Informazione Regolamentata n. 0696-19-2016	Data/Ora Ricezione 16 Febbraio 2016 22:02:42	MTA

Societa'	:	CTI BIOPHARMA
Identificativo Informazione Regolamentata	:	69608
Nome utilizzatore	:	CELLN02 - Bell
Tipologia	:	IRAG 01
Data/Ora Ricezione	:	16 Febbraio 2016 22:02:42
Data/Ora Inizio Diffusione presunta	:	16 Febbraio 2016 22:17:43
Oggetto	:	CTI BIOPHARMA REPORTS FOURTH QUARTER AND FULL YEAR 2015 FINANCIAL RESULTS

Testo del comunicato

Vedi allegato.

CTI BIOPHARMA REPORTS FOURTH QUARTER AND FULL YEAR 2015 FINANCIAL RESULTS

SEATTLE, February 16, 2016 - CTI BioPharma Corp. (NASDAQ and MTA:CTIC) today reported financial results for the fourth quarter and full year ended December 31, 2015.

"While we were disappointed and surprised by the FDA's decision to place pacritinib's IND on full clinical hold, our priority and sense of purpose has always been to do what is best for patients," said James A. Bianco, M.D., president and chief executive officer of CTI BioPharma."There remains a significant unmet medical need in the treatment of myelofibrosis, especially for those with low platelet counts. We continue to see the potential of pacritinib to help this patient population and we are committed to resolving the FDA's concerns in order to identify a path forward. Additionally, we plan to define the registration path for tosedostat, which recent interim data from a cooperative group study showed the potential therapeutic utility of this oral aminopeptidase inhibitor for older patients with AML and high-risk MDS. We ended the year with a strong financial position that we believe will enable us to achieve our goals in 2016 and beyond."

Recent Highlights

Pacritinib

- In January 2016, CTI BioPharma announced the completion of the rolling New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for pacritinib, an investigational oral kinase inhibitor with specificity for JAK2, FLT3, IRAK1 and CSF1R. CTI BioPharma and Baxalta Incorporated (Baxalta) are seeking U.S. marketing approval of pacritinib for the treatment of patients with intermediate and high-risk myelofibrosis with low platelet counts of less than 50,000 per microliter (<50,000/μL). In February 2016, the FDA placed pacritinib's investigational new drug application (IND) on a full clinical hold and CTI BioPharma subsequently withdrew its NDA.

- In December 2015, researchers presented results from a new analysis of the pivotal Phase 3 trial, PERSIST-1, evaluating pacritinib versus best available therapy, excluding treatment with JAK2 inhibitors (BAT), in patients with myelofibrosis. Data examining patient outcomes across baseline demographic factors that are associated with prognosis showed that treatment with pacritinib resulted in consistent rates of spleen volume reduction and control of disease-related symptoms across all intermediate or high-risk myelofibrosis subgroups.

Tosedostat

- In December 2015, researchers presented an update on results from an investigator-sponsored Phase 2 trial of tosedostat - CTI BioPharma's investigational oral selective aminopeptidase inhibitor - in elderly patients with either primary (de novo) acute myeloid leukemia (AML) or secondary AML. The data showed a complete response (CR) rate of 48.5 percent with tosedostat in combination with low dose cytarabine/Ara-C (LDAC) - 33 percent of these patients were still responding after a median of 506 days.

- In November 2015, CTI BioPharma announced that the United Kingdom's National Cancer Research Institute (NCRI) Haematological Oncology Clinical Studies Group has chosen to advance tosedostat to the second stage of a randomized clinical trial of low-dose cytarabine plus or minus tosedostat in older patients with AML or high risk myelodysplastic syndrome (MDS). The AML Less Intensive (LI-1) trial is designed

as a “Pick-a-Winner” trial to be able to simultaneously test a number of promising agents added to standard therapy with low-dose cytarabine in older patients with AML or MDS who are unfit for standard aggressive induction therapy. Nine regimens have been tested in the Pick-a-Winner program, of which only four, including tosedostat, have passed the initial hurdle for progression (which requires evidence of an improvement in remission rate with acceptable safety). CTI BioPharma plans to discuss potential approval pathways with regulators in the U.S. and EU in 2016.

Fourth Quarter and Full Year Financial Results

Total revenues for the fourth quarter and the full year ended December 31, 2015, were $11.3 million and $16.1 million, respectively, compared to $17.8 million and $60.1 million for the same periods in 2014. The decrease in total revenue for the full year ended December 31, 2015, as compared to December 31, 2014, is primarily due to recognition of milestone payments in 2014, specifically a $20.0 million development milestone payment received from Baxalta for completion of enrollment in the PERSIST-1 Phase 3 clinical trial of pacritinib and $17.3 million from an upfront payment under the PIXUVRI® collaboration agreement with Servier. Net product revenues of PIXUVRI for the fourth quarter and the full year ended December 31, 2015, were $1.1 million and $3.5 million, respectively, compared to $2.5 million and $6.9 million for the same periods in 2014. The decrease in net product sales for the full year ended December 31, 2015, as compared to December 31, 2014, was primarily related to the pricing and volume variances between the periods as well as the decline in average exchange rate of the euro for our euro-denominated sales.

