

**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): **March 29, 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 8.01 Other Events**

On March 29, 2017, Acorda Therapeutics, Inc. (the “Company”) issued a press release announcing results from two ongoing, long-term safety studies of CVT-301 in people with Parkinson’s that showed no differences in pulmonary function between the group receiving CVT-301 and an observational control group. These results are consistent with previously reported data from Phase 2b and Phase 3 clinical trials. The Company also announced results from separate clinical studies that assessed the safety profile of CVT-301 in people with asthma, smokers and early morning OFF. CVT-301 is an investigational, inhalable formulation of levodopa (L-dopa). It is being studied as a treatment for symptoms of OFF periods in people with Parkinson’s taking an oral carbidopa / levodopa regimen. OFF periods are characterized by the re-emergence of Parkinson’s disease symptoms. The Company plans to file a New Drug Application (NDA) in the United States by the end of the second quarter of 2017 and, pending additional data analyses, plans to file a Marketing Authorization Application (MAA) in Europe by the end of 2017. 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.

## **Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

| <i>Exhibit No.</i> | <i>Description</i>                                 |
|--------------------|--|
| 99.1               | <a href="#">Press Release dated March 29, 2017</a> |

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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.

*March 29, 2017*

**Acorda Therapeutics, Inc.**

*By: /s/ Jane Wasman*

*Name: Jane Wasman*

*Title: President, International and General Counsel*

## EXHIBIT INDEX

Exhibit No.

Description

99.1

[Press Release dated March 29, 2017](#)



**CONTACT:**

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FOR IMMEDIATE RELEASE

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**Acorda Announces Long-Term Safety Data for CVT-301**

- Pulmonary function measures over 12 months comparable between CVT-301 and observational control group
- Separate clinical studies assessed safety profile of CVT-301 in people with asthma, smokers and early morning OFF
- New Drug Application (NDA) submission planned by end Q2 2017

ARDSLEY, N.Y. – March 29, 2017 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced results from two ongoing, long-term safety studies of CVT-301 in people with Parkinson’s that showed no differences in pulmonary function between the group receiving CVT-301 and an observational control group. These results are consistent with previously reported data from Phase 2b and Phase 3 clinical trials.

CVT-301 is an investigational, inhalable formulation of levodopa (L-dopa). It is being studied as a treatment for symptoms of OFF periods in people with Parkinson’s taking an oral carbidopa / levodopa regimen. OFF periods are characterized by the re-emergence of Parkinson’s symptoms.

“We are delighted with these results, and plan to move forward with our NDA filing for CVT-301. These two studies, which include approximately 700 participants, represent the largest safety database evaluating long-term pulmonary function in people with Parkinson’s,” said Burkhard Blank, M.D., Chief Medical Officer of Acorda. “We thank the study volunteers and clinical investigators, whose willingness to participate in these trials has been essential to the progress of this program.”

The Company is conducting two separate long-term safety studies:

- CVT-301-005: a 12-month, randomized, open-label study in which 271 participants with Parkinson's who did not have a history of asthma or other chronic lung disease receive CVT-301 84 mg up to five times daily, along with usual Parkinson’s standard of care. Safety findings for participants treated with CVT-301 are compared to an observational control group of 127 participants managed with usual Parkinson’s standard of care. At the time of this analysis, all ongoing participants completed their 36 week visit and 199 participants completed their 52 week visit.
  - CVT-301-004E: participants receive one of two doses of CVT-301 (84 mg – 149 participants; 60 mg – 146 participants). There is no control arm in the study. At the time
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of this analysis, 70 participants completed their 36 week visit and 49 participants completed their 52 week visit.

Data from both studies will be presented at a future medical meeting.

The Company plans to file a New Drug Application (NDA) in the United States by the end of the second quarter of 2017 and, pending additional data analyses, plans to file a Marketing Authorization Application (MAA) in Europe by the end of 2017.

