



## Collegium Reports Second Quarter Financial Results and Provides Corporate Update

August 12, 2015

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

Michael Heffernan, Collegium's Chairman and CEO, stated, "During the second quarter, Collegium achieved a number of important milestones. The successful completion of our IPO in May 2015 provides us with substantial additional resources to launch Xtampza™ ER pending final approval by the FDA and to move another product candidate into the clinic. Additionally, the commercial team has made significant progress in preparing for a potential 2016 launch of Xtampza."

### Corporate Update

#### Key Leadership

During the second quarter, the Company announced the addition of key members to its leadership team, including Barry Duke as Chief Commercial Officer and Jack Weet as Vice President of Regulatory Affairs and Quality Assurance.

#### Commercial Organization

Collegium continues to expand its commercial team with key hires in sales, marketing, market access, operations and training. The commercial team is actively building the infrastructure required to support a potential April 2016 launch of Xtampza, pending final approval by the FDA.

Recently, Kevin O'Keeffe joined as Vice President of Market Access and Trade. Prior to joining Collegium, Mr. O'Keeffe was Senior Director of Strategic Pricing, Access & Reimbursement at Cubist Pharmaceuticals.

#### Advisory Committee

On August 7, 2015, the U.S. Food and Drug Administration (FDA) announced in the Federal Register that a joint meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and Drug Safety and Risk Management Advisory Committee of the FDA is scheduled to review the Company's New Drug Application (NDA) for Xtampza ER (oxycodone extended-release capsules) on September 11, 2015.

"At the upcoming FDA Advisory Committee, we intend to discuss the safety, efficacy and abuse-deterrent features of Xtampza ER. We will also discuss features that differentiate Xtampza ER from other abuse-deterrent formulations, including currently marketed products," stated Michael Heffernan.

#### Patent Litigation with Purdue Pharma L.P.

On August 6, 2015, the Delaware court dismissed Purdue's suit against Collegium in Delaware for lack of personal jurisdiction. Following the dismissal, the Company filed a complaint in the Southern District of New York and Purdue sued the Company in the District of Massachusetts asserting the same claims as the prior suit. On August 7, 2015, Purdue filed a motion in the Delaware court requesting reconsideration of the August 6, 2015 order that dismissed the case. We are very confident in our non-infringement and invalidity position and intend to vigorously defend ourselves with the goal of gaining final approval and launching Xtampza ER in as timely a fashion as possible.

Please see our Quarterly Report filed on Form 10-Q for additional details regarding patent litigation with Purdue.

#### Patents and Publications

**Patents** – In June 2015, we announced the issuance of an additional patent that covers the DETERx technology platform and Xtampza ER. This is the seventh Orange Book listable patent for Xtampza ER.

**Pain Medicine** – In June 2015, we announced the publication of a comparative clinical trial titled "Comparing the Effect of Tampering on the Oral Pharmacokinetic Profiles of Two Extended-Release Oxycodone Formulations with Abuse-Deterrent Properties," in the peer-reviewed medical journal, *Pain Medicine*.

**PAIN** – In August 2015, we published results from a pivotal Phase 3 clinical study titled "A Phase 3, Multi-center, Randomized, Double-blind, Placebo-controlled, Safety, Tolerability, and Efficacy Study of Xtampza™ ER in Patients with Moderate-to-severe Chronic Low Back Pain," in the peer-reviewed medical journal, *PAIN*.

### Second Quarter 2015 Financial Results

As of June 30, 2015, Collegium had cash and cash equivalents of \$112.4 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 and \$72.0 million in net proceeds from our IPO.

Net loss for the quarter ended June 30, 2015 (the "2015 Quarter") was \$4.7 million, or \$0.45 per share, as compared to a net loss of \$4.1 million, or \$5.33 per share, for the quarter ended June 30, 2014 (the "2014 Quarter"). Net loss includes stock-based compensation expense of \$601,000 and

\$6,000 for the 2015 Quarter and 2014 Quarter, respectively.

Research and development expenses were \$1.6 million for the 2015 Quarter compared to \$3.6 million for the 2014 Quarter. The \$2.0 million decrease was primarily related to a decrease in clinical trial costs of \$2.1 million due to the completion of clinical trials with Xtampza during 2014, which was partially offset by an increase in manufacturing costs of \$124,000 mainly due to costs incurred for validation batches of Xtampza.

