

**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): **May 10, 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period or complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On May 10, 2017, Collegium Pharmaceutical, Inc. issued a press release announcing its financial results for the quarterly period ended March 31, 2017. 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 May 10, 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.

Date: May 10, 2017

By: /s/ Paul Brannelly

Name: Paul Brannelly

Title: Executive Vice President and Chief
Financial Officer

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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated May 10, 2017.

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Collegium Reports First Quarter Financial Results and Provides Corporate Update

- *Xtampza® ER prescribed by more than 3,000 physicians since commercial launch*
- *Xtampza ER Notice of Allowance granted and, once issued, will extend patent protection until 2030*
- *Well capitalized with \$129.6 million in cash and cash equivalents*
- *Conference call scheduled for today at 4:30 p.m. ET*

CANTON, Mass., May 10, 2017 (GLOBE NEWSWIRE) — Collegium Pharmaceutical, Inc. (Nasdaq: COLL) today reported its financial results for the first quarter of 2017 and provided a corporate update.

“During the first quarter, we are encouraged by the continued adoption of Xtampza ER and the positive reception by both prescribers and payors. We expect that this progress will continue to accelerate as we broaden our commercial initiatives,” said Michael Heffernan, Collegium’s CEO.

Recent Milestones Include:

Commercial

- Through March, over 3,000 physicians prescribed Xtampza ER, including over 1,400 new prescribers in the first quarter alone. Since the launch, the average prescriber has increased prescribing each month and has written over seven prescriptions.
- Prescriptions for Xtampza ER continue to grow. During the first quarter of 2017, Xtampza ER prescriptions increased by 106% over the fourth quarter of 2016.
- Effective January 1, 2017, Xtampza ER is a preferred product and the exclusive oxycodone extended-release 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.
- Effective April 1, 2017, Xtampza ER is the exclusive branded oxycodone extended-release product for the Medicare Part D formularies for a large national managed care organization that covers more than 3 million lives.

Intellectual Property

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

Clinical

- In February, Collegium announced positive topline results of a human abuse potential clinical trial, which was designed to evaluate the abuse potential and pharmacokinetics of oral administration of Xtampza ER compared to chewed Xtampza ER, and crushed immediate-release oxycodone in solution in non-dependent, recreational drug abusers. The study met its primary and secondary endpoints of lower “Drug Liking” and “Take Drug Again”.

Corporate

- Collegium appointed Steven Passik, PhD, as Vice President of Scientific Affairs, Education and Policy.

First Quarter 2017 Financial Results

Collegium had cash and cash equivalents of \$129.6 million as of March 31, 2017 compared to \$153.2 million as of December 31, 2016. Cash used in operating activities for the quarter ended March 31, 2017 (the “2017 Quarter”) was \$23.7 million.

Net loss for the 2017 Quarter was \$23.1 million, or \$0.79 per share (basic and diluted), as compared to a net loss of \$15.7 million, or \$0.68 per share (basic and diluted), for the quarter ended March 31, 2016 (the “2016 Quarter”). Net loss includes stock-based compensation expense of \$1.8 million and \$1.1 million for the 2017 Quarter and 2016 Quarter, respectively.

Net product revenues for Xtampza ER were \$2.2 million for the 2017 Quarter compared to none for the 2016 Quarter. Net product revenues increased by 67% for the 2017 Quarter compared to the quarter ended December 31, 2016.

Research and development expenses were \$2.1 million for the 2017 Quarter compared to \$4.1 million for the 2016 Quarter. The decrease was primarily related to a decrease in clinical trial costs of \$1.4 million due to the completion of clinical trials in 2016 and a decrease in manufacturing costs of \$764,000 for Xtampza ER prior to FDA approval, partially offset by an increase in personnel related costs of \$237,000.

Selling, general and administrative expenses were \$22.8 million for the 2017 Quarter compared to \$11.5 million for the 2016 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 \$3.1 million to support the commercial launch of Xtampza ER and an increase in legal fees of \$822,000.

As of March 31, 2017, there were 29,458,557 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, May 10, 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: 1776-1195. 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 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.

Contact:

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

	March 31, 2017	December 31, 2016
Cash and cash equivalents	\$ 129,558	\$ 153,225
Accounts receivable	3,349	2,129
Inventory	1,495	1,316
Prepaid expenses and other current assets	2,064	1,905
Property and equipment, net	1,007	1,038
Intangible assets, net	1,973	2,103
Restricted cash	97	97
Other long-term assets	305	204
Total assets	\$ 139,848	\$ 162,017
Accounts payable and accrued expenses	\$ 13,281	\$ 17,985
Deferred revenue	8,695	4,944
Other liabilities	3,505	4,180

Stockholders' equity	114,367	134,908
Total liabilities and stockholders' equity	\$ 139,848	\$ 162,017

Collegium Pharmaceutical, Inc.

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

	Three months ended March 31,	
	2017	2016
Product revenues, net	\$ 2,172	\$ —
Costs and expenses:		
Cost of product revenues	371	—
Research and development	2,130	4,062
Selling, general and administrative	22,847	11,525
Total costs and expenses	25,348	15,587
Loss from operations	(23,176)	(15,587)
Other income (expense), net	98	(66)
Net loss	(\$23,078)	(\$15,653)
Loss per share—basic and diluted	(\$0.79)	(\$0.68)
Weighted-average shares -basic and diluted	29,350,268	23,130,153