
**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): **December 22, 2022 (December 21, 2022)**

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

(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**

Not Applicable

(Former name or former address, if changed since last report.)

Securities registered pursuant to Section 12(b) of the Exchange Act:

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.001 par value 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 December 22, 2022, Collegium Pharmaceutical, Inc. (the “Company”) issued a press release relating to the matter described in Item 8.01 of this Current Report on Form 8-K. 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.

Item 8.01 Other Events.

On December 21, 2022, the Federal Circuit Court of Appeals upheld the judgment of the U.S. District Court for the District of Delaware that certain claims of the patents protecting the Company’s product Belbuca, a buprenorphine buccal film indicated for the treatment of chronic pain, are valid. In addition to upholding the District Court’s judgement regarding the validity of certain claims in the 8,147,866 patent, expiring in 2027 (the “’866 patent”), and 9,901,539 patent, expiring in 2032 (the “’539 Patent”), the Federal Circuit vacated the District Court’s findings of invalidity with respect to certain claims of the ‘866 patent and the 9,655,843 patent (both expiring in 2027) and remanded such claims for reconsideration by the District Court.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit	Description
99.1	Press Release, dated December 22, 2022.
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL document).

SIGNATURE

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: December 22, 2022

COLLEGIUM PHARMACEUTICAL, INC.

By: /s/ Colleen Tupper

Name: Colleen Tupper

Title: Executive Vice President and Chief Financial Officer



Appeals Court Affirms Validity of Collegium's Belbuca® Patents

– Ruling bars ANDA filer Alvogen from entering market until 2032 patent expiry –

STOUGHTON, Mass., December 22, 2022 -- Collegium Pharmaceutical, Inc. (Nasdaq: COLL), a leading, diversified specialty pharmaceutical company, today announced that the Federal Circuit has upheld the judgment of the U.S. District Court for the District of Delaware that certain claims of the patents protecting Belbuca® are valid.

In addition to upholding the District Court's judgment regarding the validity of certain claims in the 8,147,866 patent, expiring in 2027 (the "'866 patent'"), and 9,901,539 patent, expiring in 2032 (the "'539 Patent'"), the Federal Circuit vacated the District Court's findings of invalidity with respect to certain claims of the '866 patent and the 9,655,843 patent (both expiring in 2027) and remanded such claims for reconsideration by the District Court.

Alvogen conceded infringement of all claims at issue in the litigation, and accordingly, Collegium expects that, by virtue of the Federal Circuit's decision, Alvogen will be barred from entering the market with its product until 2032.

"We are very pleased with the Federal Circuit's decision, which reinforces the strength of the patents supporting Belbuca," said Shirley Kuhlmann, General Counsel and Chief Administrative Officer of Collegium.

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.

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 "believes," "potential," "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 expectations relating to the timing and nature of generic competition for our products. 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, the outcome of any current or future patent infringement litigation that may be brought by or against us, and the regulatory status of our products and their generic competitors. 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.

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