

# U.S. Court of Appeals for the Federal Circuit Upholds District Court’s Decision to Invalidate AMPYRA® (dalfampridine) Patents

9/10/2018

ARDSLEY, N.Y.--(BUSINESS WIRE)-- Acorda Therapeutics, Inc. (Nasdaq:ACOR) today announced that the United States Court of Appeals for the Federal Circuit, by a 2-1 vote, has upheld the United States District Court for the District of Delaware’s decision to invalidate four AMPYRA patents. This decision affirms the District Court’s ruling on March 31, 2017 invalidating U.S. Patent Nos. 8,663,685 (the ‘685 patent), 8,007,826 (the ‘826 patent), 8,440,703 (the ‘703 patent), and 8,354,437 (the ‘437 patent) pertaining to AMPYRA® (dalfampridine) Extended Release Tablets, 10 mg. Acorda’s U.S. Patent No. 5,540,938 (the ‘938 patent), previously upheld by the District Court, expired on July 30, 2018.

“We are disappointed by the Court’s decision, as we continue to believe that our AMPYRA patents reflected true invention and were valid. We are reviewing the decision and will consider future options, including the possibility of a further appeal,” said Ron Cohen, M.D., Acorda’s President and CEO. “Following the Court’s original decision in 2017, we prepared a contingency plan that we could face generic competition, implementing a comprehensive corporate restructuring and bolstering our balance sheet. As a result, we are well-capitalized and fully focused on the potential launch of INBRIJA for Parkinson’s disease.”

## About Acorda Therapeutics

Founded in 1995, Acorda Therapeutics is a biopharmaceutical company focused on developing therapies that restore function and improve the lives of people with neurological disorders. Acorda has a pipeline of novel neurological therapies addressing a range of disorders, including Parkinson’s disease and multiple sclerosis. Acorda markets two FDA-approved therapies, including AMPYRA® (dalfampridine) Extended Release Tablets, 10 mg.

## About INBRIJA™ (levodopa inhalation powder)

INBRIJA is a self-administered, orally inhaled levodopa (L-dopa) therapy in development for the treatment of symptoms of OFF periods in people with Parkinson's disease taking a carbidopa/levodopa regimen. A New Drug Application (NDA) for INBRIJA was accepted for review by U.S. Food and Drug Administration in February 2018. FDA has set a target PDUFA date of October 5, 2018.

## Forward-Looking Statement

This press release includes forward-looking statements. All statements, other than statements of historical facts, regarding management's expectations, beliefs, goals, plans or prospects should be considered forward-looking. These statements are subject to risks and uncertainties that could cause actual results to differ materially, including: the ability to realize the benefits anticipated from acquisitions, among other reasons because acquired development programs are generally subject to all the risks inherent in the drug development process and our knowledge of the risks specifically relevant to acquired programs generally improves over time; we may need to raise additional funds to finance our operations and may not be able to do so on acceptable terms; our ability to successfully market and sell Ampyra (dalfampridine) Extended Release Tablets, 10 mg in the U.S., which will likely be materially adversely affected by the March 2017 court decision in our litigation against filers of Abbreviated New Drug Applications to market generic versions of Ampyra in the U.S.; the risk of unfavorable results from future studies of Inbrija (levodopa inhalation powder) or from our other research and development programs, or any other acquired or in-licensed programs; we may not be able to complete development of, obtain regulatory approval for, or successfully market Inbrija, or any other products under development; risks associated with complex, regulated manufacturing processes for pharmaceuticals, which could affect whether we have sufficient commercial supply of Inbrija to meet market demand, if it receives regulatory approval; third party payers (including governmental agencies) may not reimburse for the use of Ampyra, Inbrija or our other products at acceptable rates or at all and may impose restrictive prior authorization requirements that limit or block prescriptions; the occurrence of adverse safety events with our products; the outcome (by judgment or settlement) and costs of legal, administrative or regulatory proceedings, investigations or inspections, including, without limitation, collective, representative or class action litigation; competition; failure to protect our intellectual property, to defend against the intellectual property claims of others or to obtain third party intellectual property licenses needed for the commercialization of our products; and failure to comply with regulatory requirements could result in adverse action by regulatory agencies.

These and other risks are described in greater detail in our filings with the Securities and Exchange Commission. We may not actually achieve the goals or plans described in our forward-looking statements, and investors should not place undue reliance on these statements. Forward-looking statements made in this press release are made only as of the date hereof, and we disclaim any intent or obligation to update any forward-looking statements as a result of developments occurring after the date of this press release.

View source version on **businesswire.com**: <https://www.businesswire.com/news/home/20180910005687/en/>

Acorda Therapeutics, Inc.  
Felicia Vonella, 914-326-5146  
**[fvonella@acorda.com](mailto:fvonella@acorda.com)**

Source: Acorda Therapeutics, Inc.