### CVT-301-005 Detailed Safety Findings

The primary objective of this study is to assess pulmonary function. Measures include Forced Expiratory Volume in 1 second (FEV1) and diffusing capacity of the lung for carbon monoxide (DL<sub>CO</sub>). Further study details are available at <https://clinicaltrials.gov/ct2/show/NCT02352363>.

The mean changes in FEV1 (see Figure 1) and DL<sub>CO</sub> (see Figure 2) from baseline to Week 52 in the CVT-301 84 mg group were not statistically different from the observational control group.

**FIGURE 1**

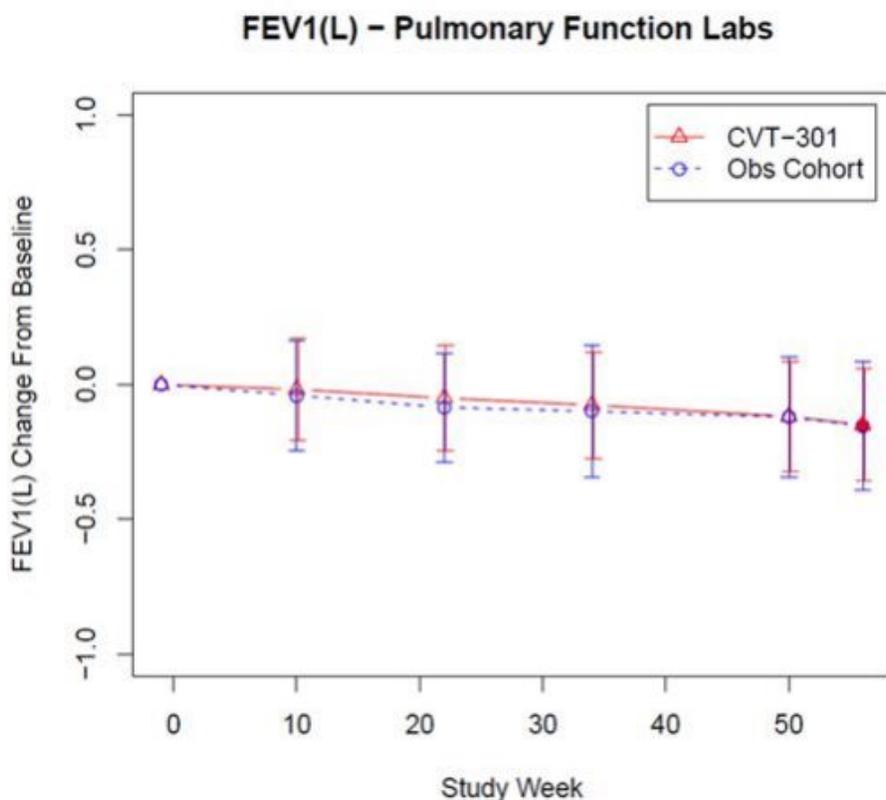
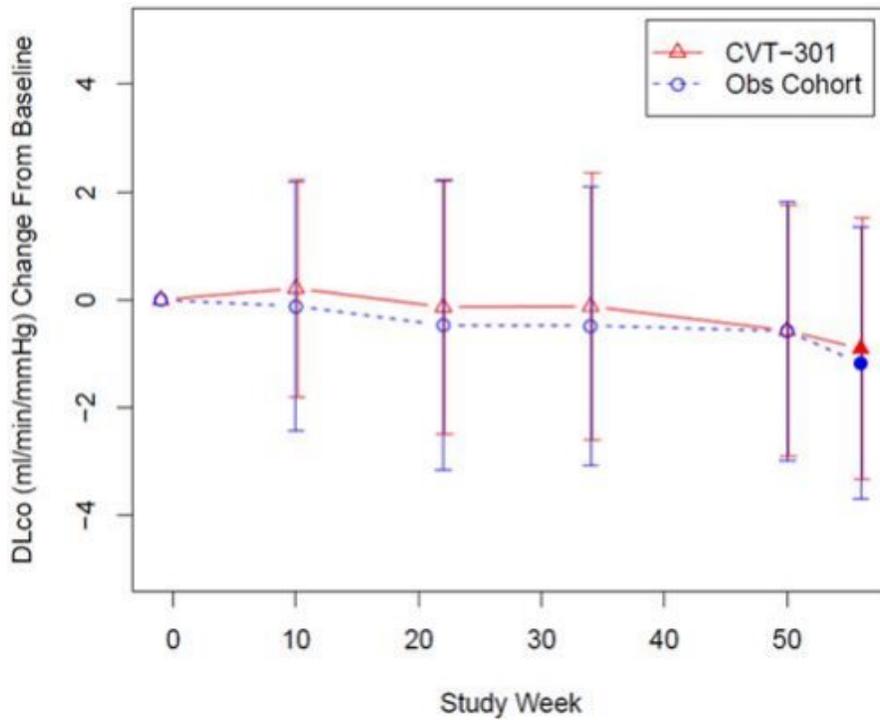


