

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 OR 15(d) of the Securities and Exchange Act of 1934**

Date of Report (Date of earliest reported): **November 10, 2016**

**COLLEGIUM PHARMACEUTICAL, INC.**

(Exact Name of Registrant as Specified in Charter)

**Virginia**  
(State or Other Jurisdiction  
of Incorporation or Organization)

**001-37372**  
(Commission File Number)

**03-0416362**  
(IRS Employer Identification  
No.)

**780 Dedham Street  
Suite 800  
Canton, MA 02021**  
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **(781) 713-3699**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Item 2.02 Results of Operations and Financial Condition.**

On November 10, 2016, Collegium Pharmaceutical, Inc. issued a press release announcing its financial results for the quarterly period ended September 30, 2016. The full text of the press release issued in connection with the announcement is attached hereto as Exhibit 99.1 and is being furnished, not filed, under Item 2.02 of this Current Report on Form 8-K.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated November 10, 2016.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**COLLEGIUM PHARMACEUTICAL, INC.**

Date: November 10, 2016

By: /s/ Paul Brannelly  
Name: Paul Brannelly  
Title: Executive Vice President and Chief  
Financial Officer

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**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
99.1	Press Release dated November 10, 2016.



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

- Broadened Xtampza ER market access with commitments from large commercial payers
- Submitted Supplemental New Drug Application to the FDA
- Submitted New Drug Submission to Health Canada

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

“It has been a very productive quarter for Collegium. We have made significant progress on the commercial launch of Xtampza® ER with broadened payer coverage, pharmacy availability, customer contracting, as well as increasing the physician prescriber base of the product,” stated Michael Heffernan, Collegium’s CEO. “Furthermore, we submitted a Supplemental New Drug Application to enhance the label for Xtampza ER and submitted a New Drug Submission to Health Canada seeking marketing approval for Xtampza ER in an important market outside of the U.S.”

### Corporate Milestones

#### Commercial

- UnitedHealth and Cigna announced availability for Xtampza ER for 15.6 million and 6.4 million contracted lives, respectively. Effective January 1, 2017, the UnitedHealth contract makes Xtampza ER a preferred product and the exclusive extended-release oxycodone product on its formulary with the removal of OxyContin from formulary.
- In September 2016, Collegium announced the launch of OpioidIQ, an online educational tool to assist physicians and other healthcare providers with more effective pain management (available at [www.OpioidIQ.com](http://www.OpioidIQ.com)). The goal of OpioidIQ is to connect healthcare providers to information and resources aimed at supporting the safe and effective management of their patients with chronic pain who are appropriate for treatment with an opioid analgesic.
- In October 2016, Collegium launched promotional material and marketing programs through its commercial organization after receiving feedback from the Office of Prescription Drug Promotion (OPDP) of the FDA.

#### Regulatory

- In October 2016, Collegium announced the submission of a Supplemental New Drug Application (sNDA) to the FDA to enhance the label for Xtampza ER. The sNDA includes comparative oral pharmacokinetic data from two clinical studies evaluating the effect of physical manipulation by crushing Xtampza ER compared to crushing the abuse-deterrent version of OxyContin.
- In October 2016, Collegium announced the submission of a New Drug Submission (NDS) to Health Canada seeking marketing approval of Xtampza ER. The NDS submission marks the first regulatory submission seeking to expand the geographic footprint of Xtampza ER in an important market outside of the U.S.

#### Publications

- During the quarter, Collegium announced three scientific publications on Xtampza ER in The Journal of Clinical Pharmacology, The Journal of the American Medical Association (JAMA) and Current Medical Research and Opinion.

#### Corporate

- In October 2016, Collegium announced a public offering of 5,000,000 shares of its common stock at a price of \$16.00 per share. The gross proceeds of this offering were \$80 million, excluding underwriters’ discounts and commissions and offering expenses payable by the Company.

### Third Quarter 2016 Financial Results

As of September 30, 2016, prior to the financing described above, Collegium had cash and cash equivalents of \$91.0 million compared to \$95.7 million as of December 31, 2015. During the nine months ended September 30, 2016, cash and cash equivalents decreased by \$4.7 million primarily due to cash used in operations of \$51.8 million, cash utilized in the acquisition of rights to Onsolis® of \$2.5 million and cash used to repay debt totaling \$2.0 million, partially offset by the net proceeds of \$51.2 million from our January 2016 follow-on offering of common stock.

