

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 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 reported): **December 28, 2015**

**COLLEGIUM PHARMACEUTICAL, INC.**

(Exact Name of Registrant as Specified in 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))

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**Item 8.01 Other Events.**

On December 28, 2015, Collegium Pharmaceutical, Inc. (the "**Company**") announced that the District Court of Massachusetts issued an order staying proceedings in relation to the three Orange Book-listed patents asserted against the Company until February 25, 2016, which is the date on which the parties are scheduled to meet for a status conference. The three patents have been previously invalidated for obviousness by the court in the Southern District of New York in Purdue Pharma, L.P.'s ("**Purdue**") suit against Teva Pharmaceuticals USA, Inc. Purdue appealed the obviousness ruling to the Federal Circuit, which heard oral arguments on November 3, 2015.

Purdue's initiation of a patent infringement action against the Company in March 2015 triggered an automatic up-to-30 month stay on the FDA's potential issuance of final regulatory approval for Xtampza. The United States Food and Drug Administration ("**FDA**") can grant final approval following the expiration of the 30-month stay period or earlier termination of the stay. If the Company receives a court order that the listed patents are invalid or not infringed, or if the Purdue litigation is settled before the 30-month stay period expires, the FDA could then provide final regulatory approval of Xtampza, at which point the product can be marketed.

The foregoing description of the court order is only a summary and is qualified in its entirety by reference to the full text of the court order, which is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference herein.

***Forward-Looking Statements***

This report contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The Company may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from the Company's current expectations. For example, there can be no guarantee that the Company will obtain final regulatory approval for Xtampza ER or any of its other product candidates from the FDA or foreign regulatory authorities; even if Xtampza ER obtains final approval, the Company may not be able to obtain the label claims that it is seeking from the FDA. Furthermore, the Company is subject to patent infringement litigation relating to Xtampza ER and may, in the future, be subject to additional litigation relating to its other product candidates, which may be expensive to defend and delay the commercialization of Xtampza ER or the Company's other product candidates. Management's expectations and, therefore, any forward-looking statements in this report could also be affected by risks and uncertainties relating to a number of other factors, including the following: the Company's ability to commercialize its product candidates; the size and growth potential of the markets for the Company's product candidates, and the Company's ability to service those markets; the

Company's ability to develop sales and marketing capabilities, whether alone or with potential future collaborators; the rate and degree of market acceptance of the Company's product candidates; the success, cost and timing of its product development activities, studies and clinical trials; the success of competing products that are or become available; and the Company's expectations regarding its ability to obtain and adequately maintain sufficient intellectual property protection for its product candidates. These and other risks are described under the heading "Risk Factors" in the Company's Registration Statement on Form S-1 (File No. 333-208641), which was initially filed with the SEC on December 18, 2015, and those risks described from time to time in other reports which the Company files with the SEC. Any forward-looking statements that the Company makes in this report speak only as of the date of this report. The Company assumes no obligation to update its 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

99.1 Court Order dated December 23, 2015

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**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: December 28, 2015

By: /s/ Paul Brannelly

Name: Paul Brannelly

Title: Executive Vice President and Chief  
Financial Officer

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**INDEX TO EXHIBITS**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Court Order dated December 23, 2015

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UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

PURDUE PHARMA L.P.,  
THE P.F. LABORATORIES, INC.,  
PURDUE PHARMACEUTICALS L.P.,  
and RHODES TECHNOLOGIES,

Plaintiffs,

v.

COLLEGIUM PHARMACEUTICAL, INC.,

Defendant.

Civil Action No.  
15-13099-FDS

**ORDER GRANTING IN PART PLAINTIFFS' MOTION FOR A PARTIAL STAY**

SAYLOR, J.

Plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., and Rhodes Technologies have moved for a stay of this litigation pending the outcome of an appeal in a separate matter before the United States Court of Appeals for the Federal Circuit. The dispute concerns three patents (U.S. Patent Nos. 7,674,799; 7,674,800; and 7,683,072) that have been adjudicated as invalid for obviousness under 35 U.S.C. § 103 by the United States District Court for the Southern District of New York. *See Purdue Pharma L.P., et al. v. Teva Pharm., USA, Inc.*, 994 F. Supp. 2d 367 (S.D.N.Y. 2014). That finding is presently on appeal to the United States Court of Appeals for the Federal Circuit. Defendant Collegium Pharmaceutical, Inc. has cross-moved for partial judgment on the pleadings and for entry of final judgment under Fed. R. Civ. P. 54(b) on the ground that the New York court's ruling should have an issue-preclusion (or collateral estoppel) effect here. *See Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 170 F.3d 1373, 1381 (Fed. Cir. 1999) (noting "[t]he established rule in the federal courts . . . that a final judgment retains all of its res judicata consequences pending

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decision of the appeal"; *Mendenhall v. Barber-Greene Co.*, 26 F.3d 1573, 1577 (Fed. Cir. 1994) (noting that "the Supreme Court [has] ruled that once the claims of a patent are held invalid in a suit involving one alleged infringer, an unrelated party who is sued for infringement of those claims may reap the benefit of the invalidity decision under principles of collateral estoppel").

