ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 12/09/13 for the Period Ending 12/09/13

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): **December 9, 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 December 9, 2013, Acorda Therapeutics, Inc. issued a press release announcing that new data from a pharmacokinetics study on Diazepam Nasal Spray found comparable pharmacokinetics (PK) whether the drug was administered during or immediately after a seizure. These data were presented at the 67th Annual Meeting of the American Epilepsy Society, in Washington, D.C. 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 December 9, 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.

December 9, 2013

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

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated December 9, 2013

EXHIBIT 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Presents New Data on Diazepam Nasal Spray at 67 th Annual Meeting of American Epilepsy Society

Study found Diazepam Nasal Spray maintained consistent pharmacokinetic profile when administered during or immediately after seizure

ARDSLEY, N.Y.—Dec 9, 2013-- Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that new data from a pharmacokinetics study on Diazepam Nasal Spray found comparable pharmacokinetics (PK) whether the drug was administered during or immediately after a seizure. These data were presented at the 67 th Annual Meeting of the American Epilepsy Society, in Washington, D.C. Diazepam Nasal Spray is being developed for the treatment of people with epilepsy who experience cluster seizures, also known as acute repetitive seizures.

“In this study, some patients received a dose of Diazepam Nasal Spray while having a seizure, while others received the dose after their seizure activity had ceased,” said Adrian Rabinowicz, M.D., FAAN, Acorda's Senior Vice President of Clinical Development and Medical Affairs. “The results suggest that delivery of Diazepam Nasal Spray was unaffected by the timing of dosage relative to seizure activity. It is critical for a person with epilepsy who experiences cluster seizures that treatment be administered as soon as possible after a cluster is recognized, in order to prevent additional seizure activity.”

This multicenter, open-label study was conducted in adults admitted to an epilepsy monitoring unit for evaluation and management of epilepsy. Of the 30 patients who completed the study, 10 were dosed during a seizure, while the other 20 patients were dosed after their seizure activity had ceased. Plasma concentrations of diazepam were measured for a period of up to 12 hours following the dose.

The overall safety and tolerability of Diazepam Nasal Spray in this study was consistent with systemic diazepam exposure established with other diazepam products. The most common local adverse events were related to the nasal route of delivery; most adverse events were mild and transient, and resolved within a day. These local events were an altered sense of taste and nasal discomfort, experienced by 26% and 23% of study subjects respectively.

Other data from this study were previously presented at the 30 th biennial International Congress of the International League Against Epilepsy and International Bureau for Epilepsy.

Acorda has submitted a New Drug Application for Diazepam Nasal Spray to the U.S. Food and Drug Administration (FDA) and will rely upon the 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.

Of the approximately 2.75 million people in the United States with epilepsy, it is estimated that about 175,000 experience cluster seizures. Cluster seizures, also known as acute repetitive seizures, are characterized by recognizable, recurring episodes of seizure clusters.

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 conditions.

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 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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