ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 05/02/14 for the Period Ending 05/02/14

Address	420 SAW MILL RIVER ROAD ARDSLEY, NY 10502
Telephone	914-347-4300
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Industry	Biotechnology & Drugs
Sector	Healthcare
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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 2, 2014**

Acorda Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**000-50513**	**13-3831168**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. 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:

☐ 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 2, 2014, Acorda Therapeutics, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) for the New Drug Application (NDA) for PLUMIAZ ™ (diazepam) Nasal Spray for the treatment of people with epilepsy who experience cluster seizures. A CRL is a communication from the FDA that informs a company that their review of the NDA is complete and the application cannot be approved in its present form. The Company is currently developing a response to address the items outlined in the letter. 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 2, 2014

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 2, 2014

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

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated May 2, 2014

EXHIBIT 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

FDA Issues Complete Response Letter for PLUMIAZ™, Investigational Medicine for Epilepsy Cluster Seizures

- Acorda Therapeutics Committed to Working with FDA

ARDSLEY, N.Y. – May 2, 2014 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) for the New Drug Application (NDA) for PLUMIAZ ™ (diazepam) Nasal Spray for the treatment of people with epilepsy who experience cluster seizures.

A CRL is a communication from the FDA that informs a company that their review of the NDA is complete and the application cannot be approved in its present form. The Company is currently developing a response to address the items outlined in the letter.

“There is an urgent need for new treatments for people with epilepsy who experience cluster seizures. We are committed to the development and commercialization of PLUMIAZ, a potential therapeutic option for these individuals,” said Ron Cohen, M.D., Acorda’s President and CEO. “We are evaluating the Complete Response Letter and expect to work closely with the FDA to address the items outlined in the letter and refile the NDA for PLUMIAZ. We expect to provide further detail as our discussions with the FDA progress.”

Based on the requirements for approval outlined in the letter, the Company does not expect PLUMIAZ to receive FDA approval in 2014.

Of the approximately 2.8 million people in the United States with epilepsy, it is estimated that about 175,000 experience cluster seizures, also known as acute repetitive seizures or bouts of increased seizure activity. These patients may experience cluster seizures even though they generally are on stable regimens of antiepileptic medications (AEDs). Currently, many of these individuals do not find the currently available outpatient therapy acceptable and default to emergency room care or no care at all. PLUMIAZ potentially offers a more viable treatment option. PLUMIAZ has received orphan drug designation for the treatment of cluster seizures.

About Epilepsy
Epilepsy is a neurological condition that produces seizures affecting a variety of mental and physical functions. Seizures are symptoms of abnormal brain activity, and occur when a brief, strong surge of electrical activity affects part or all of the brain **.**

About Acorda Therapeutics
Founded in 1995, Acorda Therapeutics is a biotechnology company focused on developing therapies that improve the lives of people with neurological disorders.

Acorda markets three FDA-approved therapies including: AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg, a treatment to improve walking in patients with multiple sclerosis (MS); ZANAFLEX CAPSULES ® (tizanidine hydrochloride) and Zanaflex tablets, a short-acting drug for the management of spasticity; and QUTENZA ® (capsaicin) 8% Patch, for the management of neuropathic pain associated with postherpetic neuralgia. AMPYRA is marketed outside the United States as FAMPYRA ® (prolonged-release fampridine tablets) by Biogen Idec under a licensing agreement from Acorda.

Acorda has one of the leading pipelines in the industry of novel neurological therapies. The Company is currently developing six clinical-stage therapies and one preclinical stage therapy that address a range of disorders including post-stroke deficits, epilepsy, stroke, peripheral nerve damage, spinal cord injury, neuropathic pain, and heart failure. For more information, please visit the Company's website at: www. acorda .com .

Forward-Looking Statements
This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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 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 Plumiaz (our trade name for 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 Diazepam Nasal Spray or other products under development; the occurrence of adverse safety events with our products; delays in obtaining or failure to obtain regulatory approval of or to successfully market Fampyra outside of the U.S. and our dependence on our collaboration partner Biogen Idec in connection therewith; competition, including the impact of generic competition on Zanaflex Capsules revenues; 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; failure to comply with regulatory requirements could result in adverse action by regulatory agencies; and the ability to obtain additional financing to support our operations. These and other risks are described in greater detail in Acorda Therapeutics' filings with the Securities & Exchange Commission. Acorda may not actually achieve the goals or plans described in its 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 Acorda disclaims any intent or

obligation to update any forward-looking statements as a result of developments occurring after the date of this release.

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