ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 06/26/13 for the Period Ending 06/26/13

Address	420 SAW MILL RIVER ROAD ARDSLEY, NY 10502
Telephone	914-347-4300
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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): **June 26, 2013**

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 June 26, 2013, Acorda Therapeutics, Inc. issued a press release announcing results of the first clinical study to assess pharmacokinetics, safety and tolerability of Diazepam Nasal Spray in people with epilepsy. Study findings were presented on June 25 at the biennial International Congress of the International League Against Epilepsy (ILAE) and International Bureau for Epilepsy (IBE), being held in Montreal, Canada. Diazepam Nasal Spray is being developed for the treatment of people with epilepsy who experience cluster seizures, also known as acute repetitive seizures. 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 June 26, 2013

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.

June 26, 2013

By: /s/David Lawrence
Name: David Lawrence
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated June 26, 2013

EXHIBIT 99.1

CONTACT:

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

FOR IMMEDIATE RELEASE

First Study of Diazepam Nasal Spray in People with Epilepsy Shows Feasibility of Dosing During Seizure

Study presented at the 30 th International Epilepsy Congress also showed pharmacokinetic and safety profile consistent with previous studies in healthy volunteers

ARDSLEY, N.Y. June 26, 2013 -- Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced results of the first clinical study to assess pharmacokinetics, safety and tolerability of Diazepam Nasal Spray in people with epilepsy. Study findings were presented on June 25 at the biennial International Congress of the International League Against Epilepsy (ILAE) and International Bureau for Epilepsy (IBE), being held in Montreal, Canada. Diazepam Nasal Spray is being developed for the treatment of people with epilepsy who experience cluster seizures, also known as acute repetitive seizures.

“The study results showed that the Diazepam Nasal Spray pharmacokinetics are comparable whether it is administered during or immediately following a seizure. For people with epilepsy who experience cluster seizures, it is critical that treatment be administered as soon as a cluster is recognized, to prevent additional seizure activity,” said Enrique Carrazana, M.D., Acorda’s Chief Medical Officer. “Diazepam Nasal Spray offers a therapeutic alternative that can be administered rapidly and conveniently.”

The study was an open-label, multi-center clinical trial, comprising 31 people with epilepsy who were admitted to epilepsy monitoring units. Each received a single dose of diazepam, administered as one spray in each nostril, during or immediately following a seizure. Blood levels of diazepam were measured serially for a period of up to 12 hours following the dose.

Results showed that diazepam was well absorbed from the nasal cavity of people with epilepsy, had a similar pharmacokinetic profile regardless of when administered relative to the seizure episode and was well tolerated. The most common adverse events were related to the nasal route of delivery; most adverse events were mild and transient, and resolved within a day. Most common among these were an altered sense of taste and nasal discomfort, experienced by 26% and 23% of study subjects respectively. The

overall safety and tolerability of Diazepam Nasal Spray in this study was consistent with the established safety profile of diazepam products.

Acorda also presented the results of a separate study showing that Diazepam Nasal Spray and an equivalent dose of the rectal gel formulation of diazepam had comparable bioavailability in healthy volunteers. These data were previously presented at the 65 th American Academy of Neurology Annual Meeting in March, 2013.

Acorda plans to submit a 505(b)(2)-type New Drug Application (NDA) for Diazepam Nasal Spray to the U.S. Food and Drug Administration (FDA) in 2013 and rely upon FDA's previous findings of safety and efficacy for diazepam rectal gel.

About Epilepsy and Cluster Seizures/Acute Repetitive Seizures
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.

The Centers for Disease Control and Prevention (CDC) estimates that approximately 2.3 million adult Americans have active epilepsy. Cluster seizures, also known as acute repetitive seizures, are characterized by recognizable, recurring episodes of seizure clusters. In the U.S., there are up to 175,000 people with epilepsy who experience cluster seizures despite being on stable regimens of antiepileptic drugs (AEDs).

About Acorda Therapeutics
Acorda Therapeutics is a biotechnology company focused on developing therapies that restore function and improve the lives of people with MS, spinal cord injury and other neurological conditions.

Acorda markets AMPYRA (R) (dalfampridine) Extended Release Tablets, 10 mg, in the United States as a treatment to improve walking in patients with multiple sclerosis (MS). This was demonstrated by an improvement in walking speed. AMPYRA is marketed outside the United States as FAMPYRA (R) (prolonged-release fampridine tablets) by Biogen Idec under a licensing agreement from Acorda. AMPYRA and FAMPYRA are manufactured under license from Alkermes Pharma Ireland Limited.

The Company also markets ZANAFLEX CAPSULES (R) (tizanidine hydrochloride) and Zanaflex tablets, a short-acting drug for the management of spasticity. Acorda also receives sales royalties on tizanidine hydrochloride capsules, an authorized generic version of ZANAFLEX CAPSULES, distributed by Actavis, Inc. under its agreement with Acorda.

Acorda has one of the leading pipelines in the industry of novel neurological therapies. The Company is developing Diazepam Nasal Spray for treatment of certain epileptic seizures. It is also studying AMPYRA to improve a range of functional impairments caused by MS, as well as its potential for use in other neurological conditions, including cerebral palsy and post-stroke deficits. In addition, Acorda is developing clinical stage compounds AC105 for acute treatment of spinal cord injury, GGF2 for treatment of heart

failure and rHIgM22, a remyelinating monoclonal antibody, for the treatment of MS. GGF2 is also being investigated in preclinical studies as a treatment for neurological conditions such as stroke and peripheral nerve damage. Chondroitinase, an enzyme that encourages nerve plasticity in spinal cord injury, is in preclinical development.

Acorda 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 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 develop ments occurring after the date of this release.

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