# Collegium Reports Third Quarter Financial Results and Provides Corporate Update

November 8, 2017

- *Xtampza® ER prescriptions grow by 49% in the third quarter*
- *FDA Approval of sNDA, including Comparative OxyContin Data*
- *Strong balance sheet provides cash runway into mid-2019*
- *Conference call scheduled for today at 4:30 p.m. ET*

CANTON, Mass., Nov. 08, 2017 (GLOBE NEWSWIRE) -- Collegium Pharmaceutical, Inc. (Nasdaq:COLL) today reported its financial results for the third quarter of 2017 and provided a corporate update.

“We are encouraged by the continued adoption of Xtampza ER with consistent prescription growth during the third quarter,” said Michael Heffernan, CEO of Collegium. “With recent formulary wins and strengthened positions at existing plans, we believe we are well positioned for next year.”

“During the third quarter, our focus on operational execution enabled us to generate momentum with Xtampza ER. We are encouraged, but not satisfied with our accomplishments,” said Joe Ciaffoni, Chief Operating Officer of Collegium. “The Collegium team will remain focused on generating momentum through the remainder of 2017, while setting the foundation upon which we will accelerate Xtampza ER in 2018.”

**Recent Milestones**

Commercial

- Prescriptions for Xtampza ER grew to 27,713 for the third quarter, a 49% increase over the second quarter of 2017.
- Prescribers of Xtampza ER grew to 5,300 since launch, including 1,266 new prescribers during the third quarter of 2017.
- Strengthened formulary position at numerous payers, including: Cigna, Humana Part D and United Healthcare commercial.

Corporate

- Strengthened our balance sheet by selling common stock through our ATM facility for gross proceeds of $32.2 million (of which $9.8 million was received during the third quarter and $22.4 million was received in October).

Clinical

- With the recent approval of our sNDA, the updated Xtampza ER label, includes:
    - **OxyContin Comparative Data** - The addition of comparative oral pharmacokinetic data, collected in two completed clinical studies evaluating the effect of physical manipulation by crushing Xtampza ER compared with the abuse-deterrent version of OxyContin (oxycodone hydrochloride extended-release tablets) and a control (oxycodone immediate-release (IR)),
    - **Oral Human Abuse Potential Study** - Results of an oral human abuse potential study comparing intact and manipulated Xtampza ER to oxycodone IR were added to the label. This study demonstrated that the oral administration of chewed and intact Xtampza ER in the fasted state was associated with statistically lower mean Drug Liking and Take Drug Again Visual Analogue Scale scores compared with crushed immediate-release oxycodone. In addition, the Drug Liking and Take Drug Again scores were similar for Xtampza ER taken in the intact and chewed states,
    - **Oral Abuse Deterrent Claim** - The addition of an oral abuse deterrent claim into the label that indicates that Xtampza ER has physicochemical properties that are expected to reduce abuse via the oral route. Xtampza ER is the only single agent oxycodone with this labelling.
- Numerous publications and presentations to show the clinical differentiation between Xtampza ER and other extended-release opioids, including:
    - Strong presence at PAINWeek 2017, including hosting two product theaters and presenting three clinical posters,

- “The comparative pharmacokinetics of physical manipulation by crushing of Xtampza ER compared with Oxycontin” (Pain Management, September 2017),

- “In Vitro Drug Release After Crushing: Evaluation of Xtampza ER and Other ER Opioid Formulations” (Clinical Drug Investigations, September 2017).

**Third Quarter 2017 Financial Results**

Beginning in the third quarter of 2017, the Company determined that it has sufficient experience with Xtampza ER to use the sell-in method of recognizing revenue, instead of the sell-through method that was used in prior quarters. Therefore, the quarter ended September 30, 2017 (the “2017 Quarter”), included a one-time $4.4 million increase to Net Product Revenue as a result of the Company’s change to the sell-in method.

Net product revenues for Xtampza ER for the 2017 Quarter were $12.0 million ($7.6 million without the one-time $4.4 million increase) compared to $408,000 for the quarter ended September 30, 2016 (the “2016 Quarter”). Net product revenues increased by 236% for the 2017 Quarter compared to the quarter ended June 30, 2017.

