
**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): **February 27, 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.

Item 2.02 Results of Operations and Financial Condition.

On February 27, 2019, Collegium Pharmaceutical, Inc. issued a press release announcing its financial results for the quarterly period and fiscal year ended December 31, 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.

Exhibit No.	Description
99.1	Press Release, dated February 27, 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: February 27, 2019



Collegium Reports Fourth-Quarter and Full-Year 2018 Financial Results

- *Xtampza[®] ER Prescriptions Grew 233% in 2018*
- *Net Revenue Increased to \$73.4 Million for Fourth Quarter 2018 and \$280.4 Million for the Full Year*
- *Cash and Cash Equivalents were \$146.6 million as of December 31, 2018, exceeding year-end cash guidance of \$145.0 million*
- *Conference call scheduled for today at 4:30 p.m. ET*

STOUGHTON, Mass., Feb. 27, 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 fourth quarter and year ended December 31, 2018 and provided a corporate update.

“2018 was a transformative year for Collegium Pharmaceutical, driven by Xtampza ER year over year prescription growth of 233% and the addition of the Nucynta Franchise to our pain portfolio,” said Joe Ciaffoni, President and Chief Executive Officer of Collegium. “The progress made in 2018 puts Collegium in a strong position to deliver a breakthrough year in 2019. We look forward to taking the next step in becoming the leader in responsible pain management.”

Key Business Highlights

- Total prescriptions for Xtampza ER grew to 94,153 in the fourth quarter of 2018, representing a 147% increase over the fourth quarter of 2017. For the full year, total prescriptions for Xtampza ER grew 233%, reaching 326,828, compared to 98,283 total prescriptions in 2017.
- There were 11,552 new prescribers of Xtampza ER in 2018, including 2,426 prescribers added in the fourth quarter, resulting in more than 18,000 physicians prescribing Xtampza ER since launch.
- The Company secured 13 new exclusive ER oxycodone formulary wins for Xtampza ER which took effect January 1, 2019. In addition to the exclusive payer wins, Xtampza ER continues to have broad-based coverage, including 91% coverage in Commercial plans and 49% coverage in Part D plans.
- Total prescriptions for the Nucynta franchise were 157,055 in the fourth quarter of 2018. For the full year, total prescriptions for the Nucynta franchise were 651,337.

Financial Results for Quarter Ended December 31, 2018

- For the quarter ended December 31, 2018 (the “2018 Quarter”), total net product revenues were \$73.4 million, which included Xtampza ER net revenues of \$18.4 million
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and Nucynta franchise net revenues of \$55.0 million. This compared to total net product revenues of \$10.8 million for the quarter ended December 31, 2017 (the “2017 Quarter”), comprising Xtampza ER net product revenues only.

- Net income for the 2018 Quarter was \$9.1 million, or \$0.27 per share (basic and diluted), compared to net loss of \$17.4 million, or \$0.54 per share (basic and diluted), for the 2017 Quarter. Net income (loss) included stock-based compensation expense of \$3.6 million and \$2.1 million for the 2018 Quarter and 2017 Quarter, respectively. For additional details related to the amendment of the Commercialization Agreement with Assertio, please refer to our Annual Report on Form 10-K filed with the Securities and Exchange Commission.
- Selling, general and administrative expenses were \$30.5 million for the 2018 Quarter, compared to \$25.1 million for the 2017 Quarter. The increase was primarily related to higher personnel costs of \$3.6 million and higher commercialization costs of \$2.3 million.
- Non-GAAP adjusted loss for the 2018 Quarter was \$3.4 million. This compared to a non-GAAP adjusted loss of \$15.3 million for the 2017 Quarter.

Full-Year 2018 Financial Highlights

- For the year ended December 31, 2018, total net product revenues were \$280.4 million, which included Xtampza ER net revenues of \$69.4 million and Nucynta franchise net revenues of \$211.0 million. This compared to total net product revenues of \$28.5 million for the year ended December 31, 2017, comprising Xtampza ER net product revenues only.
- Net loss for the year ended December 31, 2018 was \$39.1 million, or \$1.19 per share (basic and diluted), compared to a net loss of \$74.9 million, or \$2.47 per share (basic and diluted) for the year ended December 31, 2017.
- Non-GAAP adjusted loss for the year ended December 31, 2018 was \$28.2 million. This compared to a non-GAAP adjusted loss of \$66.9 million for the year ended December 31, 2017.
- Collegium had cash and cash equivalents of \$146.6 million at December 31, 2018, compared to \$118.7 million at December 31, 2017, exceeding our year-end cash guidance of \$145.0 million.
- As of December 31, 2018, there were 33,265,629 common shares outstanding.

