
**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, 2020

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:

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

Item 2.02 Results of Operations and Financial Condition.

On February 27, 2020, Collegium Pharmaceutical, Inc. issued a press release announcing its financial results for the quarterly period and fiscal year ended December 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.

To the extent that the information in this report and Exhibit 99.1 are not descriptions of historical facts regarding the Company, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Words such as “may,” “will,” “expect,” “anticipate,” “estimate,” “forecast,” “intend,” and similar expressions (as well as other words or expressions referencing future events, conditions, or circumstances) are intended to identify forward-looking statements. Examples of forward-looking statements contained in this report, including Exhibit 99.1, include, among others, statements regarding full-year 2020 guidance for Xtampza ER and Nucynta Franchise revenues, total operating expense, and Non-GAAP adjusted income. Forward-looking statements in this report, including Exhibit 99.1, involve substantial risks and uncertainties that could cause our future results, performance, or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the following: our ability to maintain regulatory approval of our products, 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 manage our relationships with licensors; 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 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.; regulatory developments impacting our products and market; 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; our ability to comply with stringent 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; 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 September 30, 2019, 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 report, including Exhibit 99.1, speak only as of the date of this report. The Company assumes no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated February 27, 2020.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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, 2020



Collegium Reports Full-Year 2019 Revenue of \$296.7 Million

– 2019 Revenue Growth of 6%, Driven by Xtampza ER revenue growth of 51% –

– Xtampza[®] ER Prescriptions Grew 49% in 2019 –

– Collegium Guides to Profitability in 2020 –

– Conference Call Scheduled for Today at 4:30 p.m. ET –

STOUGHTON, Mass., Feb. 27, 2020 -- 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, 2019 and provided a corporate update.

“In 2019 we delivered record revenue and achieved non-GAAP profitability for three consecutive quarters,” said Joe Ciaffoni, President and Chief Executive Officer of Collegium. “Driven by Xtampza ER growth and the acquisition of the Nucynta Franchise, 2020 will be a financially transformative year for Collegium.”

Recent Business Highlights

- Xtampza ER total prescriptions grew to 124,067 in the fourth quarter of 2019, representing a 37% increase over the fourth quarter of 2018. For the full year, total prescriptions for Xtampza ER grew 49%, reaching 466,378, compared to 313,152 total prescriptions in 2018.
 - The Company secured 20 new exclusive ER oxycodone formulary wins covering more than 35 million lives for Xtampza ER, which took effect January 1, 2020. With these wins, Collegium is the exclusive ER oxycodone for approximately 40% of Commercial and Part D covered lives. Xtampza ER continues to have broad-based coverage, including 95% coverage of Commercial lives and 50% coverage of Part D lives.
 - The Company announced on February 13, 2020 it closed the acquisition of the U.S. rights to the Nucynta Franchise from Assertio Therapeutics, Inc.
-

Financial Guidance for 2020

The Company reiterates its full-year 2020 financial guidance, initially provided on January 7, 2020:

- Xtampza ER revenues are expected in the range of \$150.0 million to \$160.0 million.
- Nucynta Franchise revenues are expected in the range of \$170.0 million to \$180.0 million.
- Total operating expenses are expected in the range of \$130.0 million to \$140.0 million.

In addition, the Company provides the following full-year 2020 financial guidance:

- Non-GAAP adjusted income is expected in the range of \$125.0 million to \$140.0 million

Financial Results for Quarter Ended December 31, 2019

- Xtampza ER net product revenues were \$27.4 million for the quarter ended December 31, 2019 (the “2019 Quarter”), compared to \$18.4 million for the quarter ended December 31, 2018 (the “2018 Quarter”) and \$26.5 million for the quarter ended September 30, 2019, representing an increase of 49% and 3%, respectively.
- Nucynta franchise net product revenues were \$46.8 million in the 2019 Quarter, compared to \$55.0 million for the 2018 Quarter and \$46.5 million for the quarter ended September 30, 2019, representing a decrease of 15% and increase of 1%, respectively.
- Operating expenses were \$27.5 million for the 2019 Quarter, compared to \$32.7 million for the 2018 Quarter.
- Net loss for the 2019 Quarter was \$2.2 million, or \$0.07 loss per share (basic and diluted), compared to net income of \$9.1 million, or \$0.27 income per share (basic and diluted), for the 2018 Quarter. Net loss included stock-based compensation expense of \$4.0 million and \$3.6 million for the 2019 Quarter and 2018 Quarter, respectively.
- Non-GAAP adjusted income for the 2019 Quarter was \$5.5 million, compared to a non-GAAP adjusted loss of \$3.4 million for the 2018 Quarter.

