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 7, 2020

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)

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 7.01 Regulation FD Disclosure

On January 7, 2020, Collegium Pharmaceutical, Inc. (the "Company") issued a press release announcing full-year revenue and operating expense guidance for 2020. 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. 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 and total operating expense. 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 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 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 January 7, 2020.
104	Cover Page Interactive Data File - the cover page XBRL tags are embedded within 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 7, 2020

Exhibit 99.1

Collegium Provides 2020 Financial Guidance

– Xtampza® ER Revenues Expected in the Range of $150.0 Million to $160.0 Million for 2020 –

STOUGHTON, Mass., Jan. 7, 2020 -- Collegium Pharmaceutical, Inc. (Nasdaq: COLL), a specialty pharmaceutical company committed to being the leader in responsible pain management, today provided full-year 2020 guidance for Xtampza® ER product revenues, Nucynta® franchise product revenues and total operating expenses.

"In 2020, Xtampza ER is well-positioned for the next stage of growth driven by the 15 new exclusive extended-release oxycodone formulary wins covering more than 35 million lives that took effect on January 1, 2020," said Joe Ciaffoni, President and Chief Executive Officer of Collegium. "Xtampza ER growth, as well as a commitment to leverage our existing cost structure, will drive Collegium to profitability in 2020."

Financial Guidance for 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.

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.

About Xtampza ER

Xtampza® ER is Collegium's first product utilizing the DETERx technology platform. Xtampza ER is an abuse-deterrent, extended-release, oral formulation of oxycodone approved by the FDA for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

About Nucynta ER

Nucynta® ER is an extended-release formulation of tapentadol. Tapentadol is a centrally acting synthetic analgesic. Nucynta ER is approved by the FDA for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Nucynta ER is also approved by the FDA for neuropathic pain associated with diabetic peripheral neuropathy severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

About Nucynta

Nucynta® is an immediate release formulation of tapentadol indicated for the management of acute pain severe enough to require an opioid analgesic. Tapentadol is a centrally acting synthetic analgesic.

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 our future 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 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.

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