

ACORDA THERAPEUTICS INC

FORM 8-K (Current report filing)

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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): **May 9, 2013**

Acorda Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

000-50513
(Commission
File Number)

13-3831168
(I.R.S. Employer
Identification No.)

**420 Saw Mill River Road,
Ardsley, NY**
(Address of principal executive offices)

10502
(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))
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Item 8.01**Other Events**

On May 9, 2013, Acorda Therapeutics, Inc. issued a press release announcing that data showing treatment with dalfampridine improved motor function in a preclinical model of post-stroke deficits have been published online ahead of print on May 7th in *Stroke*, a peer-reviewed journal of the American Heart Association. The data will be included in the July 2013 print edition of *Stroke*. Dalfampridine is the active ingredient in AMPYRA[®] (dalfampridine) Extended Release Tablets, 10 mg. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated May 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.

May 9, 2013

By: /s/David Lawrence

Name: David Lawrence

Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.

Description

99.1

Press Release dated May 9, 2013

**CONTACT:**

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

FOR IMMEDIATE RELEASE

Acorda Therapeutics Announces Data Showing Dalfampridine Improves Motor Function in Preclinical Model of Post-Stroke Deficits Published in *Stroke*

- Preclinical findings supported initiation of current dalfampridine clinical development program in post-stroke deficits

ARDSLEY, NY – May 9, 2013 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) today announced that data showing treatment with dalfampridine improved motor function in a preclinical model of post-stroke deficits have been published online ahead of print on May 7th in *Stroke*, a peer-reviewed journal of the American Heart Association. The data will be included in the July 2013 print edition of *Stroke*. Dalfampridine is the active ingredient in AMPYRA[®] (dalfampridine) Extended Release Tablets, 10 mg.

“These preclinical data showed that dalfampridine can improve motor function long after a stroke, when the natural recovery process has ended and stable deficits are likely to persist over time. The results informed our decision to conduct a recently completed proof-of-concept study in humans, which indicated that dalfampridine improved walking in people with post-stroke deficits,” said Andrew R. Blight, Ph.D., Acorda Therapeutics’ Chief Scientific Officer. “More than half of the nearly seven million people in the United States who live with the long term effects of a stroke have lasting mobility impairment, but there are no established treatments other than physical therapy to address these impairments. New therapies are needed, and we are moving forward with development of dalfampridine extended release tablets in this indication.”

The paper, entitled “Dalfampridine Improves Sensorimotor Function in Rats with Chronic Deficits after Middle Cerebral Artery Occlusion,” reported data from two studies that initiated treatment four or eight weeks after a permanent middle cerebral artery occlusion (pMCAO). Like the human condition, a certain amount of recovery occurs during the first several weeks after pMCAO, and there is little or no improvement in function after 4 weeks. This represents a chronic stage of stroke. In one study at 4 weeks post pMCAO, animals received high, low and vehicle doses of dalfampridine, in different

orders with a 10 day washout period between each treatment phase. In a second study, animals were treated at 8 weeks after pMCAO with ascending doses of dalfampridine.

Researchers assessed functional improvement using standard motor function tests in both the forelimbs and hind limbs. In each study, treatment with dalfampridine resulted in significant improvement in function compared to vehicle across all measures during the respective treatment periods. Improvements in the high dose phase were consistently better than those seen in the low dose phase.

Data included in the *Stroke* paper were first presented at the 2012 American Heart Association/American Stroke Association International Stroke Conference, held in New Orleans, Louisiana. This research was conducted in collaboration with Biotrofix, a preclinical research organization.

In April 2013, Acorda completed an 83-participant proof-of-concept clinical trial that showed evidence of improved walking in people with post-stroke deficits treated with dalfampridine-ER tablets. Other exploratory efficacy measures in the study are currently being analyzed. The safety findings in this study were consistent with previous clinical trials and post-marketing experience of AMPYRA in multiple sclerosis (MS). Post-stroke deficits refer to chronic neurological deficits, such as impaired walking, motor and sensory function, and dexterity that persist in people following a stroke.

Based on the findings of this proof-of-concept study, the Company is proceeding with a clinical development program for this indication

AMPYRA is approved 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 known as prolonged-, modified-, or sustained-release fampridine (FAMPYRA^(R)) in some countries outside the United States.

Important New Safety Information

Do not take AMPYRA if you are allergic to dalfampridine (4-aminopyridine), the active ingredient in AMPYRA.

Important Safety Information

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

Take AMPYRA 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 AMPYRA 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 AMPYRA.

AMPYRA may cause serious allergic reactions, including rare occurrence of anaphylaxis. Stop taking Ampyra 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.

AMPYRA 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 AMPYRA in MS patients were urinary tract infection, trouble sleeping, dizziness, headache, nausea, weakness, back pain, and problems with balance.

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

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

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[®] (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[®] (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[®] (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 rHlgM22, 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 developments occurring after the date of this release.

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