

**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): **August 8, 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 August 8, 2018, Collegium Pharmaceutical, Inc. issued a press release announcing its financial results for the quarterly period ended June 30, 2018. 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 August 8, 2018.

EXHIBIT INDEX

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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: August 8, 2018

By: /s/ Paul Brannelly

Name: Paul Brannelly

Title: Executive Vice President and Chief
Financial Officer



Collegium Reports Second Quarter Financial Results and Provides Corporate Update

- Net revenue \$73.1 million for the second quarter of 2018, 1,952% increase vs second quarter 2017, 15% vs first quarter 2018
- Xtampza ER prescriptions grew by 23% in the second quarter of 2018
- Cash balance at end of 2018 anticipated to be at least \$135.0 million
- Conference call scheduled for today at 4:30 p.m. ET

CANTON, Mass., August 8, 2018 (GLOBE NEWSWIRE) — Collegium Pharmaceutical, Inc. (Nasdaq: COLL) today reported its financial results for the second quarter of 2018 and provided a corporate update.

“We made progress towards achieving our mission of becoming the leader in responsible pain management by developing and commercializing innovative and differentiated products for people suffering from pain and our communities,” said Joe Ciaffoni, Chief Executive Officer of Collegium. “A laser focus on operational execution and stability, drove net revenue 15%, to a record \$73.1 million in the second quarter.”

“Through the first half of 2018 we continued to accelerate Xtampza ER and began to stabilize the Nucynta franchise,” said Scott Dreyer, Chief Commercial Officer of Collegium. “Xtampza ER remained the fastest growing branded ER opioid, with 349% prescription growth in the first half of 2018 versus the first half of 2017. Following the resolution of the hurricane-related supply disruption, Nucynta ER grew 1% in the second quarter.”

Recent Milestones

Corporate

- Joe Ciaffoni appointed as Collegium’s CEO, effective July 1, 2018. Joe Ciaffoni succeeded Mike Heffernan as CEO, who continues to serve as Chairman of the Board of Directors.
- Executive management team strengthened with the promotion of Scott Dreyer to the position of Executive Vice President and Chief Commercial Officer, effective July 10, 2018.

Commercial

- Xtampza ER Total prescriptions were 80,364 in the second quarter of 2018, growing 23% over the first quarter of 2018.

- In the second quarter of 2018, total prescribers of Xtampza ER grew 11% to 9,228, including 2,756 new prescribers. Since launch, 13,542 health care providers have prescribed Xtampza ER.
- Continued to strengthen formulary access; Xtampza ER added to formulary at Cigna-Healthspring Medicare Part D on April 1, 2018 as the exclusive extended release oxycodone product for the majority of lives.
- The Nucynta franchise delivered 165,573 prescriptions in the second quarter, down 2% from the first quarter. Total prescriptions for Nucynta ER grew 1% in the second quarter.

Regulatory

- In the second quarter of 2018, two patents covering Xtampza ER were issued by the United States Patent and Trademark Office. Both patents were added to the FDA Orange Book, one with expiry in 2030 and the other with expiry in 2036. With the recent additions to the patent estate, Xtampza ER is now covered by 14 patents, including four patents with expiry in the 2030’s.

First Quarter 2018 Financial Results

Net Product Revenues were \$73.1 million for the quarter ended June 30, 2018 (the “2018 Quarter”), compared to \$3.6 million for the quarter ended June 30, 2017 (the “2017 Quarter”). In the 2018 Quarter, net product revenue was \$18.1 million for Xtampza ER and \$55.0 million for the Nucynta franchise.

Net loss for the 2018 Quarter was \$13.1 million, or \$0.40 per share (basic and diluted), as compared to net loss of \$21.1 million, or \$0.72 per share (basic and diluted), for the 2017 Quarter. Net loss includes stock-based compensation expense of \$3.5 million and \$1.9 million for the 2018 Quarter and 2017 Quarter, respectively. Net loss for the 2018 Quarter includes a non-cash interest charge of \$5.9 million associated with accounting for the Nucynta franchise. Non-GAAP adjusted loss for the 2018 Quarter was \$4.9 million, compared to non-GAAP adjusted loss of \$19.2 million for the 2017 Quarter.

Research and development expenses were \$2.2 million in both the 2018 Quarter and 2017 Quarter.

Selling, general and administrative expenses were \$31.3 million for the 2018 Quarter compared to \$22.1 million for the 2017 Quarter. The increase was primarily related to higher personnel costs of \$3.1 million and higher commercialization costs, including consulting and marketing expenses of \$3.1 million primarily related to the Nucynta franchise.

Collegium had cash and cash equivalents of \$133.7 million as of June 30, 2018, compared to \$118.7 million as of December 31, 2017.

As of June 30, 2018, there were 33,179,860 common shares outstanding.

Financial Outlook

Based on our current operating plans, we believe that we will finish the year with at least \$135.0 million in cash.

Conference Call Information

To access the conference call, please dial (888) 698-6931 (U.S.) or (805) 905-2993 (International) and refer to Conference ID: 126-8317. 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 and differentiated products for people suffering from pain and our communities.

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.

