# **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): May 20, 2016

# Acorda Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

000-50513 **Delaware** (State or other jurisdiction (Commission (I.R.S. Employer File Number) Identification No.) of incorporation)

> 420 Saw Mill River Road, Ardsley, NY

(Address of principal executive offices) (Zip Code)

13-3831168

10502

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))

#### Item 8.01 Other Events

On May 20, 2016, Acorda Therapeutics, Inc. issued a press release announcing that it will discontinue development of PLUMIAZ TM (diazepam) Nasal Spray, an investigational therapy being studied for the treatment of seizure clusters in people with epilepsy. Data from the ongoing clinical trials do not demonstrate its bioequivalence to Diastat ® rectal gel, needed to re-file the New Drug Application (NDA) under section 505(b)(2). Specifically, the data demonstrated unexpectedly lower nasal mucosa absorption of diazepam in persons with epilepsy compared to studies in healthy volunteers . 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

Exhibit No. Description

99.1 Press Release dated May 20, 2016

## **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.

May 20, 2016 By: /s/ Michael Roger

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

# EXHIBIT INDEX

Exhibit No. Description

99.1 Press Release dated May 20, 2016



#### **CONTACT:**

Jeff Macdonald Acorda Therapeutics (914) 326-5232 jmacdonald@acorda.com

FOR IMMEDIATE RELEASE

# Acorda to Discontinue Development of PLUMIAZ for Treatment of Epilepsy Seizure Clusters

ARDSLEY, N.Y. (May 20, 2016) -- Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that it will discontinue development of PLUMIAZ TM (diazepam) Nasal Spray, an investigational therapy being studied for the treatment of seizure clusters in people with epilepsy. Data from the ongoing clinical trials do not demonstrate its bioequivalence to Diastat ® rectal gel, needed to re-file the New Drug Application (NDA) under section 505(b)(2). Specifically, the data demonstrated unexpectedly lower nasal mucosa absorption of diazepam in persons with epilepsy compared to studies in healthy volunteers.

"We are very disappointed by this outcome, and for those in the epilepsy community who experience seizure clusters. I want to thank the many clinicians, caregivers, people with epilepsy and their families involved with the PLUMIAZ clinical studies for their efforts to advance care for people with seizure clusters," said Ron Cohen, M.D., Acorda's President and CEO. "We will continue to focus on development of our other high potential pipeline programs, including CVT-301 and tozadenant for Parkinson's disease, and dalfampridine for post-stroke walking difficulty."

Acorda is in communication with study investigators to discontinue all ongoing clinical trials and assist in the transition of study participants. The Company will present the data at a future medical meeting.

### **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, post-stroke walking difficulty, 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.

## **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: the ability to complete the Biotie transaction on a timely basis or at all; 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 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 (diazepam) Nasal Spray, 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, any other products under development, or the products that we would acquire if 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 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 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 release.

###