

**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): **January 17, 2019**

**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.

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**Item 8.01 Other Events**

On January 17, 2019, Acorda Therapeutics, Inc. issued a press release announcing that *The Lancet Neurology* published results from SPAN SM -PD, the Phase 3 pivotal efficacy trial of INBRIJA™ (levodopa inhalation powder), also referred to as CVT-301. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release dated January 17, 2019</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.

January 18, 2019

### **Acorda Therapeutics, Inc.**

By: /s/ David Lawrence

Name: David Lawrence

Title: Chief, Business Operations and Principal Accounting Officer

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FOR IMMEDIATE RELEASE

**Acorda Announces The Lancet Neurology Publication of Phase 3 Data for INBRIJA™ (levodopa inhalation powder)**

- *SPAN SM -PD, the efficacy and safety study of INBRIJA (CVT-301), showed significant improvement in motor function during OFF periods in people with Parkinson's on a carbidopa/levodopa regimen*
- *INBRIJA was approved in the U.S. in Dec. 2018 and is expected to be available by prescription in Q1 2019*

ARDSLEY, NY – Jan. 17, 2019 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that *The Lancet Neurology* published results from SPAN SM -PD, the Phase 3 pivotal efficacy trial of INBRIJA™ (levodopa inhalation powder), also referred to as CVT-301. In the study, INBRIJA 84 mg significantly improved motor function at 30 minutes during OFF periods in people with Parkinson's taking carbidopa/levodopa, the study's primary endpoint. Onset of action was seen as early as 10 minutes and the reduction at 30 minutes was maintained at 60 minutes. Multiple secondary endpoints were supportive of the primary endpoint. Data from the study were first presented at the 2017 International Congress of Parkinson's Disease and Movement Disorders (MDS).

"A well-tolerated, effective treatment for OFF periods between doses of scheduled medications can help fulfill one of the most important unmet needs for people with Parkinson's," said lead author of the publication Peter LeWitt, M.D., Director of the Parkinson's Disease and Movement Disorders Program at Henry Ford Hospital and professor of neurology at Wayne State University School of Medicine. "The data published in *The Lancet Neurology* support INBRIJA as such a treatment option, delivering levodopa, the current 'gold standard' of Parkinson's treatment, in a novel, inhaled form."

"We're gratified to see the SPAN-PD trial paper published in one of the most highly regarded neurology journals, *The Lancet Neurology*. We believe this reflects both the quality of the study and the importance of its clinical results to people with Parkinson's," said Ron Cohen, M.D., Acorda's President and CEO. "INBRIJA was recently approved by the FDA, and we are eager to make it available to the Parkinson's community during the first quarter of 2019."

**About SPAN SM -PD (NCT02240030) and Key Results**

The Phase 3 pivotal efficacy trial for INBRIJA – SPAN-PD – was a 12-week, randomized, placebo controlled, double blind study evaluating the effectiveness of INBRIJA versus placebo in patients with Parkinson's experiencing OFF periods.



The 339 patients in the trial had mild to moderate Parkinson's and were on a n oral levodopa plus a dopa-decarboxylase inhibitor (e.g., carbidopa) . Most were on additional scheduled Parkinson's medication and were experiencing at least two hours per day of OFF time. Patients with asthma, COPD, or other chronic lung disease within the previous five years were excluded. Patients were randomized into three treatment groups: 113 in the INBRIJA 60 mg group, 114 in the INBRIJA 84 mg group and 112 with placebo.

The primary endpoint was the change in the Unified Parkinson's Disease Rating Scale (UPDRS) motor scores from pre-dose to 30 minutes post-dose, evaluated at week 12 during an in-clinic OFF period. INBRIJA 84 mg showed statistically significant improvement in motor function compared to placebo as measured by mean change in the UPDRS motor score at 30 minutes post-dose (-9.83 vs. -5.91; p=0.0088).

