

**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): **November 6, 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 November 6, 2019, Collegium Pharmaceutical, Inc. issued a press release announcing its financial results for the quarterly period ended September 30, 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 November 6, 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: November 6, 2019



Collegium Reports Third Quarter 2019 Financial Results

— *New Exclusive Formulary Wins Announced for Xtampza® ER Effective January 1, 2020 Covering More than 35 Million Lives* —

— *Xtampza® ER Net Product Revenues Were \$26.5 Million in the Third Quarter of 2019, a 56% Increase Over the Third Quarter of 2018* —

— *Cash Increased by \$5.1 Million, to \$153.8 Million as of September 30, 2019* —

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

STOUGHTON, Mass., Nov. 6, 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 quarter ended September 30, 2019 and provided a corporate update.

“Driven by strong Xtampza ER revenue growth and a commitment to leveraging our existing cost structure, we are on track to make 2019 a breakthrough year for Collegium,” said Joe Ciaffoni, President and Chief Executive Officer of Collegium. “Effective January 1, 2020, Xtampza ER will become the exclusive extended-release oxycodone for more than 35 million additional lives. These payer wins will drive the next stage of growth for Xtampza ER.”

Recent Business Highlights

- Xtampza ER formulary access continues to strengthen: As of January 1, 2020, Xtampza ER will move into an exclusive formulary position across 15 plans covering more than 35 million lives. With the addition of these new exclusive ER oxycodone formulary positions, Xtampza ER will be the exclusive branded ER oxycodone for more than 85 million lives.
 - Xtampza ER total prescriptions grew to 120,409 in the third quarter of 2019. Through the first three quarters of 2019, prescriptions grew 44% over the prior year period, and 3% compared to the second quarter of 2019.
 - Strengthened management team with the appointment of Bart Dunn to the role of Executive Vice President, Strategy and Corporate Development.
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Leading with the Science

- Collegium had a strong presence at the 13th Annual PAINWeek National Conference which took place in Las Vegas in September 2019. Four poster presentations that span Collegium’s product portfolio were presented during the conference.
- A manuscript about Nucynta ER titled, “Evaluation of Abuse and Route of Administration of Extended-Release Tapentadol Among Treatment-Seeking Individuals, as Captured by the Addiction Severity Index—Multimedia Version (ASI-MV)” was recently published in the online journal *Pain Medicine*.

Financial Results for Quarter Ended September 30, 2019

- Xtampza ER net product revenues were \$26.5 million for the quarter ended September 30, 2019 (the “2019 Quarter”), compared to \$17.0 million for the quarter ended September 30, 2018 (the “2018 Quarter”) and \$26.0 million for the quarter ended June 30, 2019, representing an increase of 56% and 2%, respectively.
- Nucynta franchise net product revenues were \$46.4 million in the 2019 Quarter, compared to \$53.1 million for the 2018 Quarter and \$49.0 million for the quarter ended June 30, 2019, representing a decrease of 13% and 5%, respectively.
- Selling, general and administrative expenses were \$30.1 million for the 2019 Quarter, compared to \$33.4 million for the 2018 Quarter.
- Net loss for the 2019 Quarter was \$6.1 million, or \$0.18 per share (basic and diluted), compared to net loss of \$16.5 million, or \$0.50 per share (basic and diluted), for the 2018 Quarter. Net loss included stock-based compensation expense of \$4.1 million and \$3.9 million for the 2019 Quarter and 2018 Quarter, respectively.
- Non-GAAP adjusted income for the 2019 Quarter was \$1.7 million, compared to a non-GAAP adjusted loss of \$8.3 million for the 2018 Quarter.
- Collegium had cash and cash equivalents of \$153.8 million as of September 30, 2019, an increase of \$5.1 million compared to the second quarter of 2019. The increase in cash and cash equivalents was primarily the result of cash provided by operating activities, partially offset by 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, November 6, 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: 958-8674. 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 internally 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. The Non-GAAP financial measure 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 for the Nucynta intangible asset, non-cash interest expense recognized on the Nucynta minimum royalty payments, 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.

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.; 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 product candidates and manufacture adequate supplies of 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; 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, 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)

	September 30, 2019	December 31, 2018
Cash and cash equivalents	\$ 153,838	\$ 146,633
Accounts receivable	84,380	77,946
Inventory	8,760	7,817
Prepaid expenses and other current assets	2,807	5,116
Property and equipment, net	11,579	9,274
Operating lease assets	9,219	—
Intangible assets, net	33,191	44,255
Other noncurrent assets	204	204
Total assets	\$ 303,978	\$ 291,245
Accounts payable and accrued expenses	\$ 32,595	\$ 42,701
Accrued rebates, returns and discounts	165,263	144,783
Term loan payable	11,500	11,500
Operating lease liabilities	10,362	—
Other noncurrent liabilities	—	676
Stockholders' equity	84,258	91,585
Total liabilities and stockholders' equity	\$ 303,978	\$ 291,245

Collegium Pharmaceutical, Inc.

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

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Product revenues, net	\$ 72,942	\$ 70,176	\$ 222,498	\$ 206,986
Costs and expenses:				
Cost of product revenues	46,754	46,007	144,572	135,951
Research and development	2,491	1,907	7,942	6,412
Selling, general and administrative	30,072	33,448	91,359	96,309
Total costs and expenses	79,317	81,362	243,873	238,672
Loss from operations	(6,375)	(11,186)	(21,375)	(31,686)
Interest expense	(228)	(5,868)	(698)	(17,726)
Interest income	494	552	1,552	1,198
Net loss	\$ (6,109)	\$ (16,502)	\$ (20,521)	\$ (48,214)
Loss per share—basic and diluted	\$ (0.18)	\$ (0.50)	\$ (0.62)	\$ (1.46)
Weighted-average shares -basic and diluted	33,481,923	33,012,174	33,360,272	32,950,584

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
GAAP net loss	\$ (6,109)	\$ (16,502)	\$ (20,521)	\$ (48,214)
Non-GAAP adjustments:				
Stock-based compensation expense	4,137	3,926	12,562	10,180
Nucynta related amortization expense (1)	3,688	32,407	11,064	94,340
Nucynta non-cash interest expense (2)	—	5,641	—	17,112
Nucynta minimum royalty payment due (3)	—	(33,750)	—	(98,250)
Total non-GAAP adjustments	<u>\$ 7,825</u>	<u>\$ 8,224</u>	<u>\$ 23,626</u>	<u>\$ 23,382</u>
Non-GAAP adjusted income (loss)	<u>\$ 1,716</u>	<u>\$ (8,278)</u>	<u>\$ 3,105</u>	<u>\$ (24,832)</u>
	First Quarter 2019	Second Quarter 2019	Third Quarter 2019	
GAAP net loss	\$ (9,700)	\$ (4,712)	\$ (6,109)	
Non-GAAP adjustments:				
Stock-based compensation expense	4,263	4,162	4,137	
Nucynta related amortization expense (1)	3,688	3,688	3,688	
Nucynta non-cash interest expense (2)	—	—	—	
Nucynta minimum royalty payment due (3)	—	—	—	
Total non-GAAP adjustments	<u>\$ 7,951</u>	<u>\$ 7,850</u>	<u>\$ 7,825</u>	
Non-GAAP adjusted income (loss)	<u>\$ (1,749)</u>	<u>\$ 3,138</u>	<u>\$ 1,716</u>	
	First Quarter 2018	Second Quarter 2018	Third Quarter 2018	Fourth Quarter 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	<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>

(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.