



Appeals Court Affirms Validity of Collegium's Belbuca® Patents

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

STOUGHTON, Mass., Dec. 22, 2022 (GLOBE NEWSWIRE) -- 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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