Key secondary endpoints for INBRIJA versus placebo also were evaluated at week 12 using a pre-specified hierarchy. The order of hierarchy was set based on probability of success, guided by a Phase 2 study. The primary endpoint (INBRIJA 84 mg vs. placebo) was tested first for statistical significance. Upon achieving significance, the secondary endpoints were tested for INBRIJA 84 mg vs. placebo as long as each preceding endpoint reached a significance level of p<0.05. The hierarchical sequence did not reach statistical significance at Step 3. Unadjusted (nominal) p-values are presented below for all key secondary endpoints.

Endpoint	Hierarchy Order	Δ	P-Value
4 mg vs. placebo			
Change in UPDRS motor score at 30 min, LS mean (primary)	1	-3.92	0.0088**
% OFF to ON and remaining ON at 60 min, Odds ratio	2	2.65	0.003**
Change in UPDRS motor score at 20 min, LS mean	3	-2.55	0.062
% subjects improved on Patient Global Impression of Change, Odds ratio	4	2.94	<0.001*
Change in UPDRS motor score at 10 min, LS mean	5	-2.26	0.046*
Change in Parkinson's disease diary off-state time, LS mean	6	-0.01	0.975

\* Statistically significant on a nominal and adjusted basis  
 Nominal p-value; not eligible for statistical significance.

Reported adverse events in at least 4 % of patients in the INBRIJA 84 mg group vs. placebo were: cough ( 15% vs. 2 %), upper respiratory tract infection (6% vs. 3 %), nausea (5% vs. 3%), discolored sputum (5% vs. 0%) and dyskinesia ( 4 % vs. 0%). Most adverse events of cough in the INBRIJA treatment groups started within the first 30 days of treatment, and these were generally assessed as mild or moderate in intensity . Two patients in the INBRIJA 84 mg group withdrew from the study due to cough .

### **About INBRIJA™ (levodopa inhalation powder)**

INBRIJA is the first and only inhaled levodopa for intermittent treatment of OFF episodes in patients with Parkinson's disease treated with carbidopa/levodopa. INBRIJA utilizes Acorda's innovative ARCUS® platform for inhaled therapeutics. A Marketing Authorization Application (MAA) for INBRIJA was submitted to the European Medicines Agency (EMA) in March 2018 and was formally validated in May 2018.

### **Important Safety Information**

INBRIJA is not to be used if patients take or have taken a nonselective monoamine oxidase inhibitor such as phenelzine or tranylcypromine within the last 2 weeks.

Before using INBRIJA, patients should tell their healthcare provider about all their medical conditions, including:

- asthma, chronic obstructive pulmonary disease (COPD), or any chronic lung disease
- daytime sleepiness from a sleep disorder or if they get drowsy/sleepy without warning or take a medicine that increases sleepiness such as sleep medicines, antidepressants, or antipsychotics
- feel dizzy, nausea, sweaty, or faint when standing from sitting/lying down
- history of abnormal movement (dyskinesia)
- mental health problem such as hallucinations or psychosis
- uncontrollable urges (for example, gambling, increased sexual urges, intense urges to spend money, or binge eating)
- glaucoma
- pregnancy or plans to become pregnant. It is not known if INBRIJA will harm an unborn baby.
- breastfeeding or plans to breastfeed. Levodopa (the medicine in INBRIJA) can pass into breastmilk and it is unknown if it can harm the baby.

Patients should tell their healthcare provider if they take:

- MAO-B inhibitors
- dopamine D2 receptor antagonists (including phenothiazines, butyrophenones, risperidone, metoclopramide), or isoniazid
- iron salts or multivitamins that contain iron salts

No more than 1 dose (2 capsules) should be taken for any OFF period. No more than 5 doses (10 capsules) of INBRIJA should be taken in a day.

INBRIJA is **for oral inhalation only**. INBRIJA capsules are **not to be swallowed or opened**.

Patients are not to drive, operate machinery, or do other activities until they know how INBRIJA affects them. Sleepiness and falling asleep suddenly can happen as late as a year after treatment is started.

