Collegium Reports Second Quarter Financial Results and Provides Corporate Update

August 10, 2016

- *Received FDA approval for Xtampza® ER, Company's lead opioid analgesic with abuse-deterrent properties*
- *Announced U.S. commercial launch of Xtampza ER*
- *Reported positive results from a clinical study comparing effect of physical manipulation of Xtampza ER with the abuse-deterrent version of OxyContin®*
- *Reported positive results from a clinical study evaluating Hydrocodone DETERx® as a second product candidate*
- *Licensed U.S. rights to commercialize ONSOLIS® (fentanyl buccal soluble film) from BioDelivery Sciences International*

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

"The second quarter of 2016 marked an important milestone for Collegium as we transitioned from a development stage company to a commercial pharmaceutical company. Following the FDA approval of our lead product, we announced the commercial launch of Xtampza® ER and our sales force is now fully engaged in promoting the product to our target physicians," stated Michael Heffernan, Collegium's CEO. "Furthermore, we continue to build our product pipeline through the advancement of our Hydrocodone DETERx® clinical development program and through the acquisition of the U.S. rights to ONSOLIS® from BioDelivery Sciences."

Corporate Milestones

Regulatory

- 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.

Commercial

- In June 2016, Collegium announced the commercial launch of Xtampza ER. The Xtampza ER commercial launch is supported by a field sales force of approximately 120 retail sales professionals with a primary focus on pain specialists. In addition, an institutional focused sales force of specialty sales representatives is targeting hospitals and long term care facilities.

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).
- In June 2016, Collegium announced positive topline results from a clinical study evaluating Hydrocodone DETERx as a second product candidate using its proprietary DETERx drug delivery technology platform.

Business Development

- In May 2016, Collegium announced the licensing of the U.S. rights to develop and commercialize ONSOLIS (fentanyl buccal soluble film) from BioDelivery Sciences International, Inc.

Second Quarter 2016 Financial Results

As of June 30, 2016, Collegium had cash and cash equivalents of $110.7 million compared to $95.7 million as of December 31, 2015. During the six months ended June 30, 2016, cash and cash equivalents increased by $15.0 million due to the net proceeds of $51.2 million from our January 2016 follow-on offering of common stock, partially offset by cash used in operations of $32.4 million and an upfront payment of $2.5 million to BioDelivery Sciences International, Inc. for the U.S. rights to ONSOLIS.

Net loss for the quarter ended June 30, 2016 (the "2016 Quarter") was $24.5 million, or $1.05 per share (basic and diluted), as compared to net loss of $4.7 million, or $0.45 per share (basic and diluted), for the quarter ended June 30, 2015 (the "2015 Quarter"). Net loss includes stock-based compensation expense of $1.4 million and $601,000 for the 2016 Quarter and 2015 Quarter, respectively.

Research and development expenses were $4.3 million for the 2016 Quarter compared to $1.6 million for the 2015 Quarter. The $2.7 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 ER and Hydrocodone DETERx,

an increase in personnel related costs of $522,000 and an increase in manufacturing costs related to Xtampza ER prior to FDA approval of $228,000.

Selling, general and administrative expenses were $20.2 million for the 2016 Quarter compared to $2.9 million for the 2015 Quarter. The $17.3 million increase was primarily related to: an increase in sales and marketing costs of $8.5 million primarily due to the preparation for the commercial launch of Xtampza ER, an increase in personnel related costs of $7.4 million primarily due to an increase in headcount and an increase in commercial costs of $676,000 primarily due to consultant costs related to analytics and strategies for commercialization of Xtampza ER.

There were 23,528,119 common shares outstanding as of June 30, 2016.

Financial Outlook

Based on our current operating plans, we expect that our existing cash resources will fund our operations into early 2018.

Conference Call Information

Collegium will host a conference call and live audio webcast on Wednesday, August 10, 2016 at 4:30 p.m. Eastern Time. To access the conference call, please dial (888)698-6931 (U.S.) or (805)905-2993 (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 proprietary DETERx® technology platform for the treatment of chronic pain and other diseases. The DETERx technology platform is designed to provide extended-release delivery, unique abuse-deterrent properties, and flexible dose administration options.

About Xtampza ER

Xtampza ER is Collegium's first product utilizing the DETERx technology platform. Xtampza ER is an abuse-deterrent, extended-release, oral formulation of oxycodone approved by the FDA 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.

LIMITATIONS OF USE

Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve Xtampza ER for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.

