
**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 25, 2021

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 25, 2021, Collegium Pharmaceutical, Inc. issued a press release announcing its financial results for the quarterly period and fiscal year ended December 31, 2020. 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 25, 2021
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 25, 2021



Collegium Reports Record Full-Year 2020 Revenue of \$310.0 Million

– 2020 First Full-Year of Profitability, Driven by Xtampza® ER Revenue Growth and the Nucynta® Acquisition –

– Collegium Reiterates Previously Issued 2021 Guidance –

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

STOUGHTON, Mass., Feb. 25, 2021 -- 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, 2020 and provided a corporate update.

“Our differentiated pain portfolio performed well during the fourth quarter, laying the groundwork for a strong start in the new year,” said Joe Ciaffoni, President and Chief Executive Officer of Collegium. “As we turn to 2021, we are encouraged by underlying trends in our business and remain focused on maximizing the potential of our portfolio and creating value for our shareholders. As always, we are committed to being the leader in responsible pain management and will continue to prioritize the health and safety of our people, customers and the communities that we serve.”

“The fourth quarter capped a financially transformative 2020 for Collegium, in which Xtampza ER growth and the acquisition of the Nucynta franchise enabled us to deliver profitability and generate significant cash flows,” said Paul Brannelly, Executive Vice President and Chief Financial Officer of Collegium. “Our 2021 outlook is supported by early Xtampza ER growth trends, expected stable profit contributions from the Nucynta franchise and our ability to continue to leverage our cost structure. This year we are focused on profitability, strong cash generation and remaining focused and disciplined in our approach to capital allocation.”

Recent Business Highlights

- Xtampza ER market share of the oxycodone extended-release market grew to 25.1% in December 2020, from 18.9% in December 2019.
- Effective January 1, 2021, the Company secured new exclusive ER oxycodone formulary wins for Xtampza ER within a major national Medicare Part D plan and several regional commercial plans, as well as parity formulary positions for select regional commercial plans. With these new exclusive and parity formulary positions, Xtampza ER will be the exclusive branded ER oxycodone for approximately 92 million lives and will be in a parity position for approximately 30 million lives.
- A publication titled, “Postmarketing Analysis of Misuse, Abuse and Diversion of Xtampza ER,” was published in the peer-reviewed medical journal, *Pain Medicine* in October. The publication contains a postmarketing analysis of real-world evidence related to Xtampza ER which provides data that can enrich the scientific and clinical evaluation of abuse deterrent formulations.
- Collegium was recognized as a 2021 Top Workplaces USA Company and was ranked #1 on Boston Business Journal’s 2021 Middle Market Leaders list.

Financial Results for Quarter Ended December 31, 2020

- Xtampza ER net product revenues were \$30.8 million for the quarter ended December 31, 2020 (the “2020 Quarter”), compared to \$27.4 million for the quarter ended December 31, 2019 (the “2019 Quarter”), representing an increase of 12%.
 - Nucynta franchise net product revenues were \$45.5 million in the 2020 Quarter, compared to \$46.8 million for the 2019 Quarter, representing a decrease of 3%.
 - Operating expenses, which includes stock-based compensation, were \$29.3 million for the 2020 Quarter, compared to \$27.5 million for the 2019 Quarter.
 - Net income for the 2020 Quarter was \$7.0 million, or \$0.20 earnings per share (basic and diluted), compared to net loss of \$2.2 million, or \$0.07 loss per share (basic and diluted), for the 2019 Quarter. Net income and net loss included stock-based compensation expense of \$6.2 million and \$4.0 million for the 2020 Quarter and 2019 Quarter, respectively.
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- Non-GAAP adjusted income for the 2020 Quarter was \$32.8 million, compared to non-GAAP adjusted income of \$5.5 million for the 2019 Quarter.
- Adjusted EBITDA for the 2020 Quarter was \$38.3 million, compared to \$5.5 million for the 2019 Quarter.

Full-Year 2020 Financial Highlights

- For the year ended December 31, 2020, total net product revenues were \$310.0 million, which included Xtampza ER net revenues of \$128.0 million and Nucynta franchise net revenues of \$182.0 million. This compared to total net product revenues of \$296.7 million for the year ended December 31, 2019, which included Xtampza ER net revenues of \$105.0 million and Nucynta franchise net revenues of \$191.7 million.
- Operating expenses, including stock-based compensation, for the year ended December 31, 2020 were \$123.6 million, compared to \$126.8 million for the year ended December 31, 2019. The decrease was primarily related to a decrease in sales and marketing expenses driven by the effects of the COVID-19 pandemic.
- Net income for the year ended December 31, 2020 was \$26.8 million, or \$0.78 earnings per share (basic) and \$0.76 earnings per share (diluted), compared to a net loss of \$22.7 million, or \$0.68 loss per share (basic and diluted) for the year ended December 31, 2019.
- Non-GAAP adjusted income for the year ended December 31, 2020 was \$133.4 million compared to \$8.6 million for the year ended December 31, 2019.
- Adjusted EBITDA for the year ended December 31, 2020 was \$139.7 million, compared to \$8.3 million for the year ended December 31, 2019.
- The Company had cash and cash equivalents of \$174.1 million at December 31, 2020.