INBRIJA can cause serious side effects including the following. Patients should tell their healthcare provider if they experience them:

- **falling asleep during normal daily activities** (such as driving, doing physical tasks, using hazardous machinery, talking, or eating) which can be without warning. If patients become drowsy while using INBRIJA, they should not drive or do activities where they need to be alert. Chances of falling asleep during normal activities increases if patients take medicines that cause sleepiness.
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- **withdrawal-emergent hyperpyrexia and confusion** (symptoms including fever, confusion, stiff muscles, and changes in breathing and heartbeat) in patients who suddenly lower or change their dose or stop using INBRIJA or carbidopa/levodopa medicines.
- **low blood pressure** with or without dizziness, fainting, nausea, and sweating. Patients should get up slowly after sitting or lying down.
- **hallucinations and other psychosis** – INBRIJA may cause or worsen psychotic symptoms including hallucinations (seeing/hearing things that are not real); confusion, disorientation, or disorganized thinking; trouble sleeping; dreaming a lot; being overly suspicious or feeling people want to harm them; believing things that are not real, acting aggressive, and feeling agitated/restless.
- **unusual uncontrollable urges** such as gambling, binge eating, shopping, and sexual urges has occurred in some people using medicines like INBRIJA.
- **uncontrolled, sudden body movements (dyskinesia)** may be caused or worsened by INBRIJA. INBRIJA may need to be stopped or other Parkinson’s medicines may need to be changed.
- **bronchospasm** – people with asthma, COPD, or other lung diseases may wheeze or have difficulty breathing after inhaling INBRIJA. If patients have these symptoms, they should stop taking INBRIJA and call their healthcare provider or go to the nearest hospital emergency room right away.
- **increased eye pressure** in patients with glaucoma. Healthcare providers should monitor this.
- **changes in certain lab values** including liver tests

The most common side effects of INBRIJA include cough, upper respiratory tract infection, nausea, and change in the color of saliva or spit.

**Please see the accompanying Full Prescribing Information available at [www.INBRIJA.com/prescribing-information.PDF](http://www.INBRIJA.com/prescribing-information.PDF).**

#### **About Parkinson’s and OFF periods**

Parkinson’s is a progressive neurodegenerative disorder resulting from the gradual loss of certain neurons. These neurons are responsible for producing dopamine and that loss causes a range of symptoms including impaired movement, muscle stiffness and tremors. As Parkinson’s progresses, people are likely to experience OFF periods, which are characterized by the return of Parkinson’s symptoms, which can occur despite underlying baseline therapy. 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 in the U.S. experience OFF periods.

#### **About ARCUS® Technology Platform**

The ARCUS Technology Platform allows systemic delivery of medication through inhalation, by transforming molecules into a light, porous dry powder. This allows delivery of substantially higher doses of medication than can be delivered via conventional dry powder technologies. ARCUS has the potential to be used in the development of a variety of inhaled medicines. Acorda acquired the ARCUS technology platform as part of the acquisition of Civitas Therapeutics in 2014.

#### **About Acorda Therapeutics**

Acorda Therapeutics develops therapies to restore function and improve the lives of people with neurological disorders. INBRIJA™ (levodopa inhalation powder) is approved for intermittent treatment of OFF episodes in patients with Parkinson’s treated with carbidopa/levodopa. INBRIJA utilizes Acorda’s innovative ARCUS® pulmonary delivery system, a technology platform designed to deliver medication

through inhalation. Acorda also markets the branded 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: we may not be able to 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; third party payers (including governmental agencies) may not reimburse for the use of Inbrija or our other products at acceptable rates or at all and may impose restrictive prior authorization requirements that limit or block prescriptions; competition for Inbrija, Ampyra and other products we may develop and market in the future, including increasing competition and accompanying loss of revenues in the U.S. from generic versions of Ampyra (dalfampridine) following our loss of patent exclusivity; 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; 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; 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; 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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