About Nucynta ER

Nucynta® ER is an extended release formulation of tapentadol. Tapentadol is a centrally acting synthetic analgesic. Nucynta ER is 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. Nucynta ER is also approved by the FDA for neuropathic pain associated with diabetic peripheral neuropathy severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

About Nucynta

Nucynta® is an immediate release formulation of tapentadol indicated for the management of acute pain severe enough to require an opioid analgesic. Tapentadol is a centrally acting synthetic analgesic.

Non-GAAP Financial Measures

To supplement our financial results presented on a U.S. generally accepted accounting principles, or GAAP, basis, we have included information about non-GAAP adjusted loss. We believe that the presentation of this non-GAAP financial measure, when viewed with our results under GAAP and the accompanying reconciliation, provides supplementary information that may be useful to analysts, investors, lenders, and other third parties in assessing the Company's performance and results from period to period. We internally use non-GAAP adjusted loss to understand, manage and evaluate the Company as we believe it represents the performance of our core business. This non-GAAP financial measure should be considered in addition to, and not a substitute for, or superior to, net income or other financial measures calculated in accordance with GAAP. Non-GAAP adjusted loss is not based on any standardized methodology prescribed by GAAP and represents GAAP net loss adjusted to exclude stock-based compensation expense, amortization expense for the Nucynta intangible asset, non-cash interest expense recognized on the Nucynta minimum royalty payments, and minimum royalty payments due and payable to Depomed in connection with the Commercialization Agreement. Any non-GAAP financial measures used by us may be calculated differently from, and therefore may not be comparable to, a non-GAAP measure used by other companies

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 plans to commercialize 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 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 and maintain reimbursement and third-party payor

contracts for our products; the costs of commercialization activities, including marketing, sales and distribution; the rate and degree of market acceptance of our products; changing market conditions for our products; 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 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 regulations relating to the manufacturing and marketing 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, uncertainties and factors are described under the heading "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, 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)

	June, 2018	December 31, 2017
Cash and cash equivalents	\$ 133,747	\$ 118,697
Accounts receivable	68,380	9,969
Inventory	8,544	1,813
Prepaid expenses and other current assets	5,622	3,005
Property and equipment, net	3,203	1,826
Intangible assets, net	453,694	—
Restricted cash	—	97
Other long-term assets	139	161
Total assets	\$ 673,329	\$ 135,568
Accounts payable and accrued expenses	\$ 42,087	\$ 14,225
Accrued rebates, returns and discounts	107,790	15,784
Asset acquisition obligations	429,271	—
Other liabilities	11,500	1,479
Stockholders' equity	82,681	104,080
Total liabilities and stockholders' equity	\$ 673,329	\$ 135,568

Collegium Pharmaceutical, Inc.

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

	Three months ended June 30,		Six months ended June 30,	
	2018	2017	2018	2017
Product revenues, net	\$ 73,061	\$ 3,560	\$ 136,810	\$ 5,732
Costs and expenses:				
Cost of product revenues	46,838	577	89,944	948
Research and development	2,237	2,179	4,505	4,309
Selling, general and administrative	31,279	22,062	62,861	44,909
Total costs and expenses	80,354	24,818	157,310	50,166
Loss from operations	(7,293)	(21,258)	(20,500)	(44,434)
Interest expense	(6,158)	—	(11,858)	—
Interest income	391	137	646	235
Net loss	(13,060)	(21,121)	(31,712)	(44,199)
Loss per share—basic and diluted	(0.40)	(0.72)	(0.96)	(1.50)
Weighted-average shares -basic and diluted	32,967,718	29,441,514	32,935,873	29,396,143

Reconciliation of GAAP to Non-GAAP Financial Information
(in thousands, except per share amounts)

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
GAAP net loss	\$ (13,060)	\$ (21,121)	\$ (31,712)	\$ (44,199)
Non-GAAP adjustments:				
Stock-based compensation expense	3,526	1,946	6,254	3,767
Nucynta related amortization expense (1)	32,407	—	61,933	—
Nucynta non-cash interest expense (2)	5,943	—	11,471	—
Nucynta minimum royalty payment due (3)	(33,750)	—	(64,500)	—
Total non-GAAP adjustments	\$ 8,126	\$ 1,946	\$ 15,158	\$ 3,767
Non-GAAP adjusted loss	\$ (4,934)	\$ (19,175)	\$ (16,554)	\$ (40,432)

	First Quarter 2018	Second Quarter 2018
	GAAP net loss	\$ (18,652)
Non-GAAP adjustments:		
Stock-based compensation expense	2,728	3,526
Nucynta related amortization expense (1)	29,526	32,407
Nucynta non-cash interest expense (2)	5,528	5,943
Nucynta minimum royalty payment due (3)	(30,750)	(33,750)
Total non-GAAP adjustments	\$ 7,032	\$ 8,126
Non-GAAP adjusted loss	\$ (11,620)	\$ (4,934)

Explanation of Adjustments:

- (1) Represents amortization expense of the Nucynta intangible asset.
 - (2) Represents non-cash interest expense recognized related to the Nucynta minimum royalty payments.
 - (3) Represents minimum royalty payment due and payable to Depomed in connection with the Commercialization Agreement.
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