

**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 28, 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.

Item 8.01 Other Events

On February 28, 2019, Acorda Therapeutics, Inc. issued a press release announcing that INBRIJA is now available by prescription in the United States. INBRIJA was approved by the U.S. Food and Drug Administration (FDA) on December 21, 2018 for intermittent treatment in people with Parkinson's taking carbidopa/levodopa who experience OFF episodes. 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	Press Release dated February 28, 2019

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.

February 28, 2019

By: /s/ David Lawrence
Name: David Lawrence
Title: Chief, Business Operations and Principal Accounting Officer

**MEDIA CONTACT**

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Announces Commercial Launch of INBRIJA™ (levodopa inhalation powder)

First and Only FDA-Approved Inhaled Levodopa for On-demand Use for OFF Periods in People with Parkinson's Taking Carbidopa/Levodopa

ARDSLEY, NY – February 28, 2019 – Acorda Therapeutics, Inc. (NASDAQ: ACOR) today announced that INBRIJA is now available by prescription in the United States. INBRIJA was approved by the U.S. Food and Drug Administration (FDA) on December 21, 2018 for intermittent treatment in people with Parkinson's taking carbidopa/levodopa who experience OFF episodes.

"OFF periods are extremely disruptive for those living with Parkinson's. We are excited that INBRIJA is now available to address this important unmet medical need, and that prescriptions are already being filled," said Ron Cohen, M.D., Acorda's President and CEO. "Our field sales and medical teams have been meeting with Movement Disorder specialists to educate them about INBRIJA and our Prescription Support Services center is available to help patients and physicians' offices navigate access and reimbursement."

INBRIJA will be available through a network of specialty pharmacies. Information about INBRIJA for healthcare professionals, people with Parkinson's and their care partners can be found at www.INBRIJA.com. Through this site, physicians can access the prescription request form and request a meeting with a sales professional. In addition, Acorda's Prescription Support Services center is available to address questions from physicians and patients from 8:00 a.m. ET to 8:00 p.m. ET at 1-888-887-3447.

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 adults with Parkinson's disease treated with carbidopa/levodopa. INBRIJA is not to be used by patients who take or have taken a nonselective monoamine oxidase inhibitor such as phenelzine or tranylcypromine within the last two weeks. 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.

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 a final decision from the European Commission is expected before the end of 2019.

Additional Important Safety Information

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
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- 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 (levodopa inhalation powder) 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) and 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.
- **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 .

Forward-Looking Statements

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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