

**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): **September 10, 2018**

Acorda Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

000-50513
(Commission
File Number)

13-3831168
(I.R.S. Employer
Identification No.)

**420 Saw Mill River Road,
Ardsley, NY**
(Address of principal executive offices)

10502
(Zip Code)

Registrant's telephone number, including area code: **(914) 347-4300**

Not Applicable

Former name or former address, if changed since last report

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:

- 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 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 September 10, 2018, Acorda Therapeutics, Inc. (the “Company”) issued a press release announcing 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. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K, and incorporated by reference into this Item 8.01.

On September 13, 2018, the Company issued a press release announcing the U.S. Food and Drug Administration (FDA) has extended the Prescription Drug User Fee Act (PDUFA) goal date for its review of the New Drug Application (NDA) of INBRIJA™ (levodopa inhalation powder) from October 5, 2018 to January 5, 2019. This extension is related to recent submissions the Company made in response to requests from FDA for additional information on chemistry, manufacturing and controls (CMC). FDA determined that these submissions constitute a major amendment and will take additional time to review. A copy of the press release is attached as Exhibit 99.2 to this Current Report on Form 8-K, and incorporated by reference into this Item 8.01.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

The following exhibits are filed herewith:

<i>Exhibit Number</i>	<i>Description</i>
99.1	Press Release dated September 10, 2018
99.2	Press Release dated September 13, 2018

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.

September 13, 2018

Acorda Therapeutics, Inc.

By: /s/ David Lawrence

Name: David Lawrence

Title: Chief, Business Operations and Principal Accounting Officer



CONTACT:
Felicia Vonella
914-326-5146
fvonella@acorda.com

FOR IMMEDIATE RELEASE

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

ARDSLEY, N.Y. – (September 10, 2018) – 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.

###

**MEDIA:**

Tierney Saccavino
(917) 783-0251
tsaccavino@acorda.com

INVESTORS:

Felicia Vonella
(914) 326-5146
fvonella@acorda.com

FOR IMMEDIATE RELEASE

**Acorda Announces FDA Extends INBRIJA NDA Review Period
New PDUFA Date of January 5, 2019**

ARDSLEY, NY – September 13, 2018 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that the U.S. Food and Drug Administration (FDA) has extended the Prescription Drug User Fee Act (PDUFA) goal date for its review of the New Drug Application (NDA) of INBRIJA™ (levodopa inhalation powder) from October 5, 2018 to January 5, 2019.

This extension is related to recent submissions Acorda made in response to requests from FDA for additional information on chemistry, manufacturing and controls (CMC). FDA determined that these submissions constitute a major amendment and will take additional time to review.

“We look forward to continuing our constructive dialogue with FDA,” said Ron Cohen, M.D., Acorda’s President and CEO. “We remain committed to bringing INBRIJA to approval for people with Parkinson’s who experience OFF periods, which are highly disruptive and in need of new therapeutic options.”

The FDA accepted Acorda’s NDA for INBRIJA in February 2018.

About Parkinson’s and OFF periods

Parkinson’s is a progressive neurodegenerative disorder resulting from the gradual loss of certain neurons responsible for producing dopamine. Approximately one million people in the U.S. and 1.2 million Europeans are diagnosed with Parkinson’s; it is estimated that approximately 40 percent of people with Parkinson’s experience OFF periods. It causes a range of symptoms including impaired movement, muscle stiffness and tremors. As Parkinson’s progresses, people will experience OFF periods, which are characterized by the re-emergence of Parkinson’s motor and non-motor symptoms. This re-emergence can occur even when an individual’s treatment regimen has been optimized.

About INBRIJA™ (levodopa inhalation powder) and ARCUS®

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.

INBRIJA utilizes Acorda’s investigational ARCUS® platform for inhaled therapeutics. INBRIJA was designed to deliver a precise dose of a dry powder formulation of L-dopa through the lung. Oral medication can be associated with variable onset of action, as the medicine is absorbed through the gastrointestinal (digestive) tract before reaching the brain. Inhaled treatments enter the body through the lungs and reach the brain, bypassing the digestive system.

The proprietary name INBRIJA has been conditionally accepted by the U.S. Food and Drug Administration (FDA).

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.

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 trial court decision in our litigation against filers of Abbreviated New Drug Applications to market generic versions of Ampyra in the U.S., which was affirmed by the appellate court in September 2018; 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.

###