

ACORDA THERAPEUTICS INC

FORM 8-K (Current report filing)

Filed 03/13/13 for the Period Ending 03/13/13

Address	420 SAW MILL RIVER ROAD ARDSLEY, NY 10502
Telephone	914-347-4300
CIK	0001008848
Symbol	ACOR
SIC Code	2836 - Biological Products, Except Diagnostic Substances
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

**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): **March 13, 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 March 13, 2013, Acorda Therapeutics, Inc. issued a press release announcing that it will present new research data at the 65th American Academy of Neurology Annual Meeting on AMPYRA[®] (dalfampridine) Extended Release Tablets, 10 mg, an FDA-approved therapy indicated to improve walking in people with multiple sclerosis, and Diazepam Nasal Spray, an investigational therapy for the treatment of cluster seizures, also known as acute repetitive seizures, in people with epilepsy. 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 March 13, 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.

March 13, 2013

By: Jane Wasman

Name: Jane Wasman

*Title: President, International, General Counsel and
Corporate Secretary*

EXHIBIT INDEX

Exhibit No.

Description

99.1

Press Release dated March 13, 2013

**CONTACT:**

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Acorda Therapeutics
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jmacdonald@acorda.com

FOR IMMEDIATE RELEASE

Acorda to Present New Research on Novel Multiple Sclerosis and Epilepsy Therapies at American Academy of Neurology 65th Annual Meeting

ARDSLEY, N.Y. – March 13, 2013 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) will present new research data at the 65th American Academy of Neurology Annual Meeting on AMPYRA[®] (dalfampridine) Extended Release Tablets, 10 mg, an FDA-approved therapy indicated to improve walking in people with multiple sclerosis, and Diazepam Nasal Spray, an investigational therapy for the treatment of cluster seizures, also known as acute repetitive seizures, in people with epilepsy.

“Acorda is focused on improving the lives of people with neurological disorders. We currently are developing seven therapies for a range of conditions, including multiple sclerosis, epilepsy and spinal cord injury,” said Ron Cohen, M.D., Acorda Therapeutics’ President and CEO. “Our presentations at AAN include new studies on AMPYRA and the first clinical data presented on Diazepam Nasal Spray. These studies have increased our understanding of the potential roles these therapies could have in addressing the urgent needs of patients with these conditions.”

Data being presented on Acorda-developed therapies at the AAN annual meeting include:

- Changes in Gait, Walking, and Balance Parameters After Withdrawal and Re-initiation of Dalfampridine Extended Release Tablets in Patients with Multiple Sclerosis: Results from the STEADY Study – P04.103 being presented Wednesday, March 20th, 7:30am – 12:00pm
- Safety and Efficacy of 5mg and 10mg Dalfampridine Extended Release Tablets in Patients with Multiple Sclerosis: First Results from a Double-Blind, Placebo-Controlled Trial – P04.096 being presented Wednesday, March 20th, 7:30am – 12:00pm
- Effects of 5mg and 10mg Dalfampridine Extended Release Tablets on 6-Minute Walk Distance in People with Multiple Sclerosis: A Subgroup Analysis of a Double-Blind, Placebo-Controlled Trial – S01.007 being presented Tuesday, March 19th at 2:30pm
- Assessment of Pharmacokinetic Linearity and Relative Bioavailability of a Nasal Diazepam Formulation Compared with Diazepam Rectal Gel In Healthy Adult Subjects – P02.214 being presented Tuesday, March 19th, 7:30am – 12:00pm

More detailed information on scientific sessions and data presentations at the AAN annual meeting can be found on the conference website (<http://www.aan.com/go/am13>).

Important Safety Information

Do not take AMPYRA if you have ever had a seizure or have certain types of kidney problems.

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.

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 AMPYRA (dalfampridine)

AMPYRA is a potassium channel blocker approved as a treatment to improve walking in patients with multiple sclerosis (MS). This was demonstrated by an increase in walking speed. AMPYRA, which was previously referred to as Fampridine-SR, is an extended release tablet formulation of dalfampridine (4-aminopyridine, 4-AP), and is known as prolonged-, modified, or sustained-release fampridine (FAMPYRA[®]) in some countries outside the United States (U.S.).

In laboratory studies, dalfampridine extended release tablets has been found to improve impulse conduction in nerve fibers in which the insulating layer, called myelin, has been damaged.

AMPYRA is being developed and commercialized in the U.S. by Acorda Therapeutics; FAMPYRA is being developed and commercialized by Biogen Idec in markets outside the U.S. based on a licensing agreement with Acorda. AMPYRA and FAMPYRA are manufactured globally by Alkermes Pharma Ireland Limited, a subsidiary of Alkermes plc, based on a supply agreement with Acorda.

AMPYRA is available by prescription in the United States. For more information about AMPYRA, including patient assistance and co-pay programs, healthcare professionals and people with MS can contact AMPYRA Patient Support Services at 888-881-1918.

AMPYRA Patient Support Services is available Monday through Friday, from 8:00 a.m. to 8:00 p.m. Eastern Time. For full U.S. Prescribing Information and Medication Guide, please visit: www.AMPYRA.com.

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 an industry-leading pipeline 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 spinal cord injury. 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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