



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

August 9, 2017

- *Collegium strengthens leadership team with key additions to executive team and Board of Directors*
- *Xtampza ER prescriptions grow by 34% in the second quarter*
- *Xtampza ER Notice of Allowance granted and, once issued, will extend patent protection until 2036*
- *Well capitalized with \$111.2 million in cash and cash equivalents*
- *Conference call scheduled for today at 4:30 p.m. ET*

CANTON, Mass., Aug. 09, 2017 (GLOBE NEWSWIRE) -- Collegium Pharmaceutical, Inc. (Nasdaq:COLL) today reported its financial results for the second quarter of 2017 and provided a corporate update.

"In the second quarter, we accelerated the growth of Xtampza ER with consistent prescription growth, especially in the second half of the quarter," said Michael Heffernan, CEO of Collegium. "We are also pleased to welcome two experienced pharmaceutical executives to Collegium. Joseph Ciaffoni has joined as our Chief Operating Officer, a newly created role within the Collegium organization, and Gwen Melincoff has joined our Board of Directors. With these additions, we have strengthened our team with significant operational, commercial and business development expertise."

### Recent Milestones

#### Corporate

- In May 2017, Collegium appointed Joe Ciaffoni as Executive Vice President and Chief Operating Officer.
- Effective today, Collegium appointed Gwen Melincoff to the Company's Board of Directors. Ms. Melincoff has over 25 years of experience in the pharmaceutical industry, including senior leadership positions at BTG International, Shire Pharmaceuticals and Adolor Corporation. Her experience includes business development, licensing, financing, marketing and product management.

#### Commercial

- Prescriptions for Xtampza ER grew to 18,632 for the quarter, a 34% increase over the first quarter of 2017.
- During the second quarter of 2017, over 1,100 prescribers wrote a prescription for Xtampza ER for the first time and over 4,000 prescribers have written since launch.
- Continued improvement in managed care:
  - Effective April 1, 2017, Xtampza ER is a preferred brand and the exclusive branded oxycodone extended-release product on Aetna Medicare Part D.
  - Effective June 1, 2017, Xtampza ER is a preferred brand and the exclusive oxycodone extended-release product on Humana Medicare Part D.
  - Effective July 1, 2017, Xtampza ER is covered by Blue Cross Blue Shield of Florida.

#### Intellectual Property

- In June 2017, a new patent covering Xtampza ER granted by the United States Patent and Trademark Office was added to the FDA Orange Book and provides additional patent protection for Xtampza ER until December 2030.
- Recently, a Notice of Allowance for a new patent covering Xtampza ER was granted by the United States Patent and Trademark Office. Once issued, the new patent will be added to the FDA Orange Book and provides additional patent protection for Xtampza ER until December 2036.

#### Clinical

- Continued success in demonstrating the clinical differentiation between Xtampza ER and alternative extended-release opioids with four new manuscripts published or accepted for publication:
  - "Relative abuse of crush resistant prescription opioid tablets via alternative oral modes of administration" (Pain Medicine, July 2017)
  - "Tolerability, safety and effectiveness of oxycodone DETERx in elderly patients >65 years of age with chronic low back pain; a randomized controlled trial" (Drugs and Aging, June 2017)
  - "The comparative pharmacokinetics of physical manipulation by crushing of Xtampza ER compared with Oxycontin" (Pain Management, Accepted for publication)

- “In Vitro Drug Release After Crushing: Evaluation of Xtampza ER and Other ER Opioid Formulations” (Clinical Drug Investigations, Accepted for publication)

## Second Quarter 2017 Financial Results

Collegium had cash and cash equivalents of \$111.2 million as of June 30, 2017 compared to \$129.6 million as of March 31, 2017 and \$153.2 million as of December 31, 2016. During the quarter ended June 30, 2017 cash used by operating activities was \$17.5 million compared to \$23.7 million for the quarter ended March 31, 2017.

Net loss for the quarter ended June 30, 2017 (the “2017 Quarter”) was \$21.1 million, or \$0.72 per share (basic and diluted), as compared to net loss of \$24.5 million, or \$1.05 per share (basic and diluted), for the quarter ended June 30, 2016 (the “2016 Quarter”). Net loss includes stock-based compensation expense of \$1.9 million and \$1.4 million for the 2017 Quarter and 2016 Quarter, respectively.

Net product revenues for Xtampza ER were \$3.6 million for the 2017 Quarter compared to none for the 2016 Quarter. Net product revenues increased by 64% for the 2017 Quarter compared to the quarter ended March 31, 2017.

