

# ACORDA THERAPEUTICS INC

## FORM 8-K (Current report filing)

Filed 12/10/14 for the Period Ending 12/10/14

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): **December 10, 2014**

**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 December 10, 2014, Acorda Therapeutics, Inc. issued a press release announcing that the first patient has been enrolled in a Phase 3 study of CVT-301 for the treatment of OFF episodes in Parkinson's disease (PD). OFF episodes are characterized by a re-emergence of PD symptoms such as tremor, muscle stiffness and impaired ability to move. 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 December 10, 2014

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## 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.**

December 10, 2014

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

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**EXHIBIT INDEX**

Exhibit No.  
99.1

Description  
Press Release dated December 10, 2014

**CONTACT:**

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FOR IMMEDIATE RELEASE

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## Acorda Announces Initiation of Phase 3 Trial of CVT-301 in Parkinson's Disease

Ardsley, N.Y. – December 10, 2014 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that the first patient has been enrolled in a Phase 3 study of CVT-301 for the treatment of OFF episodes in Parkinson's disease (PD). OFF episodes are characterized by a re-emergence of PD symptoms such as tremor, muscle stiffness and impaired ability to move.

CVT-301 is a novel, self-administered inhaled therapy designed to provide rapid, reliable delivery of a precise dose of levodopa (L-dopa) through the lungs to return people with PD to an ON state. An ON state is when a patient's symptoms are adequately controlled, allowing people with Parkinson's to more readily perform daily activities.

"Parkinson's is a debilitating neurological disease affecting over a million Americans, and as many as 10 million people worldwide," said Enrique Carrazana, M.D., Acorda Therapeutics' Chief Medical Officer. "About 350,000 people with PD in the U.S. experience OFF episodes, which can be exceptionally disruptive, impacting their lives on a daily basis, even multiple times per day. We believe CVT-301 has the potential to be an important treatment for people experiencing OFF episodes."

The multi-center, double blind, randomized trial 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 Unified Parkinson's Disease Rating Scale (UPDRS) Part III after administration of CVT-301.

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

**Phase 2b Study Results**

Positive results from the CVT-301 Phase 2b study were presented at the 2014 American Academy of Neurology Annual Meeting. In this study, participants

receiving CVT-301 showed a statistically significant and clinically important reduction in average UPDRS Part III motor score versus placebo across time points beginning at 10 and up to 60 minutes post-administration ( $p < 0.001$ ). 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 in the trial, and the incidence of drug-related adverse events was similar between treatment groups. The CVT-301 inhaler was shown to be easily self-administered in the OFF state.

“Oral L-dopa is the standard of care in reducing the symptoms of PD; however, significant challenges remain in creating an individualized treatment regimen that consistently maintains therapeutic effects as the disease progresses,” said Rick Batycky, Ph.D., Acorda Therapeutics’ Chief Technology Officer. “CVT-301 uses our proprietary ARCUS technology to deliver L-dopa through the lungs. The ARCUS technology can deliver much larger doses than is possible with standard pulmonary technologies, making it ideal for delivery of medications such as L-dopa.”

### **About ARCUS® Technology**

Acorda’s proprietary ARCUS technology platform is a dry-powder pulmonary delivery system that has potential applications in multiple disease areas. This platform allows consistent and precise delivery of significantly larger doses of medication than are possible with conventional pulmonary systems. The ARCUS inhaler is breath-actuated, operated by the user putting their lips to the device and simply breathing in.

The ARCUS technology has been used to successfully deliver more than one million doses to patients in clinical trials of various products. CVT-301 is the most advanced drug candidate using the ARCUS technology. Acorda has an extensive patent portfolio relating to CVT-301 and the ARCUS technology, which covers aspects of the formulated drug product, the inhaler, the method of drug delivery and manufacturing processes for CVT-301.

### **About Parkinson’s Disease (PD) and OFF Episodes**

Approximately one million Americans, 1.2 million Europeans and between seven and ten million people worldwide suffer from PD. PD is a progressive neurodegenerative disorder resulting from the gradual loss of certain neurons responsible for producing dopamine, which causes impairment of motor function including tremors, muscle stiffness and impaired ability to move. The standard of care for the treatment of PD symptoms is oral levodopa (L-dopa). Approximately 70% of people with PD in the United States are treated with oral L-dopa. Effective control of PD symptoms is referred to as an ON state.

As Parkinson’s disease progresses, even optimized regimens of oral L-dopa are associated with increasingly wide variability in the timing and amount of absorption into the bloodstream. This results in the unreliable control of symptoms, leading to OFF episodes, or motor fluctuations. OFF episodes, which are characterized by a re-emergence of PD symptoms, increase in frequency and severity during the course of the disease. About half of people with PD experience OFF episodes within five years of initiating oral L-dopa therapy, and about 350,000 people with PD in the U.S. alone experience OFF episodes. OFF episodes are inadequately addressed by available

therapies and are considered one of the greatest unmet medical needs facing people with PD.

### **About CVT-301**

CVT-301 is being developed as a self-administered, inhaled L-dopa therapy for treatment of OFF episodes in Parkinson's disease (PD). This is an adjunctive therapy to a patient's individually optimized oral L-dopa regimen. Acorda's proprietary ARCUS<sup>®</sup> technology provides a precise dose of a dry powder formulation of L-dopa to the lung to enable rapid and predictable absorption. CVT-301 is delivered through a pocket-size, breath-actuated inhaler designed to be patient-friendly. In the Phase 2b clinical trial, participants receiving CVT-301 showed a statistically significant and clinically important reduction in average UPDRS Part III motor score versus placebo across time points beginning at 10 and up to 60 minutes post-administration ( $p < 0.001$ ). 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 people receiving CVT-301. In the CVT-301 treatment group, lightheadedness and cough were the most frequently reported adverse events. There were no observed, treatment-associated adverse effects on lung function. Clinical studies conducted to date have been funded in part by grants from The Michael J. Fox Foundation for Parkinson's Research.

### **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<sup>®</sup> (dalfampridine) Extended Release Tablets, 10 mg, a treatment to improve walking in patients with multiple sclerosis (MS), as demonstrated by an increase in walking speed. 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](http://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 Idec 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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