

**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 Exchange Act of 1934

Date of Report (Date of earliest event reported): **May 8, 2019**

COLLEGIUM PHARMACEUTICAL, INC.

(Exact name of registrant as specified in its charter)

Virginia
(state or other jurisdiction
of incorporation)

001-37372
(Commission
File Number)

03-0416362
(I.R.S. Employer
Identification No.)

100 Technology Center Drive
Suite 300
Stoughton, MA
(Address of principal executive offices)

02072
(Zip Code)

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

(Former name or former address, if changed since last report)

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))

Indicated 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.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.001 per share	COLL	The NASDAQ Global Select Market

Item 2.02 Results of Operations and Financial Condition.

On May 8, 2019, Collegium Pharmaceutical, Inc. issued a press release announcing its financial results for the quarterly period ended March 31, 2019. 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.

Exhibit No.	Description
99.1	Press Release, dated May 8, 2019.

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.

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

Dated: May 8, 2019



Collegium Reports First Quarter 2019 Financial Results

- *Xtampza® ER Net Product Revenues of \$25.1 million in the First Quarter of 2019, a 59% increase over the First Quarter of 2018 and a 36% increase on a Consecutive-Quarter Basis*
- *Net loss of \$9.7 million in the First Quarter of 2019 compared to a net loss of \$18.7 million in the First Quarter of 2018*
- *Conference call scheduled for today at 4:30 p.m. ET*

STOUGHTON, Mass., May 8, 2019 — Collegium Pharmaceutical, Inc. (Nasdaq: COLL), a specialty pharmaceutical company committed to being the leader in responsible pain management, today reported its financial results for the first quarter ended March 31, 2019 and provided a corporate update.

“In the first quarter of 2019, we were encouraged by the acceleration of Xtampza ER, driven by 13 new exclusive ER oxycodone payer wins that took effect January 1, 2019,” said Joe Ciaffoni, President and Chief Executive Officer of Collegium. “For the remainder of 2019, we remain focused on growing Xtampza ER, maximizing the value of the Nucynta franchise and executing our mid-term growth strategy. Collegium is well positioned to become the leader in responsible pain management.”

Recent Business Highlights

- In the first quarter of 2019, Xtampza ER reached over 100,000 total prescriptions in a quarter for the first time since launch. Total prescriptions for Xtampza ER grew to 105,309 in the first quarter of 2019, representing a 71% increase over the first quarter of 2018 and 16% growth on a consecutive-quarter basis.
- The number of unique Xtampza ER prescribers grew to 12,333 in the first quarter of 2019, a 21% increase on a consecutive-quarter basis.
- In the first quarter of 2019, a new patent covering Xtampza ER was added to the FDA Orange Book, with an expiry date in 2036. With this recent addition to the patent estate, Xtampza ER is now covered by 15 Orange Book listed patents.
- In April 2019, Collegium expanded its leadership team with the appointment of Richard Malamut, M.D. as the company’s Chief Medical Officer overseeing Collegium’s Clinical Development, Medical Affairs, Regulatory and Scientific Affairs functions.

Financial Results for Quarter Ended March 31, 2019

- For the quarter ended March 31, 2019 (the “2019 Quarter”), total net product revenues were \$74.5 million, which included Xtampza ER net product revenues of \$25.1 million and Nucynta franchise net product revenues of \$49.4 million. This compared to total net
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product revenues of \$63.7 million for the quarter ended March 31, 2018 (the “2018 Quarter”), which included \$15.8 million for Xtampza ER and \$48.0 million for the Nucynta franchise.

