ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 10/15/13 for the Period Ending 10/14/13

Address	420 SAW MILL RIVER ROAD ARDSLEY, NY 10502
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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): **October 14, 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 October 14, 2013, Acorda Therapeutics, Inc. (the "Company") issued a press release announcing data from a Phase 2 proof-of-concept study of dalfampridine extended release tablets, 10 mg (dalfampridine-ER) in people with post-stroke deficits. In the study, treatment with dalfampridine-ER was well-tolerated and improved walking, as measured by the Timed 25-Foot Walk test (T25FW). The data was presented at the American Neurological Association 2013 Annual Meeting, being held in New Orleans. Top-line data from this study were disclosed by the Company in April 2013. 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 October 14, 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.

October 15, 2013

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

EXHIBIT INDEX

Exhibit No .	*Description*
99.1	Press Release dated October 14, 2013

EXHIBIT 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Therapeutics Presents Positive Dalfampridine-ER Data in Post-Stroke Deficits at American Neurological Association 2013 Annual Meeting

ARDSLEY, N.Y. – October 14, 2013 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced data from a Phase 2 proof-of-concept study of dalfampridine extended release tablets, 10 mg (dalfampridine-ER) in people with post-stroke deficits. In the study, treatment with dalfampridine-ER was well-tolerated and improved walking, as measured by the Timed 25-Foot Walk test (T25FW). The data were presented at the American Neurological Association 2013 Annual Meeting, being held in New Orleans. Top-line data from this study were disclosed by the Company in April 2013.

Post-stroke deficits refer to chronic neurological deficits, such as impaired walking, motor and/or sensory function that persist in people who have had a stroke. There are currently no pharmacologic therapies indicated to improve function in people with post-stroke deficits.

“In this proof-of-concept clinical trial of dalfampridine-ER in post-stroke deficits, we were encouraged to see a clear signal for improved walking in this population, consistent with the preclinical data. More than half of the seven million stroke survivors in the United States have walking impairment, but there are no approved medications to address this problem,” said Enrique Carrazana, M.D., Acorda’s Chief Medical Officer. “Based on the strength of the data, we are planning a larger clinical trial to further assess dalfampridine’s safety and tolerability, and potential effect on walking impairment in people with post-stroke deficits.”

The primary goals of the proof-of-concept study were to assess safety and tolerability, as well as to explore various efficacy measures. This study included 83 participants who had experienced an ischemic stroke at least six months prior to treatment and had chronic motor deficits. The average in the study was 10.4 years post-stroke, and the range was up to 35 years. As part of the crossover design, participants received either dalfampridine-ER or placebo twice daily for 14 days (Period 1), followed by a one week wash-out period in which all participants received placebo. This was followed by a second 14-day treatment period (Period 2) during which participants received the alternate treatment.

Key Safety Findings from Post-Stroke Deficits Trial
The safety findings in this study were consistent with previous clinical trials and post-marketing experience of dalfampridine-ER in multiple sclerosis (MS). The overall rate of treatment-

emergent adverse events was 54.5% and 37.0% for dalfampridine-ER and placebo, respectively. The most common adverse events reported in the study were dizziness (10.4% dalfampridine-ER, 2.5% placebo), nausea (3.9% dalfampridine-ER, 6.2% placebo), fatigue (5.2% dalfampridine-ER, 3.7% placebo), insomnia (5.2% dalfampridine-ER, 2.5% placebo) and arthralgia (2.6% dalfampridine-ER, 3.7% placebo).

Three participants experienced a seizure during the study. One occurred while the participant was taking placebo (without prior exposure to dalfampridine-ER), one occurred while the participant was taking dalfampridine-ER, and one occurred due to an intentional overdose of dalfampridine-ER. The overdose was judged by the study investigator to be a suicide attempt related to a recent family tragedy. All three participants recovered fully.

Key Efficacy Findings from Post-Stroke Deficits Trial
The primary focus of the exploratory efficacy analyses was walking, as measured by the Timed 25-Foot Walk (T25FW). In the full crossover analysis, which included all T25FW data from both treatment periods, there was a significant increase in walking speed while participants were taking dalfampridine-ER compared to placebo ($p = 0.027$).

This treatment effect was further supported by separate analyses of the two treatment periods. In both treatment periods there was a greater average improvement in walking speed among participants receiving dalfampridine-ER. These were not statistically significant given the smaller number of measurements in each period compared to the overall analysis.

The walking data were further analyzed using a threshold response analysis, in which the percent of participants achieving sequential levels of improvement over baseline (greater than or equal to 0%, 10%, 20%, 30%, 40%, 50%) was assessed. A higher percentage of patients in both periods improved at all threshold levels while on dalfampridine-ER compared to placebo.

The Company plans to begin a Phase 2b/3 study, pending successful conclusion of a multi-dose, pharmacokinetic study of a once-a-day formulation of dalfampridine-ER, as well as discussions with the U.S. Food and Drug Administration.

The results from other efficacy endpoints in the study will be presented in future scientific communications.

Dalfampridine Important Safety Information
Dalfampridine is the active ingredient in AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg, a treatment to improve walking in patients with multiple sclerosis (MS). Dalfampridine extended release tablets have not been evaluated by FDA for the treatment of post stroke deficits.

Do not take dalfampridine if you have ever had a seizure, or have certain types of kidney problems, or are allergic to dalfampridine (4-aminopyridine).

Take dalfampridine exactly as prescribed by your doctor.

You could have a seizure even if you never had a seizure before. Your chance of having a seizure is higher if you take too much dalfampridine or if your kidneys have a mild decrease of function, which is common after age 50.

Your doctor may do a blood test to check how well your kidneys are working, if that is not known before you start taking dalfampridine.

Dalfampridine may cause serious allergic reactions. Stop taking dalfampridine and call your doctor right away or get emergency medical help if you have shortness of breath or trouble breathing, swelling of your throat or tongue, or hives.

Dalfampridine should not be taken with other forms of 4-aminopyridine (4-AP, fampridine), since the active ingredient is the same.

The most common adverse events for dalfampridine in MS patients were urinary tract infection, trouble sleeping, dizziness, headache, nausea, weakness, back pain, and problems with balance.

Before taking dalfampridine tell your doctor if you are pregnant or plan to become pregnant. It is not known if dalfampridine will harm your unborn baby.

Tell your doctor if you are breast-feeding or plan to breast-feed. It is not known if dalfampridine passes into your breast milk. You and your doctor should decide if you will take dalfampridine or breast-feed. You should not do both.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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, cerebral palsy, 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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