The non-GAAP operating loss, which excludes non-cash share-based compensation expense, for the fourth quarter and full year ended December 31, 2015, was $24.4 million and $101.8 million, respectively, compared to non-GAAP operating loss of $36.2 million and $66.0 million for the same periods in 2014. The GAAP operating loss for the fourth quarter and full year ended December 31, 2015, was $26.2 million and $116.7 million, respectively, compared to a GAAP operating loss of $39.4 million and $86.2 million for the same period in 2014. The increase in operating loss for the full-year ended December 31, 2015, as compared to December 31, 2014, is predominantly associated with the Phase 3 development program for pacritinib and the PIXUVRI post-authorization Phase 3 trial as well as the milestone and the upfront payments received in 2014 mentioned above. Non-cash share-based compensation expense for the fourth quarter and full year ended December 31, 2015, was $1.8 million and $14.8 million, respectively, compared to $3.2 million and $20.2 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 fourth quarter of 2015 was $28.8 million, or $(0.13) per share, compared to a net loss of $44.2 million, or ($0.27) per share, for the same period in 2014. Net loss for the full year of 2015 was $122.6 million, or $(0.65) per share, compared to a net loss of $96.0 million, or $(0.65) per share, for the same period in 2014.

As of December 31, 2015, cash and cash equivalents totaled $128.2 million, compared to $70.9 million as of December 31, 2014.

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:

- **Commercialize PIXUVRI.** Together with Servier, CTI BioPharma intends to continue its efforts to commercialize PIXUVRI in Europe. CTI BioPharma is currently focused on educating physicians on the unmet medical need for PIXUVRI among physicians in the countries where PIXUVRI is available. A successful outcome from the post-authorization trial, PIX306, will enable the company to potentially obtain full marketing authorization from the European Commission and expand the market potential for PIXUVRI.
- **Develop Pacritinib in Myelofibrosis and Additional Indications.** Together with Baxalta, CTI BioPharma intends to develop and commercialize pacritinib for adult patients with myelofibrosis.
- **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.

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 with respect to PIXUVRI® and a late-stage development pipeline, including pacritinib 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 fourth quarter and year ended December 31, 2015 and December 31, 2014. 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. Accordingly, CTI BioPharma's non-GAAP loss from operations 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.

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 the advancement of pacritinib and exploring potential approval pathways for tosedostat, CTI BioPharma's ability to achieve its goals in 2016 and beyond, CTI BioPharma's intent to continue efforts to commercialize PIXUVRI in Europe and its ability to obtain full marketing authorization from the European Commission and expand the market potential for PIXUVRI, CTI BioPharma's plans to continue advancing the development of its pipeline candidates through cooperative group and investigator-sponsored trials. 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, the potential failure of pacritinib to prove safe and effective as determined by the FDA and/or the European Medicines Agency, changes to study protocol or design or sample size to address any patient safety, efficacy or other issues raised by the FDA or otherwise, that the FDA may expand its information request or fail to release the clinical hold or take other actions, that top-line 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 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.

# # #

CTI BioPharma Contacts:
Monique Greer
+1 206-272-4343
mgreer@ctibiopharma.com

Ed Bell
+1 206-272-4345
ebell@ctibiopharma.com

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2015	2014	2015	2014
Revenues:				
Product sales, net	$ 1,078	$ 2,472	$ 3,472	$ 6,909
License and contract revenue	10,246	15,317	12,644	53,168
Total revenues	11,324	17,789	16,116	60,077
Operating costs and expenses:				
Cost of product sold	736	296	1,940	895
Research and development	21,432	21,871	76,627	64,596
Selling, general and administrative	15,359	13,137	53,962	56,241
Acquired in-process research and development	—	21,859	—	21,859
Other operating expense	—	—	253	2,719
Total operating costs and expenses	37,527	57,163	132,782	146,310
Loss from operations	(26,203)	(39,374)	(116,666)	(86,233)
Non-operating income (expense):				
Interest income (expense)	275	(544)	(2,104)	(1,947)
Amortization of debt discount and issuance costs	(39)	(182)	(390)	(729)
Foreign exchange loss	(142)	(1,814)	(703)	(4,435)
Other non-operating income (expense)	93	—	(900)	(885)
Net loss before noncontrolling interest	(26,016)	(41,914)	(120,763)	(94,229)
Noncontrolling interest	379	345	1,341	862
Net loss attributable to CTI	(25,637)	(41,569)	(119,422)	(93,367)
Deemed dividends on preferred stock	(3,200)	(2,625)	(3,200)	(2,625)
Net loss attributable to common shareholders	(28,837)	(44,194)	(122,622)	(95,992)
Basic and diluted net loss per common share	$ (0.13)	$ (0.27)	$ (0.65)	$ (0.65)
Shares used in calculation of basic and diluted loss per common share	227,647	162,211	188,373	148,531

Balance Sheet Data (unaudited):	(amounts in thousands)	
	December 31, 2015	December 31, 2014
Cash and cash equivalents	128,182	70,933
Working capital	62,566	44,165
Total assets	144,332	92,287
Current portion of long-term debt	37,371	9,014
Long-term debt, less current portion	19,259	8,363
Total shareholders' equity	47,413	38,478

Non-GAAP Reconciliations
(In thousands)
(unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2015	2014	2015	2014
As reported - loss from operations (GAAP)	$ (26,203)	$ (39,374)	$ (116,666)	$ (86,233)
As reported - share-based compensation expense (GAAP)	1,831	3,174	14,828	20,196
As adjusted - loss from operations (Non-GAAP)	$ (24,372)	$ (36,200)	$ (101,838)	$ (66,037)

Fine Comunicato n.0696-19	Numero di Pagine: 9