Financial Guidance for 2021

The Company reiterates its full-year 2021 financial guidance, initially provided on January 6, 2021:

- Xtampza ER revenues are expected in the range of \$155.0 million to \$165.0 million
- Nucynta franchise revenues are expected in the range of \$175.0 million to \$185.0 million
- Total operating expenses are expected in the range of \$125.0 million to \$135.0 million
- Adjusted EBITDA (excluding stock-based compensation) is expected in the range of \$160.0 million to \$170.0 million

Collegium is not providing forward-looking guidance for its full-year 2021 U.S. GAAP net income (loss) or a quantitative reconciliation of forward-looking adjusted EBITDA. Please see “Non-GAAP Financial Measures” below for additional information.

Conference Call Information

The Company will host a conference call and live audio webcast on Thursday, February 25, 2021 at 4:30 p.m. Eastern Time. To access the conference call, please dial (877) 407-8037 (U.S.) or (201) 689-8037 (International) and reference the “Collegium Pharmaceutical Q4 2020 Earnings Call.” 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) and non-GAAP adjusted EBITDA. We use these non-GAAP financial measures to understand, manage and evaluate the Company as we believe they represent the performance of our core business. Because non-GAAP adjusted income (loss) and non-GAAP adjusted EBITDA are important internal measures for the Company, we believe that the presentation of these non-GAAP financial measures provide analysts, investors, lenders and other third parties insight into management’s view and assessment of the

Company's ongoing operating performance. In addition, we believe that the presentation of these non-GAAP financial measures, when viewed with our results under GAAP, 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 non-GAAP financial measures, including adjusted income (loss) and adjusted EBITDA, to portray the results of our major operations prior to considering certain income statement elements. These non-GAAP measures should be considered in addition to, and not as 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.

Adjusted EBITDA represents GAAP net income (loss) adjusted to exclude interest expense, income tax expense, depreciation, amortization, and stock-based compensation. Adjusted EBITDA as used by us may be calculated differently from, and therefore may not be comparable to, similarly titled measures used by other companies.

There are several limitations related to the use of adjusted EBITDA rather than net income (loss), which is the nearest GAAP equivalent, such as:

- adjusted EBITDA excludes depreciation and amortization, and, although these are non-cash expenses, the assets being depreciated or amortized may have to be replaced in the future, the cash requirements for which are not reflected in adjusted EBITDA;
- we exclude stock-based compensation expense from adjusted EBITDA although (a) it has been, and will continue to be for the foreseeable future, a significant recurring expense for our business and an important part of our compensation strategy and (b) if we did not pay out a portion of our compensation in the form of stock-based compensation, the cash salary expense included in operating expenses would be higher, which would affect our cash position;
- adjusted EBITDA does not reflect changes in, or cash requirements for, working capital needs;
- adjusted EBITDA does not reflect provision for income taxes or the cash requirements to pay taxes; and
- adjusted EBITDA does not reflect historical cash expenditures or future requirements for capital expenditures or contractual commitments.

The Company has not provided a reconciliation of its full-year 2021 guidance for non-GAAP adjusted EBITDA 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 in such a reconciliation, including, but not limited to, stock-based compensation expense. These items are uncertain and depend on various factors that could have a material impact on GAAP net income 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, Adjusted EBITDA, 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 the impact of the COVID-19 pandemic on our ability to conduct our business, reach our customers, and supply the market with our products; 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.; the outcome of any governmental investigation related to our business; 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 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:

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Collegium Pharmaceutical, Inc.

Unaudited Selected Consolidated Balance Sheet Information
(in thousands)

	December 31,	
	2020	2019
Cash and cash equivalents	\$ 174,116	170,019
Accounts receivable	83,320	72,953
Inventory	15,614	9,643
Prepaid expenses and other current assets	4,838	3,105
Property and equipment, net	18,988	11,854
Operating lease assets	8,391	9,047
Intangible assets, net	335,904	29,503
Restricted cash	2,547	—
Other long-term assets	123	178
Total assets	\$ 643,841	\$ 306,302
Accounts payable and accrued expenses	34,672	39,727
Accrued rebates, returns and discounts	156,554	157,549
Term notes payable	157,514	11,500
Convertible senior notes	99,575	—
Operating lease liabilities	9,495	10,094
Shareholders' equity	186,031	87,432
Total liabilities and stockholders' equity	\$ 643,841	\$ 306,302

Collegium Pharmaceutical, Inc.