FIGURE 2

DLco - Pulmonary Function Labs



Participants reporting serious adverse events (SAEs) were as follows: 13 (10.2%) in the observational control arm and 40 (14.9%) in the CVT-301 84 mg arm. Urinary tract infection occurred in four participants (1.4%) receiving CVT-301 84 mg. No other SAEs in the CVT-301 treatment group were reported at greater than 1%. There was one death in the study, a drowning in the CVT-301 84 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<br>n (%) | Observational Control<br>(n=127) | CVT-301 84 mg<br>(n=271) |
|------------------------|----------------------------------|--------------------------|
| Cough                  | 1 (0.8%)                         | 35 (12.9%)               |
| Nasopharyngitis        | 6 (4.7%)                         | 17 (6.3%)                |
| Dyskinesia             | 4 (3.1%)                         | 15 (5.5%)                |

|                               |          |           |
|-------------------------------|----------|-----------|
| Fall                          | 3 (2.4%) | 14 (5.2%) |
| Bone Fracture (various types) | 3 (2.4%) | 14 (5.2%) |

All reported fractures were judged by the investigators to be unlikely related or not related to study drug. Most reports of cough were mild (91%), none were severe. Two of 271 participants (0.7%) receiving CVT-301 discontinued the study due to cough.

Safety findings in the CVT-301-004E study, which did not have an observational arm, were consistent with those observed among participants receiving CVT-301 84 mg in the CVT-301-005 study.

### **Special Population Safety Studies**

**Asthmatics:** The Company conducted a study to evaluate the safety of CVT-301 in otherwise healthy people with mild to moderate asthma. In this crossover study, 25 participants received three inhalations of CVT-301 separated by 4 hours, as well as three placebo inhalations separated by 4 hours.

The study found that 10 of the 25 subjects experienced acute bronchoconstriction when receiving CVT-301, defined as a >15% decrease in FEV1. This change was reversible, asymptomatic and did not require rescue treatment. FEV1 in all 10 participants returned to baseline within 24 hours. The most common adverse event reported during CVT-301 administration was cough (n=15, 60%), and was characterized as mild or moderate (20% and 80%, respectively).

**Smokers:** In a study to assess the safety of CVT-301 in healthy volunteers who smoked, 25 smokers with no history of chronic lung disease and 31 healthy non-smokers received a single dose of CVT-301 84 mg. There were no significant changes in pulmonary function between the two groups following administration. The incidence of adverse events was similar across groups. These events were classified as mild by study investigators and resolved without treatment. Cough was the most frequently reported adverse event (60% - smokers; 71% - non-smokers) and was generally characterized as mild.

**Early Morning OFF:** A study of 36 participants assessed safety in people with Parkinson's who received CVT-301 concurrently with carbidopa / levodopa during their first OFF period of the day (known as early morning OFF). Using a cross-over design, participants received a single dose of CVT-301 and a single dose of placebo. There were no serious adverse events reported, and no participants discontinued because of adverse events. There was no difference in the occurrence of orthostatic hypotension between the groups. Cough was the most frequently reported adverse event (11% - CVT-301; 2.8% - placebo) and was generally characterized as mild.

### **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 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](http://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 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 Fampyra outside

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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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