Net loss for the 2017 Quarter was $13.3 million, or $0.45 per share (basic and diluted), as compared to net loss of $26.4 million, or $1.13 per share (basic and diluted), for the 2016 Quarter. Net loss includes stock-based compensation expense of $2.1 million and $1.6 million for the 2017 Quarter and 2016 Quarter, respectively.

Research and development expenses were $2.1 million for the 2017 Quarter compared to $3.3 million for the 2016 Quarter. The $1.2 million decrease was primarily related to a decrease in clinical trial costs of $604,000 due to the completion of clinical trials in 2016 and a decrease in regulatory costs of $498,000 following the FDA approval and launch of Xtampza ER in 2016.

Selling, general and administrative expenses were $22.8 million for the 2017 Quarter compared to $23.6 million for the 2016 Quarter. The $809,000 decrease was primarily related to a decrease in Post Marketing Requirement costs of $4.4 million due to one-time costs incurred upon the launch of Xtampza ER, which are partially offset by an increase in personnel related costs of $2.5 million, an increase in legal fees of $567,000 and an increase in sales training costs of $422,000.

Collegium had cash and cash equivalents of $107.6 million as of September 30, 2017 compared to $111.2 million as of June 30, 2017 and $153.2 million as of December 31, 2016. During the quarter ended September 30, 2017 cash used by operating activities was $12.6 million compared to $17.5 million for the quarter ended June 30, 2017.

As of September 30, 2017, there were 30,765,100 common shares outstanding.

Financial Outlook

Based on our current operating plans, we believe that our existing cash resources, including proceeds from common stock sold under our ATM facility that were received in October 2017, together with expected cash inflows from the commercialization of Xtampza ER will fund our operating expenses, debt service and capital expenditure requirements into mid-2019.

**Conference Call Information**

Collegium will host a conference call and live audio webcast on Wednesday, November 8, 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: 668-9689. 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; AND RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS**

**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.

**Risks From Concomitant Use With Benzodiazepines Or Other CNS Depressants**

Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death.

- Reserve concomitant prescribing of Xtampza ER and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.
- Limit dosages and durations to the minimum required.
- Follow patients for signs and symptoms of respiratory depression and sedation.

**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 from concomitant use with benzodiazepines or other CNS 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; our

ability to retain key and 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.

Contact:
Alex Dasalla
adasalla@collegiumpharma.com

**Collegium Pharmaceutical, Inc.**

**Unaudited Selected Consolidated Balance Sheet Information**
(in thousands)

| | September 30, 2017 | December 31, 2016 |
|---|---|---|
| Cash and cash equivalents | $107,611 | $153,225 |
| Accounts receivable | 5,823 | 2,129 |
| Inventory | 1,401 | 1,316 |
| Prepaid expenses and other current assets | 4,061 | 1,905 |
| Property and equipment, net | 1,632 | 1,038 |
| Intangible assets, net | 1,877 | 2,103 |
| Restricted cash | 97 | 97 |
| Other long-term assets | 171 | 204 |
| **Total assets** | **$122,673** | **$162,017** |
| | | |
| Accounts payable and accrued expenses | $24,250 | $17,985 |
| Deferred revenue | — | 4,944 |
| Other liabilities | 2,154 | 4,180 |
| Stockholders' equity | 96,269 | 134,908 |
| **Total liabilities and stockholders' equity** | **$122,673** | **$162,017** |

**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, | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| Product revenues, net | $11,950 | $408 | $17,682 | $408 |
| | | | | |
| Costs and expenses: | | | | |
| Cost of product revenues | 553 | 29 | 1,501 | 29 |
| Research and development | 2,069 | 3,254 | 6,378 | 11,617 |
| Selling, general and administrative | 22,758 | 23,567 | 67,667 | 55,266 |
| Total costs and expenses | 25,380 | 26,850 | 75,546 | 66,912 |
| | | | | |
| Loss from operations | (13,430) | (26,442) | (57,864) | (66,504) |
| Interest income (expense), net | 167 | (2) | 402 | (113) |
| **Net loss** | **($13,263)** | **($26,444)** | **($57,462)** | **($66,617)** |
| | | | | |
| Loss per share–basic and diluted | ($0.45) | ($1.13) | ($1.95) | ($2.85) |

| | | | | |
|---|---|---|---|---|
| Weighted-average shares -basic and diluted | 29,753,043 | 23,460,340 | 29,517,396 | 23,334,558 |