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

	Three months ended December 31,		Year ended December 31,	
	2020	2019	2020	2019
Product revenues, net	\$ 76,271	\$ 74,203	\$ 310,016	\$ 296,701
Cost of product revenues				
Cost of product revenues (excluding intangible asset amortization)	15,184	45,400	69,500	178,908
Intangible asset amortization	16,795	3,688	60,680	14,752
Total cost of products revenues	<u>31,979</u>	<u>49,088</u>	<u>130,180</u>	<u>193,660</u>
Gross profit	44,292	25,115	179,836	103,041
Operating expenses				
Research and development	2,472	2,398	9,772	10,340
Selling, general and administrative	26,824	25,090	113,832	116,449
Total operating expenses	<u>29,296</u>	<u>27,488</u>	<u>123,604</u>	<u>126,789</u>
Income (loss) from operations	14,996	(2,373)	56,232	(23,748)
Interest expense	(7,737)	(211)	(28,882)	(909)
Interest income	3	383	232	1,935
Income (loss) before income taxes	7,262	(2,201)	27,582	(22,722)
Provision for income taxes	304	—	830	—
Net income (loss)	<u>\$ 6,958</u>	<u>\$ (2,201)</u>	<u>\$ 26,752</u>	<u>\$ (22,722)</u>
Earnings (loss) per share — basic	<u>\$ 0.20</u>	<u>\$ (0.07)</u>	<u>\$ 0.78</u>	<u>\$ (0.68)</u>
Weighted-average shares — basic	<u>34,592,277</u>	<u>33,600,566</u>	<u>34,407,959</u>	<u>33,453,844</u>
Earnings (loss) per share — diluted	<u>\$ 0.20</u>	<u>\$ (0.07)</u>	<u>\$ 0.76</u>	<u>\$ (0.68)</u>
Weighted-average shares — diluted	<u>35,417,623</u>	<u>33,600,566</u>	<u>35,151,353</u>	<u>33,453,844</u>

Collegium Pharmaceutical, Inc.

Reconciliation of GAAP to Non-GAAP Financial Information

(in thousands, except per share amounts)
(unaudited)

	Three months ended December 31,		Year ended December 31,	
	2020	2019	2020	2019
GAAP net income (loss)	\$ 6,958	\$ (2,201)	\$ 26,752	\$ (22,722)
Non-GAAP adjustments:				
Stock-based compensation expense ⁽¹⁾	6,210	3,966	21,910	16,528
Intangible asset amortization ⁽²⁾	16,795	3,688	60,680	14,752
Non-cash interest expense ⁽³⁾	2,545	—	8,972	—
Nucynta royalty adjustment ⁽⁴⁾	—	—	14,216	—
Provision for income taxes ⁽⁵⁾	304	—	830	—
Total non-GAAP adjustments	\$ 25,854	\$ 7,654	\$ 106,608	\$ 31,280
Non-GAAP adjusted income (loss)	\$ 32,812	\$ 5,453	\$ 133,360	\$ 8,558

- (1) Represents stock-based compensation expense associated with our stock option, restricted stock unit and performance stock unit grants and our employee share purchase plan.
 - (2) Represents amortization expense from the Nucynta Intangible Asset.
 - (3) Represents non-cash interest expense recognized related to the accretion of debt discount and amortization of debt issuance costs.
 - (4) Represents non-recurring adjustment for royalty expense recognized in 2020 prior to the closing of the Nucynta Asset Purchase Agreement in February 2020. The royalty expense was included as a reduction to the base purchase price for the Nucynta Asset Purchase Agreement and, upon closing, the Company was discharged of any unpaid royalties due to Assertio.
 - (5) Represents current provision for estimated income taxes.
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Collegium Pharmaceutical, Inc.

Reconciliation of GAAP Net Income (Loss) to Adjusted EBITDA

(in thousands, except per share amounts)
(unaudited)

	Three months ended December 31,		Year ended December 31,	
	2020	2019	2020	2019
GAAP net income (loss)	\$ 6,958	\$ (2,201)	\$ 26,752	\$ (22,722)
Adjustments:				
Interest expense	7,737	211	28,882	909
Interest income	(3)	(383)	(232)	(1,935)
Provision for income taxes	304	—	830	—
Depreciation	281	196	870	731
Amortization	16,795	3,688	60,680	14,752
Stock-based compensation expense	6,210	3,966	21,910	16,528
Total adjustments	\$ 31,324	\$ 7,678	\$ 112,940	\$ 30,985
Adjusted EBITDA	\$ 38,282	\$ 5,477	\$ 139,692	\$ 8,263