ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 12/15/14 for the Period Ending 12/15/14

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 15, 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 December 15, 2014, Acorda Therapeutics, Inc. issued a press release announcing that the first patient has been enrolled in a Phase 3 clinical trial of dalfampridine for the treatment of post-stroke walking deficits (PSWD). 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 15, 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.

December 15, 2014

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

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated December 15, 2014

CONTACT:

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FOR IMMEDIATE RELEASE

Acorda Announces Initiation of Phase 3 Clinical Trial for Dalfampridine in Post-Stroke Walking Deficits

Ardsley, N.Y. – December 15, 2014 -- Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that the first patient has been enrolled in a Phase 3 clinical trial of dalfampridine for the treatment of post-stroke walking deficits (PSWD).

“Approximately three and a half million stroke survivors in the U.S. suffer ongoing mobility issues. This is a significant unmet medical need, as there are no approved medicines to improve walking in people with PSWD,” said Ron Cohen, M.D., Acorda Therapeutics' President and CEO. “Our Phase 2 trial of dalfampridine in PSWD produced promising data, showing significant improvements in walking speed. This larger Phase 3 trial will enroll a similar patient population, and include a number of assessments to evaluate the effect of dalfampridine in improving their walking.”

This multi-center, double-blind, randomized trial is expected to enroll approximately 540 participants who have experienced an ischemic stroke at least six months prior to enrollment. Participants will receive 10 mg dalfampridine, 7.5 mg dalfampridine, or placebo twice daily for 12 weeks. The primary endpoint of the study is the percentage of patients taking dalfampridine who demonstrate at least a 20% improvement in the 2 Minute Walk Test (2MinWT) compared to those receiving placebo. The 2MinWT measures the distance a person can walk in 2 minutes . Other measures will include the Timed Up and Go, which assesses mobility and balance, as well as clinician and patient-reported measures. The study also includes evaluation of safety and tolerability.

More details about the study, including enrollment criteria and contact information for study sites, can be found at: http://clinicaltrials.gov/ct2/show/NCT02271217 and www.acorda.com .

Phase 2 Study Results
In April 2013, the Company announced results from a Phase 2 study which showed participants had a significantly greater improvement in walking speed when receiving dalfampridine over two weeks of treatment than when receiving placebo, as measured by the Timed 25-Foot Walk test (T25FW). Safety findings for the study were consistent with previous clinical trials and post-marketing experience of dalfampridine in people with multiple sclerosis.

About Stroke
About 800,000 new cases of stroke occur annually in the U.S. Approximately 3.5 million stroke survivors in U.S. have ongoing mobility issues, and there are no currently approved medications for such impairments.

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

The FDA-approved form of dalfampridine (AMPYRA) is contraindicated in patients with a history of seizures, or with moderate or severe renal impairment, or history of hypersensitivity to dalfampridine or 4-aminopyridine.

Dalfampridine can cause seizures. The risk of seizures increases with increasing dalfampridine doses. Discontinue dalfampridine and do not restart if seizure occurs.
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.

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 markets three FDA-approved therapies, including AMPYRA® (dalfampridine) Extended Release Tablets, 10 mg, a treatment to improve walking in patients with multiple sclerosis (MS), as demonstrated by an increase in walking speed. The Company has one of the leading pipelines in the industry of novel neurological therapies. Acorda is currently developing a number of clinical and preclinical stage therapies. This pipeline addresses a range of disorders including post-stroke walking deficits, Parkinson’s disease, epilepsy, neuropathic pain, heart failure, MS, and spinal cord injury.

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 the ability to realize the benefits anticipated from the Civitas transaction and to successfully integrate Civitas' operations into our operations; 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, 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, or any other products under development; we may need to raise additional funds to finance our expanded operations and may not be able to do so on acceptable terms; 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; 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 Acorda Therapeutics' filings with the Securities and 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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