Collegium Reports First Quarter Financial Results and Provides Corporate Update

May 10, 2016

CANTON, Mass., May 10, 2016 (GLOBE NEWSWIRE) -- Collegium Pharmaceutical, Inc. (Nasdaq:COLL) today reported its financial results for the first quarter of 2016 and provided a corporate update.

“The beginning of this year marked a major milestone for Collegium as we received FDA approval for our lead product, Xtampza™ ER,” statedMichael Heffernan, Collegium’s CEO. “We are finalizing our launch plans and completing the training of our sales organization, as we prepare for a June launch. Collegium remains committed to supporting responsible, appropriate prescribing for only those patients suffering from pain who don’t have alternative non-opioid treatment options. Xtampza ER will provide clinicians with another treatment option for these patients. We look forward to discussing additional details of our launch plans at the upcoming Investor Day.”

Collegium’s Investor Day will take place on Wednesday, May 25th at the St. Regis Hotel in New York City (2 East 55th Street). The meeting will commence at 10:00am ET. A webcast will be available and lunch will be served.

Corporate Update

FDA Approval

In April 2016, the FDA approved Xtampza ER (oxycodone) extended-release (ER) capsules CII, a twice-daily, oxycodone medication 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. Xtampza ER is Collegium’s first product utilizing its proprietary DETERx ® technology platform, and is designed to provide adequate pain control while maintaining its drug release profile after being subjected to common methods of manipulation, including chewing and crushing the product, prior to administration. The Xtampza ER label contains information supporting the administration of the product by sprinkling the capsule contents on soft foods or into a cup, and then directly into the mouth, or through a gastrostomy or nasogastric feeding tube.

Commercial Organization

Collegium has completed recruitment for its retail, institution, and long-term care sales teams and will have them trained and deployed for the June launch. As part of the planned Collegium Investor Day on May 25, 2016, Collegium will provide additional detail regarding commercial strategies, including sales, marketing, and market access & trade.

Litigation

In February 2016, the District Court of Massachusetts issued a final judgment in favor of Collegium and against plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., and Rhodes Technologies. The judgment related to Purdue’s three Orange Book-listed patents asserted against Collegium that were the cause of the 30 month stay imposed on the New Drug Application for Xtampza ER.

Financing

In January 2016, Collegium closed a public offering of 2,750,000 shares of its common stock which generated net proceeds of $51.2 million, after deduction of underwriting discounts and commissions and other offering expenses.

Clinical Development

In May 2016, Collegium announced positive topline results from a comparative clinical trial evaluating the effect of physical manipulation by crushing of Xtampza ER compared with the abuse-deterrent version of OxyContin® (oxycodone hydrochloride extended-release tablets). The results of the study demonstrated the following:

- Crushed Xtampza ER capsule contents (microspheres) were bioequivalent to intact Xtampza ER capsules with similar Tmax, demonstrating that crushing the contents of Xtampza ER capsules did not alter the extended-release PK profile of Xtampza ER.

- Crushed OxyContin tablets were bioequivalent to crushed IR oxycodone tablets, demonstrating that crushing OxyContin compromised the integrity of the time-release formulation, transforming the drug-release PK profile from an extended-release profile to an IR profile.

In January 2016, Collegium began a clinical trial of hydrocodone DETERx, an abuse-deterrent, extended-release analgesic for the treatment of chronic pain. This proof of concept clinical trial is intended to evaluate the safety, bioavailability, and abuse deterrence properties of hydrocodone DETERx.

Publications

Journal of Opioid Management – In March 2016, we announced publication of data on the in vitro assessment of IV abuse of Xtampza ER titled “In

Vitro Assessment of the Potential for Abuse via the Intravenous Route of Oxycodone DETERx® Microspheres."

