

**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): **February 9, 2017**

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 8.0 1 Other Events

On February 9, 2017 Acorda Therapeutics, Inc. issued a press release announcing Phase 3 clinical data of CVT-301, showing a statistically significant improvement in motor function in people with Parkinson’s disease experiencing OFF periods. CVT-301 is an investigational, inhalable formulation of levodopa (L-dopa). It is being studied as a treatment for OFF periods in people with Parkinson’s disease taking an oral carbidopa / levodopa regimen. OFF periods refer to the re-emergence of Parkinson’s symptoms. 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 February 9, 2017

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.

February 9, 2017

Acorda Therapeutics, Inc.

By: /s/ David Lawrence

Name: David Lawrence

Title: Chief, Business Operations and Principal Accounting Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated February 9, 2017

**CONTACT:**

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FOR IMMEDIATE RELEASE

Acorda Announces Positive Phase 3 Clinical Trial Results for CVT-301

- SPAN-PD trial met primary endpoint: CVT-301 showed statistically significant improvement of motor function compared to placebo
- New Drug Application (NDA) submission planned for Q2 2017
- Data from two long-term safety studies expected in Q1 2017

ARDSLEY, N.Y. – February 9, 2017 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced Phase 3 clinical data of CVT-301, showing a statistically significant improvement in motor function in people with Parkinson's disease experiencing OFF periods. CVT-301 is an investigational, inhalable formulation of levodopa (L-dopa). It is being studied as a treatment for OFF periods in people with Parkinson's disease taking an oral carbidopa / levodopa regimen. OFF periods refer to the re-emergence of Parkinson's symptoms.

"We are greatly encouraged by the efficacy and safety results of this trial, which validate the positive Phase 2b results," said Burkhard Blank, M.D., Chief Medical Officer of Acorda. "We would like to express our gratitude to the study volunteers and clinical investigators who participated in this trial to advance our understanding of this potentially important therapy for people with Parkinson's."

The SPAN-PD trial had three arms: CVT-301 84 mg and 60 mg doses (equivalent to 50 mg and 35 mg fine particle doses, respectively), and placebo. The primary endpoint of the study was the change at Week 12 in Unified Parkinson's Disease Rating Scale-Part 3 (UPDRS III) score relative to placebo at 30 minutes post-treatment for the 84 mg dose. UPDRS III change for the 84 mg dose was -9.83 compared to -5.91 for placebo (p=0.009). UPDRS III is a validated scale, which measures Parkinson's motor impairment.

The safety profile of CVT-301 in this study was consistent with that observed in the Phase 2b trial. Spirometry and diffusing capacity of the lung for carbon monoxide (D_{LCO}) tests showed no notable pulmonary safety signals. The Company is currently conducting two studies to assess the long-term safety profile of CVT-301. Up to 12-month data from these studies are expected by the end of the first quarter of 2017.

The Company plans to file a New Drug Application (NDA) in the United States by the end of the second quarter of 2017, pending results of the long-term safety studies. The Company also

plans to file a Marketing Authorization Application (MAA) in Europe by the end of 2017, pending additional data analyses.

Peter LeWitt, M.D., M.Med.Sc., Director of the PD and Movement Disorders Program at Henry Ford Hospital and lead investigator of the study said, “The re-emergence of Parkinson’s disease symptoms has a major negative impact on the lives of people with this disease, as well as on their families and care partners. Managing symptoms of OFF periods continues to be a significant unmet need for people taking oral carbidopa/levodopa regimens. Delivering levodopa by the pulmonary route offers an important treatment option for people with Parkinson’s disease.”

Detailed trial results will be presented at a future medical meeting.

SPAN-PD Safety Findings

Participants reporting serious adverse events (SAEs) were as follows: 3 (2.7%) in the placebo arm, 6 (5.3%) in the 60 mg arm, and 2 (1.8%) in the 84 mg arm. There was one death in the study, a suicide in the 60 mg group, judged by the investigator to be not related to study drug.

The most common adverse events that were reported in any study arm at >5% were:

Adverse Event n (%)	Placebo (N=112)	CVT-301 60 mg (N=113)	CVT-301 84 mg (N=114)
Cough	2 (1.8%)	17 (15.0%)	17 (14.9%)
Upper Respiratory Tract Infection	3 (2.7%)	2 (1.8%)	7 (6.1%)
Throat Irritation	0	8 (7.1%)	1 (0.9%)
Nausea	3 (2.7%)	0	6 (5.3%)
Sputum Discolored	0	0	6 (5.3%)

When cough was reported, it was typically mild and reported once per participant during the course of treatment. Three of 227 participants receiving CVT-301 discontinued the study due to cough.

SPAN-PD Trial Design

The Phase 3, randomized, double-blind, placebo-controlled clinical trial evaluated the efficacy and safety of CVT-301 compared with placebo in people with Parkinson’s who experience motor fluctuations (OFF periods). All participants were on a stable regimen of oral carbidopa / levodopa, and were also maintained on their other existing Parkinson’s therapies. A total of 339 study participants were randomized and received at least one dose of CVT-301 or placebo. Participants self-administered treatment up to five times daily for 12 weeks.

The primary endpoint of the study was the change at Week 12 in Unified Parkinson's Disease Rating Scale-Part 3 (UPDRS II I) score relative to placebo at 30 minutes post-treatment for the 84 mg dose. Key secondary endpoints, measured at Week 12, included: proportion of participants achieving an ON state within 60 minutes of treatment and maintained at 60 minutes; change in UP DRS III score at 10 and 20 minutes following treatment; Patient Global Impression of Change (PGI-C) improvement; and total daily OFF time as recorded in participant diary.

About Parkinson's Disease and OFF Periods

Approximately one million people in the U.S. and 1.2 million Europeans are diagnosed with Parkinson's disease (PD); OFF periods are experienced by approximately 350,000 in the U.S. and 420,000 in Europe.

Parkinson's is a progressive neurodegenerative disorder resulting from the gradual loss of certain neurons responsible for producing dopamine. It causes a range of symptoms including impaired movement, muscle stiffness and tremors. As PD progresses, people with Parkinson's experience OFF periods, which are characterized by the re-emergence of PD symptoms. This re-emergence can occur even when an individual's treatment regimen has been optimized.

OFF periods can be very disruptive to the lives of people with Parkinson's, their families and caregivers. OFF periods can increase in frequency and severity during the course of the disease.

About CVT-301 and ARCUS[®]

CVT-301 is being developed as a self-administered, inhaled levodopa (L-dopa) therapy for the treatment of symptoms of OFF periods in people with Parkinson's disease taking an oral carbidopa / levodopa regimen.

CVT-301 utilizes Acorda's investigational ARCUS[®] platform for inhaled therapeutics. CVT-301 delivers a precise dose of a dry powder formulation of L-dopa to the lung. Oral medication can be associated with slow and 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 shortly thereafter, bypassing the digestive system.

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 has an industry leading pipeline of novel neurological therapies addressing a range of disorders, including Parkinson's disease, migraine and multiple sclerosis. Acorda markets three FDA-approved therapies, including AMPYRA[®] (dalfampridine) Extended Release Tablets, 10 mg.

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

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 complete the Biotie transaction on a timely basis; the ability to realize the benefits anticipated from the Biotie and Civitas transactions, 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; the ability to successfully integrate Biotie's operations and Civitas' operations, respectively, into our operations; we may need to raise additional funds to finance our expanded 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.; 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 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, any other products under development, or the products that we will acquire when we complete the Biotie transaction; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain and maintain regulatory approval of or to successfully market Ampyra outside of the U.S. and our dependence on our collaborator 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 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.

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