

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 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 event reported): **March 7, 2018**

COLLEGIUM PHARMACEUTICAL, INC.

(Exact Name of Registrant as Specified in its 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 for 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 March 7, 2018, Collegium Pharmaceutical, Inc. issued a press release announcing its financial results for the quarterly period and fiscal year ended December 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 March 7, 2018.

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated March 7, 2018.

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 7, 2018

By: /s/ Paul Brannelly

Name: Paul Brannelly

Title: Executive Vice President and Chief
Financial Officer



Collegium Reports Fourth Quarter Financial Results and Provides Corporate Update

- *Xtampza ER prescriptions grew by 37% in the fourth quarter*
- *FDA Approval of sNDA, including Comparative OxyContin Data in label*
- *Expanded product portfolio by licensing rights to commercialize Nucynta franchise*
- *Revenue growth and strong balance sheet provide cash runway into 2020*
- *Conference call scheduled for today at 4:30 p.m. ET*

CANTON, Mass., March 7, 2018 (GLOBE NEWSWIRE) — Collegium Pharmaceutical, Inc. (Nasdaq: COLL) today reported its financial results for the fourth quarter and year ended December 31, 2017 and provided a corporate update.

“As we strive to establish Collegium as the leader in responsible pain management, we are encouraged by the success of Xtampza ER during the fourth quarter of 2017,” said Mike Heffernan, CEO of Collegium. “Integrating the Nucynta franchise into our pain portfolio in 2018 will enhance our ability to make a positive difference in the lives of people suffering from pain.”

“In 2017, our focus on operational execution generated significant momentum with Xtampza ER,” said Joe Ciaffoni, Chief Operating Officer of Collegium. “In 2018, the Collegium team is committed to continuing this focus so that patients who require opioid pain management can benefit from abuse-deterrent Xtampza ER, as well as the Nucynta franchise.”

Recent Milestones

Commercial

- Prescriptions for Xtampza ER grew to 38,044 in the fourth quarter, a 37% increase over the third quarter of 2017.
- Prescribers of Xtampza ER grew to 6,895 since launch, including 1,603 new prescribers in the fourth quarter of 2017.
- Secured new exclusive ER oxycodone formulary wins with numerous payers, including: Optum Medicare Part D, all Medicare Advantage and select Medicare PDP plans, Humana Commercial, Navitus Commercial and UPMC Commercial and Medicare D.
- Addition of the Nucynta franchise to the pain portfolio establishes Collegium as a leader in responsible pain management. On January 9, 2018, the transaction closed. Collegium began promotion of the Nucynta franchise in mid-February 2018.

Corporate

- Strengthened leadership team with the addition of Scott Dreyer, SVP, Sales, Marketing, Commercial Capabilities and Training. Scott brings over 24 years of commercial leadership experience across sales, marketing, commercial operations and strategic planning, all within the biopharma industry. Scott joins Collegium from The Medicines Company, where he was the SVP, Marketing and Commercial Operations.

Clinical

- With the recent approval of our sNDA, the updated Xtampza ER label, includes:
 - **OxyContin Comparative Data** - The addition of comparative oral pharmacokinetic data,
 - **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,
 - **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.

Fourth Quarter and 2017 Financial Results

Net Product Revenues for Xtampza ER were \$10.8 million for the quarter ended December 31, 2017 (the “2017 Quarter”) compared to \$1.3 million for the quarter ended December 31, 2016 (the “2016 Quarter”). For the year ended December 31, 2017, Net Product Revenues were \$28.5 million compared to \$1.7 million for the year ended December 31, 2016. The quarter ended September 30, 2017 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 of recognizing revenue during the quarter.

Net loss for the 2017 Quarter was \$17.4 million, or \$0.54 per share (basic and diluted), as compared to net loss of \$27.6 million, or \$1.02 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 \$2.2 million for the 2017 Quarter compared to \$3.3 million for the 2016 Quarter. The decrease was primarily related to a decrease in product development manufacturing costs of \$664,000 and a decrease in research-related regulatory costs of \$584,000.

Selling, general and administrative expenses were \$25.1 million for the 2017 Quarter compared to \$25.4 million for the 2016 Quarter. The decrease was primarily related to higher sales and marketing costs of \$3.4 million in the 2016 Quarter due to the launch of Xtampza and a decrease in Post Marketing Requirements and other regulatory costs of \$1.4 million in the 2017 Quarter. These decreases were partially offset by increased personnel related costs of \$2.8 million and a one-time impairment charge of \$1.8 million relating to the termination of the Onsolis license and development agreement.

Collegium had cash and cash equivalents of \$118.7 million as of December 31, 2017, compared to \$153.2 million as of December 31, 2016. Cash used in operating and investing activities for the 2017 Quarter was \$13.5 million.

As of December 31, 2017, there were 32,770,678 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 and the Nucynta franchise will fund our operating expenses, debt service and capital expenditure requirements into 2020.

Conference Call Information

Collegium will host a conference call and live audio webcast on Wednesday, March 7, 2018 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: 764-8078. 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 becoming the leader in responsible pain management by developing and commercializing innovative, differentiated products for patients suffering from pain.

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 presentation 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 ability to commercialize our product candidates and grow sales of our products; our ability to effectively commercialize in-licensed products and manage our relationships with licensors, including our ability to satisfy our royalty payment obligations in connection with such 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 and maintain 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 by or against us, including litigation with Purdue Pharma, L.P. and Teva Pharmaceuticals USA, Inc.; 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 secure adequate supplies of active pharmaceutical ingredient for each of our products and product candidates; our ability to comply with stringent U.S. and foreign government regulation in the manufacture of pharmaceutical products, including U.S. Drug Enforcement Agency, or DEA, 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; our customer concentration, which may adversely affect our financial condition and results of operations; 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 presentation speak only as of the date of this presentation. 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)

	December 31, 2017	December 31, 2016
Cash and cash equivalents	\$ 118,697	\$ 153,225
Accounts receivable	9,969	2,129
Inventory	1,813	1,316
Prepaid expenses and other current assets	3,005	1,905
Property and equipment, net	1,826	1,038
Intangible assets, net	—	2,103
Restricted cash	97	97
Other long-term assets	161	204
Total assets	\$ 135,568	\$ 162,017
Accounts payable and accrued expenses	\$ 14,225	\$ 17,985
Accrued rebates, returns and discounts	15,784	—
Deferred revenue	—	4,944
Other liabilities	1,479	4,180
Stockholders' equity	104,080	134,908
Total liabilities and stockholders' equity	\$ 135,568	\$ 162,017

Collegium Pharmaceutical, Inc.

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

	Three months ended December 31,		Year ended December 31,	
	2017	2016	2017	2016
Product revenues, net	\$ 10,794	\$ 1,303	\$ 28,476	\$ 1,711
Costs and expenses:				
Cost of product revenues	1,094	184	2,595	213
Research and development	2,194	3,331	8,572	14,948
Selling, general and administrative	25,089	25,367	92,756	80,632
Total costs and expenses	28,377	28,882	103,923	95,793
Loss from operations	(17,583)	(27,579)	(75,447)	(94,082)
Interest income (expense), net	180	20	582	(94)
Net loss	\$ (17,403)	\$ (27,559)	\$ (74,865)	\$ (94,176)
Loss per share—basic and diluted	\$ (0.54)	\$ (1.02)	\$ (2.47)	\$ (3.88)
Weighted-average shares -basic and diluted	32,485,572	27,100,231	30,265,262	24,262,945