2015 was $61.2 million, or $0.35 per share, compared to $56.4 million, or $0.39 per share, for the same period in 2014.

As of June 30, 2015, cash and cash equivalents totaled $54.9 million, compared to $70.9 million as of December 31, 2014.

**2015 Financial Outlook**

CTI BioPharma reaffirms prior financial guidance that it expects total revenues for 2015 will be approximately $50 million to $55 million, and it 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 on factors previously outlined in the Company's fourth quarter and full year 2014 financial results press release.

**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 Baxalta, 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 investigator-sponsored trials.
- **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 advancing the development of its other pipeline candidates through cooperative group and investigator sponsored trials. 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 will evaluate additional potential 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 second quarter 2015 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 / 10:30 p.m. CET. Participants can access the call at 1-888-334-3034 (domestic) or +1 719-325-2126 (international). To access the live audio webcast or the subsequent archived recording, visit CTI BioPharma's website, 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 5965031. The telephone replay will be available until Thursday, August 13, 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.

**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 second quarter and six months ended June 30, 2015 and 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 measure for the second quarter and six months ended June 30, 2015 and 2014 to its most directly comparable GAAP measure 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, including, in particular, expectations with respect to the potential therapeutic utility of pacritinib (such as the ability to meet a current unmet medical need in the treatment of patients with myelofibrosis and the potential for pacritinib in other blood-related cancers), potentially starting a regulatory submission for pacritinib late in Europe in 2015, completion of PERSIST-2, the potential therapeutic utility of tosedostat in the treatment of patients with AML, or AML that has evolved from MDS, the anticipated completion of enrollment in PERSIST-2, CTI BioPharma's ability to achieve its articulated business and financial plan, goals, objectives and projections, and CTI BioPharma's projected revenues and non-GAAP operating loss and the expectations and assumption on which they are based. In particular, this release addresses data regarding the PERSIST-1 study and an investigator-sponsored Phase 2 trial of tosedostat, and should be evaluated together with applicable secondary endpoints, safety and additional data as and when 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 clinical trial results observed to date may differ from future results or that different 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 PIXUVRI, pacritinib, tosedostat 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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2015 | 2014 | 2015 | 2014 |
| Revenues: | | | | |
| Product sales, net | $ 849 | $ 1,148 | $ 1,654 | $ 2,416 |
| License and contract revenue | 251 | 195 | 2,174 | 338 |
| Total revenues | 1,100 | 1,343 | 3,828 | 2,754 |
| | | | | |
| Operating costs and expenses: | | | | |
| Cost of product sold | 183 | 202 | 373 | 347 |
| Research and development | 19,320 | 14,017 | 36,791 | 26,196 |
| Selling, general and administrative | 12,624 | 13,792 | 24,921 | 30,542 |
| Other operating expense | — | — | 253 | — |
| Total operating costs and expenses | 32,127 | 28,011 | 62,338 | 57,085 |
| Loss from operations | (31,027) | (26,668) | (58,510) | (54,331) |
| Non-operating income (expense): | | | | |
| Interest expense | (597) | (467) | (1,091) | (931) |
| Amortization of debt discount and issuance costs | (131) | (185) | (311) | (363) |
| Foreign exchange gain (loss) | 185 | (160) | (543) | (165) |
| Other non-operating income (expense) | (1,196) | 1 | (1,196) | (885) |
| Net loss before noncontrolling interest | (32,766) | (27,479) | (61,651) | (56,675) |
| Noncontrolling interest | 170 | 80 | 458 | 274 |
| Net loss | (32,596) | (27,399) | (61,193) | (56,401) |
| Basic and diluted net loss per common share | $ (0.19) | $ (0.19) | $ (0.35) | $ (0.39) |
| | | | | |
| Shares used in calculation of basic and diluted net loss per common share | 175,458 | 144,453 | 174,706 | 143,302 |

| Balance Sheet Data (unaudited): | (amounts in thousands) | |
|---|---|---|
| | June 30, 2015 | December 31, 2014 |
| Cash and cash equivalents | 54,864 | 70,933 |
| Working capital | 30,766 | 44,165 |
| Total assets | 73,458 | 92,287 |
| Current portion of long-term debt | 2,824 | 9,014 |
| Long-term debt, less current portion | 48,800 | 8,363 |
| Total shareholders' equity (deficit) | (15,528) | 38,478 |

Non-GAAP Reconciliations
(In thousands)
(unaudited)

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2015 | 2014 | 2015 | 2014 |
| As reported - loss from operations (GAAP) | $ (31,027) | $ (26,668) | $ (58,510) | $ (54,331) |
| As reported - share-based compensation expense (GAAP) | 2,773 | 5,356 | 7,109 | 13,185 |
| As adjusted - loss from operations (Non-GAAP) | $ (28,254) | $ (21,312) | $ (51,401) | $ (41,146) |

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