# 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): **April 5, 2022**

# COLLEGIUM PHARMACEUTICAL, INC.
(Exact Name of Registrant as Specified in its Charter)

| **Virginia** | **001-37372** | **03-0416362** |
|---|---|---|
| (State or Other Jurisdiction of Incorporation or Organization) | (Commission File Number) | (IRS Employer Identification No.) |

**100 Technology Center Drive**
**Suite 300**
**Stoughton, MA 02072**
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **(781) 713-3699**

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))

Indicate 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 April 5, 2022, Collegium Pharmaceutical, Inc. (the “Company”) issued a press release announcing full-year revenue, adjusted operating expense and adjusted EBITDA guidance for 2022. 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 Current Report on Form 8-K, including Exhibit 99.1 furnished herewith, 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 Current Report on Form 8-K, including Exhibit 99.1 furnished herewith, include, among others, statements related to our full-year 2022 financial guidance, including total projected product revenue, adjusted operating expenses and adjusted EBITDA, current and future market opportunities for our products and our assumptions related thereto, expectations (financial or otherwise) and intentions, and other statements that are not historical facts. 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. Actual results may differ materially from management’s expectations and such forward-looking statements in this Current Report on Form 8-K, including Exhibit 99.1 furnished herewith, could be affected as a result of various important factors, including risks relating to, among others: risks related to the ability to realize the anticipated benefits of our acquisition of BDSI, including the possibility that the expected benefits from the BDSI acquisition will not be realized or will not be realized within the expected time period; the risk that BDSI’s business will not be integrated successfully; negative effects of the consummation of the BDSI acquisition on the market price of our common stock and/or operating results; unknown liabilities; risks related to future opportunities and plans for the products acquired with BDSI, including uncertainty of the expected financial performance of such products; 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 Reports on Form 10-K and Quarterly Reports on Form 10-Q and other filings with the SEC. Any forward-looking statements that we make in this Current Report on Form 8-K, including Exhibit 99.1 furnished herewith, speak only as of the date of this Current Report on Form 8-K. 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 Current Report on Form 8-K.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| | |
|---|---|
| 99.1 | Press Release of Collegium Pharmaceutical, Inc. dated April 5, 2022 |
| 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.

Dated: April 5, 2022

Collegium Pharmaceutical, Inc.

By: /s/ Colleen Tupper
Name: Colleen Tupper
Title: Executive Vice President and Chief Financial Officer

**Exhibit 99.1**

**Collegium Provides 2022 Financial Guidance**

*– Total Product Revenues Expected in the Range of $450.0 million to $465.0 million –*

*– Adjusted Operating Expenses Expected in the Range of $130.0 million to $140.0 million –*

*– Adjusted EBITDA Expected in the Range of $235.0 million to $250.0 million –*

**STOUGHTON, Mass., April 5, 2022** -- Collegium Pharmaceutical, Inc. (Nasdaq: COLL), a leading, diversified specialty pharmaceutical company, today announced updated financial guidance for the full year 2022 to include the expected impact of the BioDelivery Sciences International Inc. ("BDSI") acquisition. As previously announced, the Company completed the acquisition of BDSI on March 22, 2022.

"2022 is a pivotal year, as we take actions to advance our mission of building a leading, diversified specialty pharmaceutical company committed to improving the lives of people living with serious medical conditions," said Joe Ciaffoni, President and Chief Executive Officer of Collegium. "Near-term, we are laser-focused on seamless integration of BDSI, maximizing the potential of the portfolio, renegotiation of Xtampza ER contracts to ensure <65% gross-to-nets by January 2023, and allocating capital to create long term shareholder value."

"We anticipate significant product revenue growth in 2022, driven by Xtampza ER and the addition of the BDSI product portfolio," said Colleen Tupper, Chief Financial Officer of Collegium. "We have already made significant progress on cost savings following the close of the BDSI acquisition and are on track to exceed targeted run rate synergies of at least $75 million. Our operating expense guidance reflects our expectation that we will recognize the majority of cost savings in the immediate term, and we also continue to anticipate an acceleration in our cash flows moving forward."

**Financial Guidance for 2022**

- Total product revenues are expected in the range of $450.0 million to $465.0 million, up approximately 65% at the midpoint compared to net product revenue of $276.9 million in 2021.
- Total adjusted operating expenses, which excludes stock-based compensation expense, are expected in the range of $130.0 million to $140.0 million.
- Total adjusted EBITDA which excludes stock-based compensation, are expected in the range of $235.0 million to $250.0 million

Please see "Non-GAAP Financial Measures" below for additional information.

**About Collegium Pharmaceutical, Inc.**

Collegium is a diversified, specialty pharmaceutical company committed to improving the lives of people living with serious medical conditions. 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 certain non-GAAP financial measures such as adjusted EBITDA and adjusted operating expenses. We use these non-GAAP financial measures to understand, manage and evaluate our business as we believe they provide additional information on the performance of our business. We believe that the presentation of these non-GAAP financial measures, taken in conjunction with our results under GAAP, provide analysts, investors, lenders and other third parties insight into our view and assessment of our ongoing operating performance. In addition, we believe that the presentation of these non-GAAP financial measures, when viewed with our results under GAAP, provide supplementary information that may be useful to analysts, investors, lenders, and other third parties in assessing our performance and results from period to period. We report these non-GAAP financial measures to portray the results of our operations prior to considering certain income statement elements. These non-GAAP financial 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.

Adjusted EBITDA is a non-GAAP financial measure that represents GAAP net income adjusted to exclude interest expense, interest income, the benefit from or provision for income taxes, depreciation, amortization, stock-based compensation, restructuring expenses, acquisition costs and litigation settlements. 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, 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 the benefit from or provision for income taxes or the cash requirements to pay taxes;
- adjusted EBITDA does not reflect historical cash expenditures or future requirements for capital expenditures or contractual commitments;
- we exclude restructuring expenses from adjusted EBITDA. Restructuring expenses primarily include employee severance and contract termination costs. The amount and/or frequency of these restructuring expenses are not part of our underlying business;
- we exclude acquisition costs related to the acquisition of BDSI from adjusted EBITDA; and
- we exclude litigation settlements from adjusted EBITDA, as well as any applicable income items or credit adjustments due to subsequent changes in estimates. This does not include our legal fees to defend claims, which are expensed as incurred.

Adjusted operating expenses is a non-GAAP financial measure that represents GAAP operating expenses adjusted to exclude stock-based compensation expense, restructuring, acquisition costs, and litigation settlements.

The Company has not provided a reconciliation of its full-year 2022 guidance for adjusted EBITDA or adjusted operating expenses to the most directly comparable forward-looking GAAP measures 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 and operating expenses 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 related to our full-year 2022 financial guidance, including total projected product revenue, adjusted operating expenses and adjusted EBITDA, current and future market opportunities for our products and our assumptions related thereto, expectations (financial or otherwise) and intentions, and other statements that are not historical facts. 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. Actual results may differ materially from management's expectations and such forward-looking statements in this press release could be affected as a result of various important factors, including risks relating to, among others: risks related to the ability to realize the anticipated benefits of our acquisition of BDSI, including the possibility that the expected benefits from the BDSI acquisition will not be realized or will not be realized within the expected time period; the risk that BDSI's business will not be integrated successfully; negative effects of the consummation of the BDSI acquisition on the market price of our common stock and/or operating results; unknown liabilities; risks related to future opportunities and plans for the products acquired with BDSI, including uncertainty of the expected financial performance of such products; 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 Reports on Form 10-K and Quarterly Reports on Form 10-Q 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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