General and administrative expenses were \$2.9 million for the 2015 Quarter compared to \$523,000 for the 2014 Quarter. The \$2.4 million increase was primarily related to: an increase in salaries and wages of \$1.2 million primarily due to increased headcount, bonuses and stock compensation expense, an increase in legal and consulting fees of \$402,000 primarily due to costs related to litigation and an increase in commercial costs of \$237,000 primarily due to consultant costs related to analytics and strategies for commercialization of Xtampza.

There were 20,687,787 common shares outstanding as of June 30, 2015.

#### **Conference Call Information**

The Company will host a conference call and live audio webcast on Thursday, August 13, 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 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.

In addition, Collegium's preclinical studies and clinical trials have shown that the contents of the Xtampza capsule can be removed from the capsule and sprinkled on food, directly into the mouth or administered through feeding tubes, without compromising their drug release profile, safety or abuse-deterrent characteristics. By contrast, OxyContin<sup>®</sup> OP, which is formulated in hard tablets, has a black box warning label stating that crushing, dissolving or chewing can cause rapid release and absorption of a potentially fatal dose of the active ingredient. Approximately 11 million patients in the United States suffer from chronic pain and have difficulty swallowing.

#### **About Collegium Pharmaceutical, Inc.**

Collegium is a specialty pharmaceutical company focused on developing a portfolio of products that incorporate its patent-protected DETERx<sup>®</sup> 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. The new drug application, or NDA, submission for Xtampza ER, the Company's lead product candidate, was accepted for review by the FDA on February 10, 2015. The FDA set a Prescription Drug User Fee Act, or PDUFA, goal date of October 12, 2015 for completion of its review of the Xtampza ER NDA.

#### **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 approval for Xtampza or any of our other product candidates from the U.S. Food and Drug Administration ("FDA") or foreign regulatory authorities; even if Xtampza is approved, 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 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 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. 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, and those risks described from time to time in other reports which we file with the Securities and Exchange Commission.

**Collegium Pharmaceutical, Inc.**  
**Unaudited Selected Balance Sheet Information**  
(in thousands)

June 30,	December 31,
<u>2015</u>	<u>2014</u>

Cash and cash equivalents	\$112,413	\$1,634
Prepaid expenses and other current assets	1,219	2,862
Property and equipment, net	445	514
Restricted cash	<u>97</u>	<u>80</u>
<b>Total assets</b>	<b><u>\$114,174</u></b>	<b><u>\$5,090</u></b>

Accounts payable and accrued expenses	\$3,910	\$4,164
Other liabilities	7,845	13,167
Convertible redeemable preferred stock	--	77,107
Stockholders' equity (deficit)	<u>102,419</u>	<u>(89,348)</u>
<b>Total liabilities and stockholders' equity (deficit)</b>	<b><u>\$114,174</u></b>	<b><u>\$5,090</u></b>

**Collegium Pharmaceutical, Inc.**  
**Unaudited Condensed Statements of Operations**  
(in thousands, except share and per share amounts)

	Three months ended June 30,		Six months ended June 30,	
	2015	2014	2015	2014
Operating expenses:				
Research and development	\$1,641	\$3,565	\$3,086	\$6,834
General and administrative	<u>2,934</u>	<u>523</u>	<u>5,120</u>	<u>999</u>
Total operating expenses	<u>4,575</u>	<u>4,088</u>	<u>8,206</u>	<u>7,833</u>
Loss from operations	(4,575)	(4,088)	(8,206)	(7,833)
Other expense, net	<u>(99)</u>	<u>(29)</u>	<u>(163)</u>	<u>(59)</u>
Net loss	<u>(\$4,674)</u>	<u>(\$4,177)</u>	<u>(\$8,369)</u>	<u>(\$7,892)</u>
Net loss per share—basic and diluted	<u>(\$0.45)</u>	<u>(\$5.33)</u>	<u>(\$0.18)</u>	<u>(\$10.36)</u>
Weighted-average number of common shares used in net loss per share -basic and diluted	<u>11,791,546</u>	<u>926,239</u>	<u>6,426,431</u>	<u>919,465</u>

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