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): January 6, 2021

COLLEGIUM PHARMACEUTICAL, INC.

(Exact name of registrant as specified in its charter)

Virginia	**001-37372**	**03-0416362**
(state or other jurisdiction of incorporation)	**(Commission File Number)**	**(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)

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

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 7.01 Regulation FD Disclosure

On January 6, 2021, Collegium Pharmaceutical, Inc. (the "Company") issued a press release announcing full-year revenue, adjusted EBITDA, and operating expense guidance for 2021. A copy of the press release is attached hereto as Exhibit 99.1 and is being furnished, not filed, under Item 7.01 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. 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 report and Exhibit 99.1 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 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 report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated January 6, 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: January 6, 2021

Exhibit 99.1

Collegium Provides 2021 Financial Guidance

– Xtampza® ER Revenues Expected in the Range of $155.0 million to $165.0 million –

– Nucynta® Franchise Revenues Expected in the Range of $175.0 million to $185.0 million –

– Adjusted EBITDA Expected in the Range of $160.0 million to $170.0 million –

STOUGHTON, Mass., January 6, 2021 -- Collegium Pharmaceutical, Inc. (Nasdaq: COLL), a specialty pharmaceutical company committed to being the leader in responsible pain management, today announced its 2021 full-year financial guidance.

"Collegium achieved a financially transformative year in 2020, driven by Xtampza ER growth and the acquisition of the Nucynta franchise. We delivered on our broad operational objectives and prioritized the health and safety of our people, customers and the communities that we serve," said Joe Ciaffoni, President and Chief Executive Officer of Collegium. "As we head into 2021, we remain steadfast in our commitment to being the leader in responsible pain management, maximizing the potential of our differentiated pain portfolio and creating value for our shareholders."

"Our 2021 revenue outlook is supported by Xtampza ER growth, stable profit contribution from the Nucynta franchise and a commitment to leverage our cost structure," said Paul Brannelly, Executive Vice President and Chief Financial Officer of Collegium. "This year, we expect to generate significant cash flow from operations and will deploy our balance sheet in a disciplined manner that invests in the long-term growth of our company."

Financial Guidance for 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
- Adjusted EBITDA (excluding stock-based compensation) is expected in the range of $160.0 million to $170.0 million
- Total operating expenses are expected in the range of $125.0 million to $135.0 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.

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 EBITDA. 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 non-GAAP adjusted EBITDA is an important internal measure for the Company, we believe that the presentation of this non-GAAP financial measure provides 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 this non-GAAP financial measure, 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 EBITDA, to portray the results of our major operations prior to considering certain income statement elements. Non-GAAP adjusted EBITDA 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.

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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 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.

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