Current Medical Research and Opinion – In April 2016, we announced the publication of an analysis of the duration of effect of Xtampza™ ER administered every 12 hours during the Double-blind Maintenance Phase of a multicenter, 12-week clinical study titled "Evaluation of the Durability of Pain Relief Throughout a 12-Hour Dosing Interval of a Novel, Extended-Release, Abuse-Deterrent Formulation of Oxycodone – Oxycodone DETERx®."

First Quarter 2016 Financial Results

As of March 31, 2016, Collegium had cash and cash equivalents of $134.7 million compared to $95.7 million as of December 31, 2015. During the three months ended March 31, 2016 (the "2016 Quarter"), cash and cash equivalents increased due to the net proceeds of $51.2 million from our January 2016 follow-on offering of common stock.

Net loss for the 2016 Quarter was $15.7 million, or loss per share of $0.68 (basic and diluted), as compared to net loss of $3.7 million, or earnings per share-basic of $0.34 and loss per share-diluted of $0.65, for the quarter ended March 31, 2015 (the "2015 Quarter"). Net loss includes stock-based compensation expense of $1.1 million and $113,000 for the 2016 Quarter and 2015 Quarter, respectively.

Research and development expenses were $4.1 million for the 2016 Quarter compared to $1.4 million for the 2015 Quarter. The $2.6 million increase was primarily related to an increase in clinical trial costs of $1.7 million due to the initiation of clinical trials for Xtampza and our second product candidate, an increase in manufacturing costs related to Xtampza of $428,000 and an increase in personnel related costs of $356,000.

Selling, general and administrative expenses were $11.5 million for the 2016 Quarter compared to $2.2 million for the 2015 Quarter. The $9.3 million increase was primarily related to: an increase in personnel related costs of $3.9 million primarily due to an increase in headcount, an increase in sales and marketing costs of $3.0 million primarily due to the preparation for the commercial launch of Xtampza, an increase in commercial costs of $871,000 primarily due to consultant costs related to analytics and strategies for commercialization of Xtampza, an increase in professional fees of $517,000 primarily due to recruitment and other professional fees and an increase in insurance costs of $286,000 due to directors' and officers' insurance.

There were 23,513,105 common shares outstanding as of March, 31, 2016.

Financial Outlook

Based on our current operating plans, Collegium expects that its existing cash resources will fund its operations into early 2018.

Conference Call Information

The Company will host a conference call and live audio webcast on Tuesday, May 10, 2016 at 4:30 p.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

Xtampza ER is an opioid agonist product indicated 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.

For Important Safety Information Visit, http://www.xtampzaer.com/.

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.

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," "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. 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 products and product candidates; the existence of any patent infringement or similar litigation relating to any of our products or product candidates, and costs and delays associated with such litigation; the size and growth potential of the markets for our product and 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 and 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 our Annual Report on Form 10-K for the year ended December 31, 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 Consolidated Balance Sheet Information
(in thousands)

	March 31, 2016	December 31, 2015
Cash and cash equivalents	$134,730	$ 95,697
Prepaid expenses and other current assets	821	1,186
Property and equipment, net	695	738
Restricted cash	97	97
Total assets	**$136,343**	**$ 97,718**
Accounts payable and accrued expenses	$ 8,401	$ 5,765
Other liabilities	6,206	6,881
Convertible redeemable preferred stock	-	-
Stockholders' equity	121,736	85,072
Total liabilities and stockholders' equity	**$136,343**	**$ 97,718**

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

	Three Months Ended March 31,	
	2016	2015
Operating expenses:		
Research and development	$ 4,062	$ 1,445
Selling, general and administrative	11,525	2,185
Total operating expenses	15,587	3,630
Loss from operations	(15,587)	(3,630)
Other expense, net	(66)	(64)
Net loss	**$ (15,653)**	**$ (3,694)**
Earnings (loss) per share–basic	$ (0.68)	$ 0.34
Earnings (loss) per share–diluted	$ (0.68)	$ (0.65)
Weighted-average shares-basic	23,130,153	1,001,704
Weighted-average shares-diluted	23,130,153	7,554,524

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