Full-Year 2019 Financial Highlights

- For the year ended December 31, 2019, total net product revenues were \$296.7 million, which included Xtampza ER net revenues of \$105.0 million and Nucynta franchise net revenues of \$191.7 million. This compared to total net product revenues of \$280.4 million for the year ended December 31, 2018, which included Xtampza ER net revenues of \$69.4 million and Nucynta franchise net revenues of \$211.0 million.
 - Operating expenses for the year ended December 31, 2019 were \$126.8 million, compared to \$135.4 million for the year ended December 31, 2018. The decrease was primarily related to a decrease in sales, marketing and consulting costs of \$8.1 million, primarily due to higher one-time costs incurred in 2018 to commercialize the Nucynta franchise.
 - Net loss for the year ended December 31, 2019 was \$22.7 million, or \$0.68 per share (basic and diluted), compared to a net loss of \$39.1 million, or \$1.19 per share (basic and diluted) for the year ended December 31, 2018.
 - Non-GAAP adjusted income for the year ended December 31, 2019 was \$8.6 million. This compared to a non-GAAP adjusted loss of \$28.2 million for the year ended December 31, 2018.
 - The Company had cash and cash equivalents of \$170.0 million at December 31, 2019,
-

Conference Call Information

The Company will host a conference call and live audio webcast on Thursday, February 27, 2020 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: 829-8360. An audio webcast will be accessible from the Investors 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 GAAP basis, we have included information about non-GAAP adjusted income (loss). We use this non-GAAP financial measure to understand, manage and evaluate the Company as we believe it represents the performance of our core business. Because this non-GAAP financial measure is an important internal measure for the Company, we believe that the presentation of the non-GAAP financial measure provides analysts, investors and lenders insight into management's view and assessment of the Company's ongoing operating performance. In addition, 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 report this non-GAAP financial measure in order to portray the results of our major operations – commercializing innovative, differentiated products for people suffering from pain – prior to considering certain income statement elements. 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 income (loss) is not based on any standardized methodology prescribed by GAAP and represents GAAP net income (loss) adjusted to exclude stock-based compensation expense, amortization expense, non-cash interest expense, and minimum royalty payments due and payable in connection with the Nucynta 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.

The Company has not provided a reconciliation of its full-year 2020 guidance for non-GAAP adjusted income (loss) to the most directly comparable forward-looking GAAP measure because it is unable to predict, without unreasonable efforts, the timing and amount of items that would be included such a reconciliation. These items are uncertain and depend on various factors that could have a material impact on GAAP net income (loss) for the guidance period.

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. Examples of forward-looking statements contained in this press release include, among others, statements regarding financial guidance for Xtampza ER and Nucynta Franchise revenues, total operating expenses, current and future market opportunities for our products and our assumptions related thereto. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results, performance, or achievements 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 expectations related to the potential impact of the Nucynta acquisition on our future operating results; our ability to commercialize and grow sales of our products; our ability to manage our relationships with licensors; the success of competing products that are or become available; our ability to obtain and maintain regulatory approval of our products and any product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product; the size of the markets for our products and product candidates, and our ability to service those markets; 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 costs of commercialization activities, including marketing, sales and distribution; changing market conditions for our products; the outcome of any patent infringement, opioid-related or other litigation that may be brought by or against us, including litigation with Purdue Pharma, L.P. and Teva Pharmaceuticals USA, Inc.; the outcome of any governmental investigation related to the manufacture, marketing and sale of opioid medications; our ability to secure adequate supplies of active pharmaceutical ingredient for each of our products and manufacture adequate supplies of commercially saleable inventory; our ability to obtain funding for our operations and business development; regulatory developments in the U.S.; our expectations regarding our ability to obtain and maintain sufficient intellectual property protection for our products; 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; our customer concentration; 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, 2019 and other filings 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
adasalla@collegiumpharma.com

Collegium Pharmaceutical, Inc.