Net loss for the quarter ended September 30, 2016 (the “2016 Quarter”) was \$26.4 million, or \$1.13 per share (basic and diluted), as compared to net loss of \$9.4 million, or \$0.46 per share (basic and diluted), for the quarter ended September 30, 2015 (the “2015 Quarter”). Net loss includes stock-based compensation expense of \$1.6 million and \$503,000 for the 2016 Quarter and 2015 Quarter, respectively.

Net product revenues for Xtampza ER were \$408,000 for the 2016 Quarter compared to none for the 2015 Quarter.

Research and development expenses were \$3.3 million for the 2016 Quarter compared to \$3.4 million for the 2015 Quarter. The decrease was primarily related to a decrease in consulting costs of \$956,000 related to the FDA advisory committee in 2015 and a decrease in manufacturing costs for Xtampza ER prior to FDA approval of \$657,000, partially offset by an increase in clinical trial costs of \$533,000 due to the initiation of clinical trials for Xtampza ER and Hydrocodone DETERx, an increase in manufacturing transfer costs related to Onsolis of \$499,000 and an increase in personnel related costs of \$369,000.

Selling, general and administrative expenses were \$23.6 million for the 2016 Quarter compared to \$5.9 million for the 2015 Quarter. The increase was primarily related to: an increase in personnel related costs of \$8.8 million primarily due to an increase in headcount, an increase in Post Marketing Requirement costs required with FDA approval of Xtampza ER of \$4.8 million, an increase in sales and marketing costs of \$2.3 million primarily due to support for the commercial launch of Xtampza ER, and an increase in commercial costs of \$1.2 million primarily due to consultant costs related to analytics and strategies for commercialization of Xtampza ER.

As of September 30, 2016, there were 23,588,985 common shares outstanding. As part of our follow-on offering subsequently completed in October 2016, we issued an additional 5,000,000 shares. In connection with the follow-on offering, the underwriters have the option to purchase an additional 750,000 shares within 30 days from the date of the final prospectus.

## **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 as well as the proceeds of our follow-on offering completed in October 2016, 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 Thursday, November 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

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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

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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/>

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### **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; 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, 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.

### **Contact:**

Douglas Carlson  
Vice President, Corporate Development  
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**Unaudited Selected Consolidated Balance Sheet Information**  
(in thousands)

	September 30, 2016	December 31, 2015
Cash and cash equivalents	\$ 91,028	\$ 95,697
Accounts receivable, net	1,679	—
Inventory	1,576	—
Prepaid expenses and other current assets	1,086	1,186
Property and equipment, net	772	738
Intangible assets, net	2,273	—
Restricted cash	97	97
Other long-term assets	214	—
<b>Total assets</b>	<b>\$ 98,725</b>	<b>\$ 97,718</b>
Accounts payable and accrued expenses	\$ 15,607	\$ 5,765
Deferred revenue	3,938	—
Other liabilities	4,855	6,881
Stockholders' equity	74,325	85,072
<b>Total liabilities and stockholders' equity</b>	<b>\$ 98,725</b>	<b>\$ 97,718</b>

**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,	
	2016	2015	2016	2015
Product revenues, net	\$ 408	\$ —	\$ 408	\$ —
Costs and expenses:				
Cost of product revenues	29	—	29	—
Research and development	3,254	3,358	11,617	6,444
Selling, general and administrative	23,567	5,907	55,266	11,027
<b>Total costs and expenses</b>	<b>26,850</b>	<b>9,265</b>	<b>66,912</b>	<b>17,471</b>
Loss from operations	(26,442)	(9,265)	(66,504)	(17,471)
Other expense, net	(2)	(97)	(113)	(259)
<b>Net loss</b>	<b>\$ (26,444)</b>	<b>\$ (9,362)</b>	<b>\$ (66,617)</b>	<b>\$ (17,730)</b>
Loss per share—basic and diluted	\$ (1.13)	\$ (0.46)	\$ (2.85)	\$ (0.94)
Weighted-average shares -basic and diluted	23,460,340	20,531,406	23,334,558	11,179,756