- Research and development expenses were \$3.0 million for the 2019 Quarter compared to \$2.3 million for the 2018 Quarter. The increase was primarily related to an increase in employee-related expenses, including stock-based compensation expense.
- Selling, general and administrative expenses were \$32.4 million for the 2019 Quarter, compared to \$31.6 million for the 2018 Quarter. The increase was primarily related to an increase in our sales and marketing costs associated with Xtampza ER and the Nucynta franchise, increased professional fees and an increase in stock-based compensation, offset by lower regulatory-related costs.
- Net loss for the 2019 Quarter was \$9.7 million, or \$0.29 per share (basic and diluted), compared to net loss of \$18.7 million, or \$0.57 per share (basic and diluted), for the 2018 Quarter. Net loss included stock-based compensation expense of \$4.3 million and \$2.7 million for the 2019 Quarter and 2018 Quarter, respectively.
- Non-GAAP adjusted loss for the 2019 Quarter was \$1.7 million. This compared to a non-GAAP adjusted loss of \$11.6 million for the 2018 Quarter.
- Collegium had cash and cash equivalents of \$134.9 million as of March 31, 2019, compared to \$146.6 million as of December 31, 2018. The decrease from the prior quarter was the result of lower cash receipts due to the extension of payment terms for a major wholesaler, as well as capital expenditures related to the buildout of additional manufacturing capacity.

Conference Call Information

Collegium will host a conference call and live audio webcast on Wednesday, May 8, 2019 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: 419-0474. An audio webcast will be accessible from the Investor Relations section of the Company’s website: www.collegiumpharma.com. The webcast will be available for replay on the Company’s website approximately two hours after the event.

About Collegium Pharmaceutical, Inc.

Collegium is a specialty pharmaceutical company committed to being the leader in responsible pain management. Collegium’s headquarters are located in Stoughton, Massachusetts. For more information, please visit the company’s website at www.collegiumpharma.com.

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 Assertio 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. Please see the section of this press release titled "Reconciliation of GAAP to Non-GAAP Financial Information" for a reconciliation of non-GAAP adjusted loss to its most directly comparable GAAP measure.

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," "forecasts," "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 our ability to obtain and maintain regulatory approval of our products and product candidates; our ability to effectively commercialize in-licensed products and manage our relationships with licensors; the success of competing products that are or become available; our ability to obtain reimbursement and third-party payor contracts for our products; the rate and degree of market acceptance of 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 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; 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, 2018, and 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:
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Collegium Pharmaceutical, Inc.

Unaudited Selected Consolidated Balance Sheet Information
(in thousands)

	March 31, 2019	December 31, 2018
Cash and cash equivalents	\$ 134,910	\$ 146,633
Accounts receivable	85,139	77,946
Inventory	8,741	7,817
Prepaid expenses and other current assets	5,053	5,116
Property and equipment, net	9,962	9,274
Operating lease assets	9,766	—
Intangible assets, net	40,567	44,255
Other long-term assets	224	204
Total assets	\$ 294,362	\$ 291,245
Accounts payable and accrued expenses	\$ 33,570	\$ 42,701
Accrued rebates, returns and discounts	152,328	144,783
Term loan payable	11,500	11,500
Operating lease liabilities	10,614	—
Other liabilities	—	676
Stockholders' equity	86,350	91,585
Total liabilities and stockholders' equity	\$ 294,362	\$ 291,245

Collegium Pharmaceutical, Inc.

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

	Three months ended March 31,	
	2019	2018
Product revenues, net	\$ 74,516	\$ 63,749
Costs and expenses:		
Cost of product revenues	49,164	43,106
Research and development	2,992	2,268
Selling, general and administrative	32,352	31,582
Total costs and expenses	<u>84,508</u>	<u>76,956</u>
Loss from operations	(9,992)	(13,207)
Interest expense	(234)	(5,700)
Interest income	526	255
Net loss	<u>\$ (9,700)</u>	<u>\$ (18,652)</u>
Loss per share — basic and diluted	\$ (0.29)	\$ (0.57)
Weighted-average shares - basic and diluted	<u>33,331,917</u>	<u>32,903,674</u>

Reconciliation of GAAP to Non-GAAP Financial Information

(in thousands, except per share amounts)

(unaudited)

	<u>Three months ended March 31,</u>	
	<u>2019</u>	<u>2018</u>
GAAP net loss	\$ (9,700)	\$ (18,652)
Non-GAAP adjustments:		
Stock-based compensation expense	4,263	2,728
Nucynta related amortization expense (1)	3,688	29,526
Nucynta non-cash interest expense (2)	—	5,528
Nucynta minimum royalty payment due (3)	—	(30,750)
Total non-GAAP adjustments	\$ 7,951	\$ 7,032
Non-GAAP adjusted loss	\$ (1,749)	\$ (11,620)

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 in connection with the Nucynta Commercialization Agreement.
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