Unaudited Selected Consolidated Balance Sheet Information
(in thousands)

	December 31,	
	2019	2018
Cash and cash equivalents	\$ 170,019	\$ 146,633
Accounts receivable	72,953	77,946
Inventory	9,643	7,817
Prepaid expenses and other current assets	3,105	5,116
Property and equipment, net	11,854	9,274
Operating lease assets	9,047	—
Intangible assets, net	29,503	44,255
Other noncurrent assets	178	204
Total assets	\$ 306,302	\$ 291,245
Accounts payable and accrued expenses	39,727	\$ 42,701
Accrued rebates, returns and discounts	157,549	144,783
Term loan payable	11,500	11,500
Operating lease liabilities	10,094	—
Other noncurrent liabilities	—	676
Stockholders' equity	87,432	91,585
Total liabilities and stockholders' equity	\$ 306,302	\$ 291,245

Collegium Pharmaceutical, Inc.

Unaudited Condensed Statements of Operations

(in thousands, except share and per share amounts)

	Three months ended December 31,		Years ended December 31,	
	2019	2018⁽¹⁾	2019	2018
Product revenues, net	\$ 74,203	\$ 73,427	\$ 296,701	\$ 280,413
Costs and expenses:				
Cost of product revenues	49,088	29,726	193,660	165,677
Research and development	2,398	2,249	10,340	8,661
Selling, general and administrative	25,090	30,451	116,449	126,760
Total costs and expenses	76,576	62,426	320,449	301,098
Loss from operations	(2,373)	11,001	(23,748)	(20,685)
Interest expense	(211)	(2,404)	(909)	(20,130)
Interest income	383	489	1,935	1,687
Net loss	<u>\$ (2,201)</u>	<u>\$ 9,086</u>	<u>\$ (22,722)</u>	<u>\$ (39,128)</u>
(Loss) Earnings per share - basic	<u>\$ (0.07)</u>	<u>\$ 0.27</u>	<u>\$ (0.68)</u>	<u>\$ (1.19)</u>
Weighted-average shares - basic	33,600,566	33,250,180	33,453,844	32,953,808
(Loss) Earnings per share - diluted	<u>\$ (0.07)</u>	<u>\$ 0.27</u>	<u>\$ (0.68)</u>	<u>\$ (1.19)</u>
Weighted-average shares - diluted	33,600,566	33,769,765	33,453,844	32,953,808

(1) - In the fourth quarter of 2018, the Company executed the Third Amendment to the Nucynta Commercialization Agreement, which eliminated the guaranteed minimum royalty payment obligations after 2018. As a result, the Company remeasured the remaining contractual obligation as of the Amendment Date and reduced the intangible asset. Consequently, amortization expense included within cost of product revenues was \$15,494 in the fourth quarter compared to \$32,407, \$32,407 and \$29,526 in the third, second and first quarters, respectively. Similarly, interest expense associated with the minimum royalty payments was \$2,169 in the fourth quarter compared to \$5,641, \$5,943 and \$5,528 in the third, second and first quarters, respectively. For further detail, please refer to our annual report on form 10-K.

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

	Three months ended		Years ended	
	December 31,		December 31,	
	2019	2018	2019	2018
GAAP net income (loss)	\$ (2,201)	\$ 9,086	\$ (22,722)	\$ (39,128)
Non-GAAP adjustments:				
Stock-based compensation expense	3,966	3,598	16,528	13,778
Nucynta related amortization expense (1)	3,688	15,494	14,752	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	\$ 7,654	\$ (12,489)	\$ 31,280	\$ 10,893
Non-GAAP adjusted income (loss)	\$ 5,453	\$ (3,403)	\$ 8,558	\$ (28,235)
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	2019	2019	2019	2019
GAAP net loss	\$ (9,700)	\$ (4,712)	\$ (6,109)	\$ (2,201)
Non-GAAP adjustments:				
Stock-based compensation expense	4,263	4,162	4,137	3,966
Nucynta related amortization expense (1)	3,688	3,688	3,688	3,688
Total non-GAAP adjustments	\$ 7,951	\$ 7,850	\$ 7,825	\$ 7,654
Non-GAAP adjusted income (loss)	\$ (1,749)	\$ 3,138	\$ 1,716	\$ 5,453
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	2018	2018	2018	2018
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	\$ 7,032	\$ 8,126	\$ 8,224	\$ (12,489)
Non-GAAP adjusted loss	\$ (11,620)	\$ (4,934)	\$ (8,278)	\$ (3,403)

(1) Represents amortization expense of the Nucynta Intangible Asset.

(2) Represents non-cash interest expense associated with the minimum royalty payments of the Nucynta Commercialization Agreement.

(3) Represents minimum royalty payment due and payable in connection with the Nucynta Commercialization Agreement.