ACORDA THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 05/31/12 for the Period Ending 05/31/12

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 31, 2012**

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.)

15 Skyline Drive, Hawthorne, NY	**10532**
(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 May 31, 2012, Acorda Therapeutics, Inc. ("Acorda") issued a press release announcing that it will present research at the 4 th Collaborative Meeting of the Consortium of Multiple Sclerosis Centers (CMSC) and Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) that examines the impact of walking impairment on different aspects of the lives of people with multiple sclerosis (MS), as well as the use of AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg in the United States. The six company-sponsored posters will be presented on Friday, June 1 at the CMSC/ACTRIMS meeting, being held in San Diego, CA. Acorda-sponsored research being presented at the CMSC/ACTRIMS meetings includes:

- Sustained-Release Fampridine and Mobility in Multiple Sclerosis: Beyond the Timed 25-Foot Walk Test: A Case Series – Poster SX04
- Walking Speed and Health-Related Quality of Life in Multiple Sclerosis – Poster SX06
- Clinical Importance of Accelerometer Output in Multiple Sclerosis – Poster DX 67
- Demographic Assessment of Dalfampridine Extended Release Tablets Usage – Poster SX16
- Patient or Caregiver Knowledge of Dalfampridine Safety and Use Information – Poster SX17
- Prescriber Utilization Study of Dalfampridine Extended Release Tablets – Poster SX18

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 May 31, 2012

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 31, 2012

By: /s/ David Lawrence
Name: David Lawrence
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	*Description*
99.1	Press Release dated May 31, 2012

EXHIBIT 99.1

CONTACT:

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FOR IMMEDIATE RELEASE

New Research Presented at 4 th Collaborative Meeting of CMSC and ACTRIMS Expands Understanding of MS-Related Walking Impairment and Clinical Usage of AMPYRA ®

HAWTHORNE, N.Y. – May 31, 2012 – Acorda Therapeutics, Inc. (Nasdaq: ACOR) will present research at the 4 th Collaborative Meeting of the Consortium of Multiple Sclerosis Centers (CMSC) and Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) that examines the impact of walking impairment on different aspects of the lives of people with multiple sclerosis (MS), as well as the use of AMPYRA ® (dalfampridine) Extended Release Tablets, 10 mg in the United States. The six company-sponsored posters will be presented on Friday, June 1 at the CMSC/ACTRIMS meeting, being held in San Diego, CA.

“AMPYRA is the only FDA-approved therapy to improve walking in people with MS. Although walking is one of our most critical functional capabilities, and is impaired in more than half of all MS patients, there has been limited research on the pharmacologic treatment of walking impairment in MS. In part this was due to the lack of treatment options prior to AMPYRA’s availability in 2010,” said Ron Cohen, M.D., Acorda Therapeutics’ President and CEO. “By supporting research that explores ways to better characterize walking impairment and more precisely quantify its impact in real-world settings, we can gain a better understanding of how improved walking may benefit people with MS.”

Acorda-sponsored research being presented at the CMSC/ACTRIMS meetings includes:

- Sustained-Release Fampridine and Mobility in Multiple Sclerosis: Beyond the Timed 25-Foot Walk Test: A Case Series – Poster SX04
- Walking Speed and Health-Related Quality of Life in Multiple Sclerosis – Poster SX06
- Clinical Importance of Accelerometer Output in Multiple Sclerosis – Poster DX 67
- Demographic Assessment of Dalfampridine Extended Release Tablets Usage – Poster SX16
- Patient or Caregiver Knowledge of Dalfampridine Safety and Use Information – Poster SX17
- Prescriber Utilization Study of Dalfampridine Extended Release Tablets – Poster SX18

More detailed information on scientific sessions and data presentations at the CMSC/ACTRIMS meeting can be found on the conference website (http://www.cmsc-actrims.org/).

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

Important Safety Information
AMPYRA can cause seizures; the risk of seizures increases with increasing AMPYRA doses. AMPYRA is contraindicated in patients with a prior history of seizure. Discontinue AMPYRA use if seizure occurs.

AMPYRA is contraindicated in patients with moderate or severe renal impairment (CrCl less-than or equal to 50 mL/min); the risk of seizures in patients with mild renal impairment (CrCl 51-80 mL/min) is unknown, but AMPYRA plasma levels in these patients may approach those seen at a dose of 15 mg twice daily, a dose that may be associated with an increased risk of seizures; estimated CrCl should be known before initiating treatment with AMPYRA.

AMPYRA should not be taken with other forms of 4-aminopyridine (4-AP, fampridine), since the active ingredient is the same. Urinary tract infections were reported more frequently as adverse reactions in patients receiving AMPYRA 10 mg twice daily compared to placebo.

The most common adverse events (incidence greater-than or equal to 2% and at a rate greater than the placebo rate) for AMPYRA in MS patients were urinary tract infection, insomnia, dizziness, headache, nausea, asthenia, back pain, balance disorder, multiple sclerosis relapse, paresthesia, nasopharyngitis, constipation, dyspepsia, and pharyngolaryngeal pain.

For full U.S. Prescribing Information and Medication Guide for AMPYRA, please visit: www.AMPYRA.com .

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 at 888-881-1918. 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 Watson Pharmaceutics, Inc. under its agreement with Acorda.

Acorda is developing an industry-leading pipeline of novel neurological therapies. The Company is studying AMPYRA to improve a range of functional impairments caused by MS, as well as its use in other neurological conditions, including cerebral palsy and chronic stroke. In addition, Acorda is developing clinical stage compounds AC105 for acute treatment of spinal cord injury and GGF2 for treatment of heart failure. GGF2 is also being investigated in preclinical studies as a treatment for neurological conditions such as stroke and spinal cord injury. Additional preclinical programs include rHIgM22, a remyelinating monoclonal antibody for the treatment of MS, and chondroitinase, an enzyme that encourages nerve plasticity in spinal cord injury.

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 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 any acquired or in-licensed programs; 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; 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 and Exchange Commission. Acorda Therapeutics 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 press release are made only as of the date hereof, and Acorda Therapeutics disclaims any intent or obligation to update any forward-looking statements as a result of developments occurring after the date of this press release.