Conference Call Information:

Collegium will host a conference call and live audio webcast on Wednesday, Feb. 27, 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: 926-7259. 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)

	December 31, 2018	December 31, 2017
Cash and cash equivalents	\$ 146,633	\$ 118,697
Accounts receivable	77,946	9,969
Inventory	7,817	1,813
Prepaid expenses and other current assets	5,116	3,005
Property and equipment, net	9,274	1,826
Intangible assets, net	44,255	—
Restricted cash	—	97
Other long-term assets	204	161
Total assets	\$ 291,245	\$ 135,568
Accounts payable and accrued expenses	\$ 42,701	\$ 14,225
Accrued rebates, returns and discounts	144,783	15,784
Other liabilities	12,176	1,479
Stockholders' equity	91,585	104,080
Total liabilities and stockholders' equity	\$ 291,245	\$ 135,568

Collegium Pharmaceutical, Inc.

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

	<u>Three months ended December 31,</u>		<u>Years ended December 31,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Product revenues, net	\$ 73,427	\$ 10,794	\$ 280,413	\$ 28,476
Costs and expenses:				
Cost of product revenues	29,726	1,094	165,677	2,595
Research and development	2,249	2,194	8,661	8,572
Selling, general and administrative	30,451	25,089	126,760	92,756
Total costs and expenses	<u>62,426</u>	<u>28,377</u>	<u>301,098</u>	<u>103,923</u>
Loss from operations	11,001	(17,583)	(20,685)	(75,447)
Interest expense	(2,404)	—	(20,130)	—
Interest income	489	180	1,687	582
Net income (loss)	<u>\$ 9,086</u>	<u>\$ (17,403)</u>	<u>\$ (39,128)</u>	<u>\$ (74,865)</u>
Earnings (loss) per share - basic	\$ 0.27	\$ (0.54)	\$ (1.19)	\$ (2.47)
Weighted-average shares - basic	<u>33,250,180</u>	<u>32,485,572</u>	<u>32,953,808</u>	<u>30,265,262</u>
Earnings (loss) per share - diluted	\$ 0.27	\$ (0.54)	\$ (1.19)	\$ (2.47)
Weighted-average shares - diluted	<u>33,769,765</u>	<u>32,485,572</u>	<u>32,953,808</u>	<u>30,265,262</u>

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

	<u>Three months ended December 31,</u>		<u>Years ended December 31,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
GAAP net income (loss)	\$ 9,086	\$ (17,403)	\$ (39,128)	\$ (74,865)
Non-GAAP adjustments:				
Stock-based compensation expense	3,598	2,078	13,778	7,945
Nucynta related amortization expense (1)	15,494	—	109,834	—
Nucynta non-cash interest expense (2)	2,169	—	19,281	—
Nucynta minimum royalty payment due (3)	(33,750)	—	(132,000)	—
Total non-GAAP adjustments	<u>\$ (12,489)</u>	<u>\$ 2,078</u>	<u>\$ 10,893</u>	<u>\$ 7,945</u>
Non-GAAP adjusted loss	<u>\$ (3,403)</u>	<u>\$ (15,325)</u>	<u>\$ (28,235)</u>	<u>\$ (66,920)</u>
	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>
	<u>2018</u>	<u>2018</u>	<u>2018</u>	<u>2018</u>
GAAP net income (loss)	\$ (18,652)	\$ (13,060)	\$ (16,502)	\$ 9,086
Non-GAAP adjustments:				
Stock-based compensation expense	2,728	3,526	3,926	3,598
Nucynta related amortization expense (1)	29,526	32,407	32,407	15,494
Nucynta non-cash interest expense (2)	5,528	5,943	5,641	2,169
Nucynta minimum royalty payment due (3)	(30,750)	(33,750)	(33,750)	(33,750)
Total non-GAAP adjustments	<u>\$ 7,032</u>	<u>\$ 8,126</u>	<u>\$ 8,224</u>	<u>\$ (12,489)</u>
Non-GAAP adjusted loss	<u>\$ (11,620)</u>	<u>\$ (4,934)</u>	<u>\$ (8,278)</u>	<u>\$ (3,403)</u>

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 Assertio in connection with the Commercialization Agreement.