

**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 and Exchange Act of 1934

Date of Report (Date of earliest event reported): **February 22, 2018 (February 22, 2018)**

COLLEGIUM PHARMACEUTICAL, INC.

(Exact Name of Registrant as Specified in its Charter)

Virginia
(State or Other Jurisdiction
of Incorporation or Organization)

001-37372
(Commission File Number)

03-0416362
(IRS Employer Identification
No.)

**780 Dedham Street
Suite 800
Canton, MA 02021**
(Address of principal executive offices) (Zip Code)

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

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 8.01. Other Events.

On February 22, 2018, Collegium Pharmaceutical, Inc. ("Collegium") filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Teva Pharmaceuticals USA, Inc. ("Teva"). The lawsuit was filed under the Hatch-Waxman Act for Teva's infringement of eleven Collegium patents for Xtampza ER listed in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book— U.S. Patents Nos. 7,771,707; 8,449,909; 8,557,291; 8,758,813; 8,840,928; 9,044,398; 9,248,195; 9,592,200; 9,682,075; 9,737,530; and 9,763,883. The lawsuit was filed in response to a paragraph IV certification Collegium received from Teva stating that Teva had submitted an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") for a generic version of Xtampza ER (oxycodone) extended-release capsules for oral use.

Teva, as an ANDA applicant, is required to make certain certifications to the FDA concerning any patents listed for the approved product in the Orange Book. A paragraph IV certification is a certification that the new product will not infringe an approved product's listed patents, or that such patents are invalid.

These eleven Collegium patents for Xtampza ER were granted following review by the U.S. Patent and Trademark Office, are presumed to be valid under governing law, and can only be invalidated in federal court with clear and convincing evidence. Teva's paragraph IV certification alleges that these eleven U.S. patents are invalid, unenforceable, and/or will not be infringed by Teva's proposed product.

Under the Hatch-Waxman Act, Collegium was permitted to file suit within 45 days from its receipt of the paragraph IV certification and thereby automatically stay or bar the FDA from approving Teva's ANDA for 30 months or until a district court decision that is adverse to the asserted patents, whichever is earlier. Collegium believes the assertions in Teva's paragraph IV certification do not have merit, and Collegium intends to vigorously enforce its intellectual property rights relating to Xtampza ER.

Collegium cautions you that statements included in this report that are not a description of historical facts are forward-looking statements. Collegium may, in some cases, use terms such as “predicts,” “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 include, without limitation, statements regarding Collegium’s intention to vigorously enforce its intellectual property rights. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Collegium’s actual future results may differ materially from its current expectations due to the risks and uncertainties inherent in its business. These risks include, but are not limited to: Collegium’s ability to successfully enforce its intellectual property rights, and to defend its patents; the possibility that Collegium may be required to file lawsuits to defend the patent rights covering its product, and the substantial costs associated with such lawsuits; the possible introduction of generic competition to Xtampza ER; and other risks described under the heading “Risk Factors” in Collegium’s Annual Report on Form 10-K for the year ended December 31, 2016, and those risks described from time to time in other reports that Collegium files with the Securities and Exchange Commission. Any forward-looking statements made in this report speak only as of the date of this report. Collegium assumes no obligation to update any forward-looking statements contained in this report whether as a result of new information, future events or otherwise, after the date of this report.

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.

Date: February 22, 2018

By: /s/ Paul Brannelly

Name: Paul Brannelly

Title: Executive Vice President and Chief Financial Officer