Collegium Reports Third Quarter Financial Results and Provides Corporate Update

November 12, 2015

CANTON, Mass., Nov. 12, 2015 (GLOBE NEWSWIRE) -- Collegium Pharmaceutical, Inc. (Nasdaq:COLL) today reported its financial results for the third quarter of 2015 and provided a corporate update.

"During the last few months, Collegium achieved a number of important milestones in moving Xtampza™ ER closer to market launch upon final approval," stated Michael Heffernan, Collegium's CEO. "We were very encouraged by the FDA Advisory Committees' unanimous vote in support of approval of Xtampza ER and subsequently the FDA's tentative approval of the Xtampza ER NDA. Additionally, the commercial team has made significant progress in preparing for a potential April 2016 launch of Xtampza."

Corporate Update

Commercial Organization

Collegium's commercial team is actively building the infrastructure required to support a potential April 2016 launch of Xtampza ER, pending final approval by the FDA. Recently, the commercial team completed hiring its senior management team, adding Jack Maroney as Vice President of Sales. Mr. Maroney has over 25 years' experience in the industry, most recently as Vice President of Sales, Specialty Markets at Sunovion Pharmaceuticals Inc.

Advisory Committee

On September 11, 2015, the Anesthetic and Analgesic Drug Products Advisory Committee and Drug Safety and Risk Management Advisory Committee of the U.S. Food and Drug Administration (FDA) voted unanimously (23-0) to support the approval of Xtampza ER.

FDA Tentative Approval

On November 6, 2015, the FDA granted tentative approval to the Xtampza ER NDA for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. With a tentative approval, the FDA has determined that Xtampza ER meets the required quality, safety and efficacy standards for approval but it is subject to an automatic stay of up to 30 months as a result of patent litigation filed by Purdue Pharma, L.P (Purdue) in March 2015. Purdue claims that Xtampza ER infringes three Orange Book listed patents that were recently found to be invalid by the United States District Court for the Southern District of New York and are currently under appeal. If Collegium receives a court order that the listed patents are invalid or not infringed, or if Collegium settles the Purdue litigation prior to the expiration of the 30-month period, the FDA can then provide final approval of Xtampza ER, at which point the product can be marketed.

Third Quarter 2015 Financial Results

As of September 30, 2015, Collegium had cash and cash equivalents of $105.5 million compared to $1.6 million as of December 31, 2014. During 2015, cash and cash equivalents increased significantly due to the $44.8 million net proceeds from issuance of our Series D convertible redeemable preferred stock in March 2015 and $72.0 million in net proceeds from our IPO in May 2015.

Net loss for the quarter ended September 30, 2015 (the "2015 Quarter") was $9.4 million, or $0.46 per share, as compared to a net loss of $6.6 million, or $7.85 per share, for the quarter ended September 30, 2014 (the "2014 Quarter"). Net loss includes stock-based compensation expense of $503,000 and $5,000 for the 2015 Quarter and 2014 Quarter, respectively.

Research and development expenses were $3.4 million for the 2015 Quarter compared to $5.8 million for the 2014 Quarter. The $2.4 million decrease was primarily related to a decrease in clinical trial costs of $4.4 million due to the completion of clinical trials with Xtampza during 2014, which was partially offset by an increase in consulting costs of $1.1 million mainly due to costs associated with the FDA Advisory Committee meeting and an increase in manufacturing costs related to Xtampza ER of $588,000.

General and administrative expenses were $5.9 million for the 2015 Quarter compared to $687,000 for the 2014 Quarter. The $5.2 million increase was primarily related to: an increase in commercial costs of $2.9 million primarily due to consultant costs related to analytics and strategies for commercialization of Xtampza ER, an increase in salaries and wages of $1.6 million primarily due to increases in headcount, bonuses and stock compensation expense and an increase in insurance costs of $297,000 due to directors' and officers' insurance.

There were 20,687,829 common shares outstanding as of September 30, 2015.

Conference Call Information

The Company will host a conference call and live audio webcast on Thursday, November 12, 2015 at 8:00 a.m. ET. To access the conference call, please dial (866)864-3220 (U.S.) or (704)908-0478 (International). An audio webcast will be accessible from the Investor Relations section of the Company's website: http://www.collegiumpharma.com/. An archived webcast will be available on the Company's website approximately two hours after the event.

About Collegium Pharmaceutical, Inc.

Collegium is a specialty pharmaceutical company focused on developing a portfolio of products that incorporate its patent-protected DETERx®

technology platform for the treatment of chronic pain and other diseases. The DETERx oral drug delivery technology is designed to provide extended-release delivery, unique abuse-deterrent properties, and flexible dose administration options.

About Xtampza ER

Collegium's lead product candidate, Xtampza ER, is an abuse-deterrent, extended-release, oral formulation of oxycodone, in development for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Collegium developed Xtampza using its proprietary DETERx technology platform to address common methods of abuse, including chewing, crushing and/or dissolving, and then taking it orally or snorting or injecting.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. We may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from the company's current expectations. For example, there can be no guarantee that we will obtain final approval for Xtampza ER or any of our other product candidates from the FDA or foreign regulatory authorities; even if Xtampza ER obtains final approval, we may not be able to obtain the label claims that we are seeking from the FDA. Furthermore, we are subject to patent infringement litigation relating to Xtampza ER and may, in the future, be subject to additional litigation relating to our other product candidates, which may be expensive to defend and delay the commercialization of Xtampza ER or our other product candidates. Management's expectations and, therefore, any forward-looking statements in this press release could also be affected by risks and uncertainties relating to a number of other factors, including the following: our ability to commercialize our product candidates; the size and growth potential of the markets for our product candidates, and our ability to service those markets; our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators; the rate and degree of market acceptance of our product candidates; the success, cost and timing of our product development activities, studies and clinical trials; the success of competing products that are or become available; and our expectations regarding our ability to obtain and adequately maintain sufficient intellectual property protection for our product candidates. These and other risks are described under the heading "Risk Factors" in a Current Report on Form 8-K, which was filed with the Securities and Exchange Commission ("SEC") on June 19, 2015, and those risks described from time to time in other reports which we file with the SEC. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

Collegium Pharmaceutical, Inc.

Unaudited Selected Balance Sheet Information

(in thousands)

	September 30, 2015	December 31, 2014
Cash and cash equivalents	$105,460	$1,634
Prepaid expenses and other current assets	866	2,862
Property and equipment, net	627	514
Restricted cash	97	80
Total assets	**$107,050**	**$5,090**
Accounts payable and accrued expenses	$5,918	$4,164
Other liabilities	7,571	13,167
Convertible redeemable preferred stock	--	77,107
Stockholders' equity (deficit)	93,561	(89,348)
Total liabilities and stockholders' equity (deficit)	**$107,050**	**$5,090**

Collegium Pharmaceutical, Inc.

Unaudited Condensed Statements of Operations

(in thousands, except share and per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Operating expenses:				
Research and development	$3,358	$5,818	$6,444	$12,652
General and administrative	5,907	687	11,027	1,686
Total operating expenses	9,265	6,505	17,471	14,338
Loss from operations	(9,265)	(6,505)	(17,471)	(14,338)
Other expense, net	(97)	(51)	(259)	(110)
Net loss	**($9,362)**	**($6,556)**	**($17,830)**	**($14,448)**
Net loss per share–basic and diluted	($0.46)	($7.85)	($0.94)	($18.26)
Weighted-average number of common shares used in net loss per share -basic and diluted	20,531,406	940,627	11,179,756	926,597

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