Collegium contends that its accused product, a pharmaceutical, is essentially awaiting final FDA approval, and that it cannot obtain that approval until either (1) 30 months have passed since the filing of a patent infringement suit or (2) the district court enters final judgment of invalidity or non-infringement. *See* 35 U.S.C. § 355(c)(3)(C). Collegium contends that the finding of invalidity should be given an issue-preclusion effect, notwithstanding the appeal, and that the imposition of a stay is unwarranted and will unfairly force it to delay the launch of its product. It appears that for a variety of technical and practical reasons, Collegium would not likely be able to launch its product any earlier than April 16, 2016.

Normally, a stay of litigation is the appropriate method to preserve the status quo when the outcome of an appeal in another case may be dispositive of the current proceeding. *See, e.g., Hewlett-Packard Co. v. Berg*, 61 F.3d 101, 105 (1st Cir. 1995). This case, however, presents some unusual circumstances. The Federal Circuit heard argument on the appeal on November 3, 2015. It is, of course, unclear when the Federal Circuit will issue its ruling, and what that ruling will be; nonetheless, there is a substantial possibility that it will issue its decision before April 2016. In the meantime, a court of competent jurisdiction has found the patents invalid after a three-week bench trial, and this Court cannot lightly assume that the finding of invalidity will be reversed. There is thus a substantial possibility that the sale of a new and potentially beneficial pharmaceutical may be delayed without good cause if the Court grants plaintiffs' motion to stay the case.

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Conversely, if the Court grants Collegium's motion, and subsequently one or more of the patents are found to be valid (assuming Collegium is found to have infringed those patents), plaintiffs will suffer an injury. While that injury could be addressed through money damages and, if appropriate, a preliminary and permanent injunction, plaintiffs would suffer an injury nonetheless. Plaintiffs may also (although it is by no means clear) lose the benefit of the 30-month stay under 35 U.S.C. § 355(c)(3)(C) if the judgment is reversed on appeal. *See Sanofi-Aventis v. FDA*, 725 F. Supp. 2d 92, 99 (D.D.C. 2010) (concluding that the 30-month stay is terminated by a later, second judgment "without regard to the appellate process" of the first judgment).

Under the circumstances, the Court will take a relatively cautious approach. In the short term, it will impose a stay of these proceedings, as a stay appears justified and reasonable given the consequences to plaintiffs—and the efficiency of the litigation as a whole—that a judgment by this Court would immediately cause. Over time, however, the equities of continuing the stay may well change. If the Federal Circuit still has not ruled as the prospective Collegium launch date in April 2016 becomes ever closer, it may well be appropriate for the Court to lift the stay and enter a final judgment based on issue-preclusion principles in order to permit Collegium to obtain final FDA approval and enter the market with its new product.(1) For at least the next two months, however, the balance of equities favors imposition of a stay pending a ruling from the Federal Circuit. A stay of that duration appears unlikely to harm Collegium or delay the release of its product.

(1) If the Court eventually adopts Collegium's proposal, it may be a relatively simple matter to unwind any entry of final judgment by this Court. Collegium has represented to the Court that if the Federal Circuit reverses the New York court's finding of invalidity, any judgment of this Court giving collateral estoppel effect to the New York court's judgment should be vacated without undue delay. Collegium has further represented to the Court that if plaintiffs file an appeal of any judgment entered in this proceeding, a stay of that appeal pending a decision on the merits by the Federal Circuit would be appropriate.

The Court will therefore impose a partial stay of this proceeding (assuming that the Federal Circuit has not ruled) until February 25, 2016. On that date, the Court will hold a further hearing to determine whether the stay should be continued or final judgment should enter for Collegium as to its First Claim for Relief.

Accordingly, and for the foregoing reasons, plaintiffs' cross-motion to stay is GRANTED IN PART. This matter, including a disposition of defendant's motion for partial judgment on the pleadings and for entry of final judgment, is hereby STAYED pending the February 25, 2016 status conference. The Court reserves judgment on the issue whether the stay should continue beyond that date. Should the United States Court of Appeals for the Federal Circuit issue a decision in *Purdue Pharma L.P. v. Epic Pharma, LLC*, No. 2014-1294 before that date, the parties are directed to provide the Court with a copy of that decision promptly, and to notify the clerk as to whether a hearing or conference should be held prior to February 25.

**So Ordered.**

/s/ F. Dennis Saylor IV

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F. Dennis Saylor IV

United States District Judge

Dated: December 23, 2015