

ACORDA THERAPEUTICS INC

FORM 8-K (Current report filing)

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Address	420 SAW MILL RIVER ROAD ARDSLEY, NY 10502
Telephone	914-347-4300
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**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): **June 16, 2015**

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))
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Item 8.01**Other Events**

On June 16, 2015, Acorda Therapeutics, Inc.(the “Company”) issued a press release announcing that it has presented data from a Phase 2b clinical trial of CVT-301, an inhaled levodopa (L-dopa) under development for the episodic treatment of OFF episodes associated with Parkinson’s disease (PD). OFF episodes are characterized by a re-emergence of PD motor symptoms, such as impaired ability to move, muscle stiffness and tremor. The trial showed that patients experiencing an OFF episode, treated with CVT-301, showed significantly greater improvements in motor function than patients treated with inhaled placebo; the difference in improvement was already apparent 10 minutes after dosing and was durable for at least an hour, the longest time point at which patients were measured. These data were presented at the 19th International Congress of Parkinson's Disease and Movement Disorders (MDS) in San Diego, CA. 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.

Item 9.01**Financial Statements and Exhibits**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated June 16, 2015

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.

Acorda Therapeutics, Inc.

June 16, 2015

By: /s/ Michael Rogers
Name: Michael Rogers
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.

Description

99.1

Press Release dated June 16, 2015

**CONTACT:**

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FOR IMMEDIATE RELEASE

Acorda Presents Data on Inhaled Levodopa Therapy CVT-301 at International Congress of Parkinson's Disease and Movement Disorders

Ardsley, N.Y. (June 16, 2015) -- Acorda Therapeutics, Inc. (Nasdaq:ACOR) today presented data from a Phase 2b clinical trial of CVT-301, an inhaled levodopa (L-dopa) under development for the episodic treatment of OFF episodes associated with Parkinson's disease (PD). OFF episodes are characterized by a re-emergence of PD motor symptoms, such as impaired ability to move, muscle stiffness and tremor. The trial showed that patients experiencing an OFF episode, treated with CVT-301, showed significantly greater improvements in motor function than patients treated with inhaled placebo; the difference in improvement was already apparent 10 minutes after dosing and was durable for at least an hour, the longest time point at which patients were measured. These data were presented at the 19th International Congress of Parkinson's Disease and Movement Disorders (MDS) in San Diego, CA.

“Oral levodopa, or L-dopa, is the current gold standard of care for Parkinson's disease. However, as the disease progresses, the majority of people will experience OFF episodes, even while on L-dopa therapy,” said Enrique Carrazana, M.D., Chief Medical Officer of Acorda. “Based on the successful results of this study, we have initiated a Phase 3 clinical and a long-term safety trial to further assess the potential of CVT-301 to reduce the duration of OFF episodes in people taking oral L-dopa. We believe that if successful, these results, together with the existing Phase 2b data, will enable Acorda to file a New Drug Application with the FDA.”

The Phase 2b trial was a randomized, double blind, placebo-controlled, multicenter study in 86 people with PD for the treatment of OFF episodes. Participants were randomized to self-administer CVT-301 or placebo as an adjunct to oral PD medications. Participants received 35mg of CVT-301 or placebo delivered to the lung in weeks 1 and 2, and 50mg of drug or placebo delivered to the lung in weeks 3 and 4. In-office assessments of the Unified Parkinson's Disease Rating Scale Part 3 (UPDRS III) were performed at weeks 1, 2 and 4. The primary endpoint was defined as the mean change from baseline in UPDRS III score (10-60 minutes post dose) after 4 weeks of treatment. UPDRS III is an established scale to monitor PD motor impairment, and is considered a standard in the field.

In this study, participants receiving CVT-301 showed a statistically significant and clinically important reduction in average UPDRS III motor score compared to placebo ($p < 0.01$) and across all measured time points beginning at 10 and up to 60 minutes post-administration ($p < 0.05$). Both doses of CVT-301 were well tolerated, with no increase relative to placebo in troublesome or non-troublesome dyskinesias during ON periods. There were no serious adverse events reported in the drug group, and the incidence of drug-related adverse events was similar between treatment groups. The most common adverse events were dizziness, headache and cough; there were no adverse events on cardiovascular or lung function. PD patients were able to self-administer treatment while in an OFF state.

“OFF episodes have a major negative impact on the lives of people with Parkinson’s disease, as well as on their loved ones and care partners. Effective treatment options are desperately needed,” said Robert Hauser, M.D., Professor of Neurology, Molecular Pharmacology and Physiology at the University of South Florida and one of the authors of the poster. “The study results reported today indicate that patients treated with CVT-301 had rapid, clinically meaningful improvements in motor function. This suggests CVT-301 has the potential to be an exciting new therapy to treat OFF episodes in people with Parkinson’s. I am looking forward to the results of the ongoing clinical studies, which are designed to provide confirmatory information about the safety and efficacy of CVT-301 in treating OFF episodes.”

The poster was chosen by the MDS Congress Scientific Program Chairs for a Guided Poster Tour Presentation. The poster is also under consideration for inclusion in the Blue Ribbon Highlights session, which will provide a critical overview of the best presentations highlighting the relevance, novelty and quality of both clinical and basic research.

Data from this study were presented at the 2014 American Academy of Neurology Annual Meeting and the 18th International Congress of Parkinson's Disease and Movement Disorders.

About CVT-301 Phase 3 Program

Based on the results of the Phase 2b trial, Acorda has initiated a Phase 3 clinical trial that is expected to enroll approximately 345 participants across three arms: 50mg, 35mg, or placebo. These are the same doses used in the Phase 2b study. The primary outcome measure is improvement on the UPDRS III after administration of CVT-301.

More details about the study, including enrollment criteria, can be found at www.acorda.com or <http://clinicaltrials.gov/ct2/show/NCT02240030?term=CVT-301&rank=2>

About Acorda Therapeutics

Founded in 1995, Acorda Therapeutics is a biotechnology company focused on developing therapies that restore function and improve the lives of people with neurological disorders.

Acorda markets three FDA-approved therapies, including AMPYRA® (dalfampridine) Extended Release Tablets, 10 mg. The Company has one of the leading pipelines in the industry of novel neurological therapies. Acorda is currently developing a number of clinical and preclinical stage therapies. This pipeline addresses a range of disorders including post-stroke walking deficits, Parkinson's disease, epilepsy, neuropathic pain, heart failure, MS and spinal cord injury.

For more information, please visit the Company's website at: www.acorda.com.

Forward Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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 the Civitas transaction and to successfully integrate Civitas' operations into our operations; our ability to successfully market and sell Ampyra in the U.S.; third party payers (including governmental agencies) may not reimburse for the use of Ampyra or our other products at acceptable rates or at all and may impose restrictive prior authorization requirements that limit or block prescriptions; the risk of unfavorable results from future studies of Ampyra or from our other research and development programs, including CVT-301, Plumiaz, or any other acquired or in-licensed programs; we may not be able to complete development of, obtain regulatory approval for, or successfully market CVT-301, Plumiaz, or any other products under development; we may need to raise additional funds to finance our expanded operations and may not be able to do so on acceptable terms; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain regulatory approval of or to successfully market Fampyra outside of the U.S. and our dependence on our collaboration partner Biogen in connection therewith; 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 Acorda Therapeutics' filings with the Securities and Exchange Commission. Acorda may not actually achieve the goals or plans described in its forward-looking statements, and investors should not place undue reliance on these statements. Forward-looking statements made in this release are made only as of the date hereof, and Acorda disclaims any intent or obligation to update any forward-looking statements as a result of developments occurring after the date of this release.

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