

**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): **March 9, 2017**

**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 March 9, 2017, Collegium Pharmaceutical, Inc. issued a press release announcing its financial results for the quarterly period and fiscal year ended December 31, 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 March 9, 2017.

**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: March 9, 2017

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 March 9, 2017.



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

- *Xtampza® ER prescribed by more than 2,400 physicians since commercial launch*
- *ONSOLIS® patent issued that extends patent protection until 2027*
- *Well capitalized with \$153.2 million in cash and cash equivalents*

CANTON, Mass., March 9, 2017 (GLOBE NEWSWIRE) — Collegium Pharmaceutical, Inc. (Nasdaq: COLL) today reported its financial results for the fourth quarter of 2016 and provided a corporate update.

“We have made significant progress on the commercial launch of Xtampza ER. Through mid-February, more than 2,400 physicians have prescribed Xtampza ER, including 800 first time prescribers in 2017 alone,” stated Michael Heffernan, Collegium’s CEO. “With broadened payer coverage and improved pharmacy availability, we are building a solid foundation for a successful commercial launch.”

### Recent Milestones Include:

#### Commercial

- Through mid-February, over 2,400 physicians prescribed Xtampza ER, including 800 new prescribers in 2017 alone. Since the launch, the average prescriber has written over six prescriptions.
- Prescriptions for Xtampza ER continue to grow. Over the last 13 weeks, Xtampza ER prescriptions increased by 148%. Over the last 5 weeks, Xtampza ER prescriptions increased by 26%.
- Effective January 1, 2017, Xtampza ER is a preferred product and the exclusive extended-release oxycodone product on UnitedHealth commercial formulary with the removal of OxyContin from formulary.
- Effective January 1, 2017, Xtampza ER is one of three preferred brands on Cigna commercial formulary.

#### Intellectual Property

- In March 2017, a new patent covering ONSOLIS® (fentanyl buccal soluble film) was issued by the United States Patent and Trademark Office. The new patent will provide additional patent protection until July 2027.

#### Corporate

- During the fourth quarter of 2016, Collegium announced a public offering of its common stock raising net proceeds of \$86.2 million. With this additional funding, 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.

### Fourth Quarter 2016 Financial Results

Collegium had cash and cash equivalents of \$153.2 million as of December 31, 2016 compared to \$95.7 million as of December 31, 2015. Cash used in operating and investing activities for the quarter ended December 31, 2016 (the “2016 Quarter”) was \$23.6 million.

Net loss for the 2016 Quarter was \$27.6 million, or \$1.02 per share (basic and diluted), as compared to net loss of \$9.5 million, or \$0.46 per share (basic and diluted), for the quarter ended December 31, 2015 (the “2015 Quarter”). Net loss includes stock-based compensation expense of \$1.6 million and \$1.0 million for the 2016 Quarter and 2015 Quarter, respectively.

Net product revenues for Xtampza ER were \$1.3 million for the 2016 Quarter compared to none for the 2015 Quarter. Net product revenues increased by 219% for the 2016 Quarter compared to the quarter ended September 30, 2016.

Research and development expenses were \$3.3 million for the 2016 Quarter compared to \$1.5 million for the 2015 Quarter. The increase was primarily related an increase in manufacturing transfer costs related to Onsolis of \$957,000, an increase in clinical trial costs of \$870,000 for Xtampza ER and Hydrocodone DETERx, and an increase in personnel related costs of \$385,000, partially offset by a decrease in Xtampza ER manufacturing costs of \$422,000.

Selling, general and administrative expenses were \$25.4 million for the 2016 Quarter compared to \$7.9 million for the 2015 Quarter. The increase was primarily related to: an increase in personnel related costs of \$7.3 million, an increase in sales and marketing costs of \$5.3 million due to support for Xtampza ER, an increase in regulatory fees of \$1.7 million and an increase in Post Marketing Requirement costs required with FDA approval of \$982,000.

As of December 31, 2016, there were 29,364,100 common shares outstanding.

### Conference Call Information

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<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.

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#### **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,

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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, 2015, and those risks described from time to time in other reports which we file with the SEC, including our Annual Report on Form 10-K for the year ended December 31, 2016 which will be filed soon. 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  
adassalla@collegiumpharma.com

### Collegium Pharmaceutical, Inc. Unaudited Selected Consolidated Balance Sheet Information (in thousands)

	December 31, 2016	December 31, 2015
Cash and cash equivalents	\$ 153,225	\$ 95,697
Accounts receivable, net	2,129	—
Inventory	1,316	—
Prepaid expenses and other current assets	1,905	1,186
Property and equipment, net	1,038	738
Intangible assets, net	2,103	—
Restricted cash	97	97
Other long-term assets	204	—
<b>Total assets</b>	<b>\$ 162,017</b>	<b>\$ 97,718</b>
Accounts payable and accrued expenses	\$ 17,985	\$ 5,765
Deferred revenue	4,944	—
Other liabilities	4,180	6,881
Stockholders’ equity	134,908	85,072
<b>Total liabilities and stockholders’ equity</b>	<b>\$ 162,017</b>	<b>\$ 97,718</b>

**Unaudited Condensed Statements of Operations**  
(in thousands, except share and per share amounts)

	Three months ended December 31,		Year ended December 31,	
	2016	2015	2016	2015
Product revenues, net	\$ 1,303	\$ —	\$ 1,711	\$ —
Costs and expenses:				
Cost of product revenues	184	—	213	—
Research and development	3,331	1,531	14,948	7,975
Selling, general and administrative	25,367	7,905	80,632	18,932
Total costs and expenses	28,882	9,436	95,793	26,907
Loss from operations	(27,579)	(9,436)	(94,082)	(26,907)
Other income (expense), net	20	(89)	(94)	(348)
<b>Net loss</b>	<b>\$ (27,559)</b>	<b>\$ (9,525)</b>	<b>\$ (94,176)</b>	<b>\$ (27,255)</b>
Loss per share—basic and diluted	\$ (1.02)	\$ (0.46)	\$ (3.88)	\$ (1.48)
Weighted-average shares -basic and diluted	27,100,231	20,558,205	24,262,945	13,542,282