Research and development expenses were \$2.2 million for the 2017 Quarter compared to \$4.3 million for the 2016 Quarter. The \$2.1 million decrease was primarily related to a decrease in clinical trial costs of \$1.8 million due to the completion of clinical trials in 2016 and a decrease in manufacturing costs of \$579,000 for Xtampza ER prior to FDA approval, partially offset by an increase in manufacturing costs of \$209,000 for clinical trials associated with our hydrocodone product candidate.

Selling, general and administrative expenses were \$22.1 million for the 2017 Quarter compared to \$20.2 million for the 2016 Quarter. The \$1.9 million increase was primarily related to an increase in personnel related costs of \$4.0 million, an increase in legal fees of \$583,000 and an increase in sales and marketing costs of \$482,000. These increases were partially offset by a decrease in consulting costs of \$3.0 million following the launch of Xtampza in June 2016.

As of June 30, 2017, there were 29,565,411 common shares outstanding.

## Financial Outlook

Based on our current operating plans, we believe that our existing cash resources, together with expected cash inflows from the commercialization of Xtampza ER will fund our operating expenses, debt service and capital expenditure requirements into 2019.

## Conference Call Information

Collegium will host a conference call and live audio webcast on Wednesday, August 9, 2017 at 4:30 p.m. Eastern Time. To access the conference call, please dial (888)698-6931 (U.S.) or (805)905-2993 (International) and refer to Conference ID: 5785-1943. 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<sup>®</sup> 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<sup>®</sup> 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 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 obtain and maintain regulatory approval of our products and product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product; our plans to commercialize our product candidates and grow sales of our products; the size and growth potential of the markets for our products and product candidates, and our ability to service those markets; the success of competing products that are or become available; our ability to obtain reimbursement and third-party payor contracts for our products; the costs of commercialization activities, including marketing, sales and distribution; our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators; the rate and degree of market acceptance of our products and product candidates; changing market conditions for our products and product candidates; the outcome of any patent infringement or other litigation that may be brought against us, including litigation with Purdue Pharma, L.P.; our ability to attract collaborators with development, regulatory and commercialization expertise; the success, cost and timing of our product development activities, studies and clinical trials; our ability to obtain funding for our operations; regulatory developments in the United States and foreign countries; our expectations regarding our ability to obtain and adequately maintain sufficient intellectual property protection for our products and product candidates; our ability to operate our business without infringing the intellectual property rights of others; the performance of our third-party suppliers and manufacturers; our ability to comply with stringent U.S. and foreign government regulation in the manufacture of pharmaceutical products, including U.S. Drug Enforcement Agency compliance; the loss of key scientific or management personnel; our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act; and the accuracy of our estimates regarding expenses, revenue, capital requirements and need for additional financing. 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, 2016, 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, 2017	December 31, 2016
Cash and cash equivalents	\$ 111,209	\$ 153,225
Accounts receivable	4,877	2,129
Inventory	1,520	1,316
Prepaid expenses and other current assets	3,009	1,905

Property and equipment, net	1,583	1,038
Intangible assets, net	1,925	2,103
Restricted cash	97	97
Other long-term assets	295	204
<b>Total assets</b>	<b>\$ 124,515</b>	<b>\$ 162,017</b>
Accounts payable and accrued expenses	\$ 15,811	\$ 17,985
Deferred revenue	10,361	4,944
Other liabilities	2,830	4,180
Stockholders' equity	95,513	134,908
<b>Total liabilities and stockholders' equity</b>	<b>\$ 124,515</b>	<b>\$ 162,017</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,	
	2017	2016	2017	2016
Product revenues, net	\$ 3,560	\$ —	\$ 5,732	\$ —
Costs and expenses:				
Cost of product revenues	577	—	948	—
Research and development	2,179	4,301	4,309	8,363
Selling, general and administrative	22,062	20,173	44,909	31,698
Total costs and expenses	24,818	24,474	50,166	40,061
Loss from operations	(21,258)	(24,474)	(44,434)	(40,061)
Interest income (expense), net	137	(46)	235	(111)
<b>Net loss</b>	<b>(\$21,121)</b>	<b>(\$24,520)</b>	<b>(\$44,199)</b>	<b>(\$40,172)</b>
Loss per share—basic and diluted	(\$0.72)	(\$1.05)	(\$1.50)	(\$1.73)
Weighted-average shares -basic and diluted	29,441,514	23,417,378	29,396,143	23,273,765

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Collegium Pharmaceutical, Inc