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): July 26, 2019

Acorda Therapeutics, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-31938**	**13-3831168**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
420 Saw Mill River Road, Ardsley, NY		**10502**
(Address of Principal Executive Offices)		**(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 (see General Instructions A.2. below):

☐ 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock (Par Value $0.01)	ACOR	Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company 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 July 26, 2019, Acorda Therapeutics, Inc. issued a press release announcing that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion recommending INBRIJA's approval by the European Commission (EC). The recommended indication is: Inbrija is indicated for the intermittent treatment of episodic motor fluctuations (off episodes) in adult patients with Parkinson's disease (PD) treated with a levodopa/dopa-decarboxylase inhibitor. The European Commission (EC) will now consider the CHMP positive opinion in its decision of whether to grant marketing authorization for INBRIJA in Europe; the final EC decision is expected in the coming months. The review of this application is being conducted under the centralized licensing procedure, and the final decision will be applicable in all 28 member states of the European Union, as well as Iceland, Liechtenstein and Norway. 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

Exhibit No.	*Description*
99.1	Press Release dated July 26, 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.

July 26, 2019

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

EXHIBIT 99.1

MEDIA CONTACT
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Felicia Vonella
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FOR IMMEDIATE RELEASE

Acorda Receives Positive CHMP Opinion for INBRIJA™ (levodopa inhalation powder)

ARDSLEY, N.Y. – July 26, 2019 - Acorda Therapeutics, Inc. (NASDAQ: ACOR) today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion recommending INBRIJA's approval by the European Commission (EC). The recommended indication is: Inbrija is indicated for the intermittent treatment of episodic motor fluctuations (off episodes) in adult patients with Parkinson's disease (PD) treated with a levodopa/dopa-decarboxylase inhibitor. The European Commission (EC) will now consider the CHMP positive opinion in its decision of whether to grant marketing authorization for INBRIJA in Europe; the final EC decision is expected in the coming months. The review of this application is being conducted under the centralized licensing procedure, and the final decision will be applicable in all 28 member states of the European Union, as well as Iceland, Liechtenstein and Norway.

INBRIJA was approved by the U.S. Food and Drug Administration on December 21, 2018 for the intermittent treatment of OFF episodes (also known as OFF periods) in people with Parkinson's disease treated with carbidopa/levodopa.

"We are delighted that INBRIJA has achieved this important milestone, and look forward to the EC's final decision later this year. There are approximately 1.2 million people in the EU living with Parkinson's. We estimate that 40% of these individuals experience OFF periods, which are considered extremely disruptive," said Ron Cohen, M.D., Acorda's President and CEO. "Acorda is currently evaluating partnering opportunities to commercialize INBRIJA in Europe."

The positive CHMP decision is based on a clinical program for INBRIJA that included approximately 900 people with Parkinson's on a levodopa/dopa-decarboxylase inhibitor regimen experiencing OFF periods. The results of the Phase 3 pivotal efficacy trial – SPAN SM -PD – were published in *The Lancet Neurology* .

SPAN-PD was a 12-week, randomized, placebo controlled, double blind study evaluating the effectiveness of INBRIJA in patients with mild to moderate Parkinson's experiencing OFF periods.

The SPAN-PD trial met its primary endpoint, with patients showing a statistically significant improvement in motor function at the Week 12 visit, as measured by a reduction in Unified Parkinson's Disease Rating Scale (UPDRS) Part III score for INBRIJA 84 mg (n=114) compared to placebo (n=112) at 30 minutes post-dose (-9.83 points and -5.91 points respectively; p=0.009). Onset of action was seen as early as 10 minutes.

The most common adverse reactions with INBRIJA (at least 5% and greater than placebo) in this pivotal trial were cough (15% vs. 2%), upper respiratory tract infection (6% vs. 3%), nausea (5% vs. 3%) and sputum discolored (5% vs. 0%).

INBRIJA was also studied in a Phase 3 long-term, active-controlled, randomized, open-label study (N=398) assessing safety and tolerability over one year. This study showed the average reduction in FEV_1 (forced expiratory volume in 1 second) from baseline was the same (-0.1 L) for the INBRIJA and observational cohorts. Patients with chronic obstructive pulmonary disease (COPD), asthma, or other chronic respiratory disease within the last five years were excluded from this study.

About Acorda Therapeutics
Acorda Therapeutics develops therapies to restore function and improve the lives of people with neurological disorders. INBRIJA is a prescription medicine used for the return of Parkinson's symptoms (known as OFF episodes) in adults treated with carbidopa-levodopa medicines. 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 Parkinson's and OFF Periods
Parkinson's is a progressive neurodegenerative disorder resulting from the gradual loss of certain neurons in the brain. 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 INBRIJA (levodopa inhalation powder)
INBRIJA is the first and only inhaled levodopa 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 platform for inhaled therapeutics.

Additional Important Safety Information (U.S.)
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 (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 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 pharma ceuticals, 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 a nd 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 acceptab le 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 produ cts; 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 intellect ual 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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