Xtampza ER is not indicated as an as-needed (prn) analgesic.

The Full Prescribing Information for Xtampza ER contains the following Boxed Warning:

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL INGESTION; NEONATAL OPIOID WITHDRAWAL SYNDROME; and CYTOCHROME P450 3A4 INTERACTION

Addiction, Abuse, and Misuse
Xtampza ER exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing Xtampza ER and monitor all patients regularly for the development of these behaviors or conditions.

Life-Threatening Respiratory Depression
Serious, life-threatening, or fatal respiratory depression may occur with use of Xtampza ER. Monitor for respiratory depression, especially during initiation of Xtampza ER or following a dose increase.

Accidental Ingestion
Accidental ingestion of even one dose of Xtampza ER, especially by children, can result in a fatal overdose of oxycodone.

Neonatal Opioid Withdrawal Syndrome
Prolonged use of Xtampza ER during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

Cytochrome P450 3A4 Interaction
The concomitant use of Xtampza ER with all cytochrome P450 3A4 inhibitors may result in an increase in oxycodone plasma concentrations, which could increase or prolong adverse drug effects and may cause potentially fatal respiratory depression. In addition, discontinuation of a concomitantly used cytochrome P450 3A4 inducer may result in an increase in oxycodone plasma concentration. Monitor patients receiving Xtampza ER and any CYP3A4 inhibitor or inducer.

IMPORTANT SAFETY INFORMATION

Xtampza ER is contraindicated in patients with: significant respiratory depression; acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment; known or suspected gastrointestinal obstruction, including paralytic ileus; and hypersensitivity (e.g., anaphylaxis) to oxycodone.

Xtampza ER contains oxycodone, a Schedule II controlled substance. As an opioid, Xtampza ER exposes users to the risks of addiction, abuse, and misuse. As extended-release products, such as Xtampza ER, deliver the opioid over an extended period of time, there is a greater risk for overdose and death due to the larger amount of oxycodone present.

Potential serious adverse events caused by opioids include addiction, abuse, and misuse, life-threatening respiratory depression, neonatal opioid withdrawal syndrome, risks of concomitant use or discontinuation of cytochrome P450 3A4 inhibitors and inducers, risks due to interactions with central nervous system depressants, risk of life-threatening respiratory depression in patients with chronic pulmonary disease or in elderly, cachectic, or debilitated patients, adrenal insufficiency, severe hypotension, risks of use in patients with increased intracranial pressure, brain tumors, head injury, or impaired consciousness, risks of use in patients with gastrointestinal conditions, risk of use in patients with seizure disorders, withdrawal, risks of driving and operating machinery, and laboratory monitoring.

The most common AEs (>5%) reported by patients in the Phase 3 clinical trial during the titration phase were: nausea (16.6%), headache (13.9%), constipation (13.0%), somnolence (8.8%), pruritus (7.4%), vomiting (6.4%), and dizziness (5.7%).

For Important Safety Information visit including full prescribing information visit: http://www.xtampzaer.com/

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)

	June 30, 2016	December 31, 2015
Cash and cash equivalents	$110,747	$ 95,697
Accounts receivable, net	2,952	-
Inventory	1,214	-
Prepaid expenses and other current assets	1,537	1,186
Property and equipment, net	676	738
Intangible assets, net	2,500	-
Restricted cash	97	97
Total assets	**$119,723**	**$ 97,718**
Accounts payable and accrued expenses	$ 11,610	$ 5,765
Deferred revenue	3,926	-
Other liabilities	5,531	6,881
Stockholders' equity	98,656	85,072
Total liabilities and stockholders' equity	**$119,723**	**$ 97,718**

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,	
	2016	2015	2016	2015
Operating expenses:				
Research and development	$ 4,301	$ 1,641	$ 8,363	$ 3,086
Selling, general and administrative	20,173	2,934	31,698	5,120
Total operating expenses	24,474	4,575	40,061	8,206

Loss from operations	(24,474)	(4,575)	(40,061)	(8,206)
Other expense, net	(46)	(99)	(111)	(163)
Net loss	**$ (24,520)**	**$ (4,674)**	**$ (40,172)**	**$ (8,369)**
Loss per share–basic and diluted	$ (1.05)	$ (0.45)	$ (1.73)	$ (0.18)
Weighted-average shares -basic and diluted	23,417,378	11,791,546	23,273,765	6,426,431

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Collegium Pharmaceutical, Inc